Ascension Health
Medication Request Guidelines

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

ABATACEPT - SQ

Generic	Brand	HICL	GCN	Exception/Other
ABATACEPT	ORENCIA (SQ)	37825		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Has the treatment been prescribed by or is it being supervised by a rheumatologist?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: Approval requires supervision by a rheumatologist; that the patient is 18 years or older; a diagnosis of rheumatoid arthritis; a trial of one of the following DMARDS (disease-modifying antirheumatic drug) such as methotrexate, leflunomide, hydroxychloroquine, sulfasalazine; a trial of a TNF inhibitor (such as Humira, Enbrel, Simponi, or Cimzia-which may require prior authorization); and that the patient is currently taking or has a contraindication to methotrexate.

2. Is the patient 18 years or older?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: Approval requires supervision by a rheumatologist; that the patient is 18 years or older; a diagnosis of rheumatoid arthritis; a trial of one of the following DMARDS (disease-modifying antirheumatic drug) such as methotrexate, leflunomide, hydroxychloroquine, sulfasalazine; a trial of a TNF inhibitor (such as Humira, Enbrel, Simponi, or Cimzia-which may require prior authorization); and that the patient is currently taking or has a contraindication to methotrexate.

3. Does the patient have active rheumatoid arthritis?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: Approval requires supervision by a rheumatologist; that the patient is 18 years or older; a diagnosis of rheumatoid arthritis; a trial of one of the following DMARDS (disease-modifying antirheumatic drug) such as methotrexate, leflunomide, hydroxychloroquine, sulfasalazine; a trial of a TNF inhibitor (such as Humira, Enbrel, Simponi, or Cimzia-which may require prior authorization); and that the patient is currently taking or has a contraindication to methotrexate.

CONTINUED ON NEXT PAGE

INITIAL CRITERIA (CONTINUED)

4. Is the patient intolerant to or has the patient failed at least one of the following DMARDS: methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine?

   If yes continue to #5.
   If no, do not approve.
   DENIAL TEXT: Approval requires supervision by a rheumatologist; that the patient is 18 years or older; a diagnosis of rheumatoid arthritis; a trial of one of the following DMARDS (disease-modifying antirheumatic drug) such as methotrexate, leflunomide, hydroxychloroquine, sulfasalazine; a trial of a TNF inhibitor (such as Humira, Enbrel, Simponi, or Cimzia-which may require prior authorization); and that the patient is currently taking or has a contraindication to methotrexate..

5. Has the patient failed at least one of the following: Enbrel, Humira, Remicade, Simponi or Cimzia?

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: Approval requires supervision by a rheumatologist; that the patient is 18 years or older; a diagnosis of rheumatoid arthritis; a trial of one of the following DMARDS (disease-modifying antirheumatic drug) such as methotrexate, leflunomide, hydroxychloroquine, sulfasalazine; a trial of a TNF inhibitor (such as Humira, Enbrel, Simponi, or Cimzia-which may require prior authorization); and that the patient is currently taking or has a contraindication to methotrexate.

6. Is the patient currently taking methotrexate or does the patient have a contraindication to methotrexate?

   PAC NOTE: For requests for the IV dosage form of Orencia, please see the Orencia IV PA Guideline.

   If yes, for the treatment of rheumatoid arthritis, **APPROVE THE INITIATION OF ORENCIA THERAPY FOR A MAXIMUM #4 SYRINGES PER MONTH FOR 3 MONTHS (START DATE TODAY).**
   APPROVAL TEXT: Renewal requires the patient to have experienced or maintained a 20% or greater improvement in tender and swollen joint count or maintained previously documented response and be on methotrexate or has a contraindication to methotrexate.

   If no, do not approve.
   DENIAL TEXT: Approval requires supervision by a rheumatologist; that the patient is 18 years or older; a diagnosis of rheumatoid arthritis; a trial of one of the following DMARDS (disease-modifying antirheumatic drug) such as methotrexate, leflunomide, hydroxychloroquine, sulfasalazine; a trial of a TNF inhibitor (such as Humira, Enbrel, Simponi, or Cimzia-which may require prior authorization); and that the patient is currently taking or has a contraindication to methotrexate.

CONTINUED ON NEXT PAGE

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

ABATACEPT - SQ

RENEWAL CRITERIA

1. Has the patient experienced 20% or greater improvement in tender and swollen joint count?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: Renewal requires the patient to have experienced or maintained a 20% or greater improvement in tender and swollen joint count or maintained previously documented response and be on methotrexate or has a contraindication to methotrexate.

2. Is the patient currently on methotrexate or have a contraindication to methotrexate?

   If yes, for the treatment of rheumatoid arthritis, **APPROVE THE RENEWAL OF ORENCIA THERAPY FOR 12 MONTHS FOR A MAXIMUM #4 SYRINGES PER MONTH.**
   APPROVAL TEXT: Renewal requires the patient to have experienced or maintained a 20% or greater improvement in tender and swollen joint count or maintained previously documented response and be on methotrexate or has a contraindication to methotrexate.
   If no, do not approve.
   DENIAL TEXT: Renewal requires the patient to have experienced or maintained a 20% or greater improvement in tender and swollen joint count or maintained previously documented response and be on methotrexate or has a contraindication to methotrexate.

RATIONALE
Ensure appropriate diagnostic, utilization and safety criteria are met for the management of requests for abatacept.

FDA APPROVED INDICATIONS
Monotherapy or concomitant use with DMARDs other than TNF antagonists in patients with moderate to severe active rheumatoid arthritis or concomitantly with MTX for moderately to severely active polyarticular juvenile idiopathic arthritis in pediatric patients 6 years of age and older.

Adult Rheumatoid Arthritis (RA)
Moderately to severely active RA in adults. ORENCIA may be used as monotherapy or concomitantly with DMARDs other than TNF antagonists.

Juvenile Idiopathic Arthritis
Moderately to severely active polyarticular juvenile idiopathic arthritis in pediatric patients 6 years of age and older. ORENCIA may be used as monotherapy or concomitantly with MTX.

Important Limitations of Use
Should not be given concomitantly with TNF antagonists.

REFERENCES

- Bristol-Myers Squibb Corp. Orencia package insert. Princeton, NJ. September 2011.
- Orencia. MedImpact P&T Monograph, November 2011.

Created: 11/11
Effective: 03/20/12 Client Approval: 02/16/12

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

ADALIMUMAB

Generic	Brand	HICL	GCN	Exception/Other
ADALIMUMAB	HUMIRA	24800		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Has this drug been prescribed by or is it currently being supervised by a rheumatologist, dermatologist, or gastroenterologist?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: Approval requires supervision by a dermatologist, rheumatologist, or gastroenterologist and a diagnosis of active rheumatoid arthritis, active psoriatic arthritis, juvenile idiopathic arthritis, ankylosing spondylitis, chronic plaque psoriasis, moderate to severe Crohn's disease, or moderately to severely active ulcerative colitis.

2. Does the patient have active rheumatoid arthritis?

   If yes, continue to #3.
   If no, continue to #5.

3. Has the patient previously tried or does the patient have a contraindication to at least one of the following DMARDs: methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine?

   If yes continue to #4.
   If no, do not approve.
   DENIAL TEXT: Approval requires supervision by a rheumatologist, a diagnosis of active rheumatoid arthritis, a trial of at least one DMARD (disease-modifying antirheumatic drug) such as methotrexate, hydroxychloroquine, leflunomide, or sulfasalazine; and that the patient is currently taking or has a contraindication to methotrexate.

4. Is the patient currently taking methotrexate or does the patient have a contraindication to methotrexate?

   If yes, **APPROVE FOR 3 MONTHS FOR ONE KIT (#2 SYRINGES/PENS) PER MONTH.**
   APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

   If no, do not approve.
   DENIAL TEXT: Approval requires supervision by a rheumatologist, a diagnosis of active rheumatoid arthritis, a trial of at least one DMARD (disease-modifying antirheumatic drug) such as methotrexate, hydroxychloroquine, leflunomide, or sulfasalazine, and that the patient is currently taking or has a contraindication to methotrexate.

CONTINUED ON NEXT PAGE

ADALIMUMAB

INITIAL CRITERIA (CONTINUED)

5. Does the patient have active psoriatic arthritis?

   If yes, continue to #6.
   If no, continue to #7.

6. Has the patient previously tried or does the patient have a contraindication to at least one of the following DMARD agents: methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine?

   If yes, **APPROVE FOR 3 MONTHS FOR ONE KIT (#2 SYRINGES/PENS) PER MONTH.**
   APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

   If no, do not approve.
   DENIAL TEXT: Approval requires supervision by a rheumatologist; a diagnosis of active psoriatic arthritis, and that the patient has tried at least one DMARD (disease-modifying antirheumatic drug) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine.

7. Does the patient have ankylosing spondylitis?

   If yes, **APPROVE FOR 3 MONTHS FOR ONE KIT (#2 SYRINGES/PENS) PER MONTH.**
   APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

   If no, continue to #8.

8. Does the patient have juvenile idiopathic arthritis?

   If yes, continue to #9.
   If no, continue to #11.

9. Has the patient previously tried or does the patient have a contraindication to at least one of the following DMARD agents: methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine?

   If yes, continue to #10.
   If no, do not approve.
   DENIAL TEXT: Approval requires supervision by a rheumatologist; a trial of at least one DMARD (disease-modifying antirheumatic drug) such as methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide; and that the patient is currently taking or has a contraindication to methotrexate.

CONTINUED ON NEXT PAGE

ADALIMUMAB

INITIAL CRITERIA (CONTINUED)

10. Is the patient currently taking methotrexate or does the patient have a contraindication to methotrexate?

    If yes, **APPROVE FOR 3 MONTHS FOR ONE KIT (#2 SYRINGES/PENS, 20MG/0.4ML IF 15-30KG (33-66 LBS) IN WEIGHT OR 40MG/0.8ML IF ≥ 30KG WEIGHT) PER MONTH.**
    APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

    If no, do not approve.
    DENIAL TEXT: Approval requires supervision by a rheumatologist; a trial of at least one DMARD (disease-modifying antirheumatic drug) such as methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide; and that the patient is currently taking or has a contraindication to methotrexate.

11. Does the patient have chronic moderate to severe plaque psoriasis?

    If yes, continue to #12.
    If no, continue to #14.

12. Does the plaque psoriasis involve ≥ 10% body surface area (BSA) or do the psoriatic lesions affect the hands, feet, or genital area?

    If yes, continue to #13.
    If no, do not approve.
    DENIAL TEXT: Approval requires supervision by a dermatologist; a diagnosis of plaque psoriasis; psoriatic lesions covering greater than 10% of BSA (Body Surface Area) or lesions on the hands, feet, or genital area; and a trial of or a contraindication to one or more forms of preferred therapy (e.g., PUVA, UVB, methotrexate or cyclosporine).

13. Has the patient previously tried at least one or more forms of preferred therapy (e.g. PUVA, UVB, acitretin, methotrexate, or cyclosporine)?

    If yes, **APPROVE PSORIASIS STARTER PACKAGE (CONTAINS #4 X 40MG SYRINGES) X 1, THEN APPROVE FOR 2 MONTHS FOR ONE KIT (#2 SYRINGES/PENS) PER MONTH.**
    APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

    If no, do not approve.
    DENIAL TEXT: Approval requires supervision by a dermatologist; a diagnosis of plaque psoriasis; psoriatic lesions covering greater than 10% of BSA (Body Surface Area) or lesions on the hands, feet, or genital area; and a trial of or a contraindication to one or more forms of preferred therapy (e.g., PUVA, UVB, methotrexate or cyclosporine).

CONTINUED ON NEXT PAGE

INITIAL CRITERIA (CONTINUED)

14. Does the patient have a diagnosis of moderate to severe Crohn's Disease?

    If yes, continue to #15.
    If no, continue to #16.

15. Has the patient tried one or more conventional therapies for Crohn's disease such as: corticosteroids (i.e. budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine?

    If yes, **APPROVE CROHN'S DISEASE STARTER PACKAGE (CONTAINS #6 X 40MG SYRINGES) X 1, THEN APPROVE FOR 2 MONTHS FOR ONE KIT (#2 SYRINGES/PENS) PER MONTH.**
    APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

    If no, do not approve.
    DENIAL TEXT: Approval requires supervision by a gastroenterologist, a diagnosis of moderate to severe Crohn's disease, and a trial of one or more conventional therapies for Crohn's disease such as corticosteroids (e.g. methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine.

16. Does the patient have a diagnosis of moderately to severely active ulcerative colitis?

    If yes, continue to #17.
    If no, do not approve.
    DENIAL TEXT: Approval requires supervision by a dermatologist, rheumatologist, or gastroenterologist and a diagnosis of active rheumatoid arthritis, active psoriatic arthritis, juvenile idiopathic arthritis, ankylosing spondylitis, chronic plaque psoriasis, moderate to severe Crohn's disease, or moderately to severely active ulcerative colitis.

17. Has the patient tried or does the patient have a contraindication to one or more of the following preferred therapy agents: sulfasalazine, corticosteroids, methotrexate, azathioprine, olsalazine, Asacol, Pentasa, cyclosporine, or mercaptopurine?

    If yes, **APPROVE FOR THREE KITS (#6 SYRINGES/PENS) X 1, THEN APPROVE FOR 2 MONTHS FOR ONE KIT (#2 SYRINGES/PENS) PER MONTH.**
    APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

    If no, do not approve.
    DENIAL TEXT: Approval requires supervision by a dermatologist, rheumatologist, or gastroenterologist and a trial of one or more of the following preferred therapy agents: sulfasalazine, corticosteroids, methotrexate, azathioprine, olsalazine, Asacol, Pentasa, cyclosporine, or mercaptopurine.

CONTINUED ON NEXT PAGE

ADALIMUMAB

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have active rheumatoid arthritis, psoriatic arthritis, or juvenile idiopathic arthritis?

   If yes, continue to #5.
   If no, continue to #2.

2. Does the patient have ankylosing spondylitis?

   If yes, continue to #6.
   If no, continue to #3.

3. Does the patient have chronic plaque psoriasis?

   If yes, continue to #7.
   If no, continue to #4.

4. Does the patient have Crohn's Disease or ulcerative colitis?

   If yes, **APPROVE FOR 12 MONTHS FOR ONE KIT (#2 SYRINGES/PENS) PER MONTH.**
   APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

   If no, do not approve.
   DENIAL TEXT: Renewal requires a diagnosis of rheumatoid arthritis, psoriatic arthritis, juvenile idiopathic arthritis, ankylosing spondylitis, chronic plaque psoriasis, Crohn's disease, or ulcerative colitis.

CONTINUED ON NEXT PAGE

ADALIMUMAB

RENEWAL CRITERIA (CONTINUED)

5. Has the patient experienced 20% or greater improvement in tender joint count and swollen joint count while on therapy?

   If yes, process as follows:
   - For rheumatoid arthritis, continue to #8.
   - For psoriatic arthritis, continue to #9.
   - For juvenile idiopathic arthritis, **APPROVE FOR 12 MONTHS FOR ONE KIT (#2 SYRINGES/PENS) PER MONTH.**
     APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

   If no, do not approve.
   RHEUMATOID ARTHRITIS DENIAL TEXT: Renewal requires a diagnosis of rheumatoid arthritis, a 20% improvement in tender or swollen joint count while on therapy, and concurrent methotrexate therapy or a contraindication to methotrexate.
   PSORIATIC ARTHRITIS DENIAL TEXT: Renewal requires a diagnosis of psoriatic arthritis and a 20% improvement in tender or swollen joint count while on therapy.
   JUVENILE IDIOPATHIC ARTHRITIS DENIAL TEXT: Renewal requires a diagnosis of juvenile idiopathic arthritis and has experienced or maintained a 20% improvement in tender or swollen joint count while on therapy.

6. Has the patient experienced an improvement of at least 50% or 2 units (scale of 1-10) in the Bath ankylosing spondylitis disease activity Index (BASDAI)?

   If yes, continue to #9.
   If no, do not approve.
   DENIAL TEXT: Renewal requires a diagnosis of ankylosing spondylitis and at least a 50% improvement or increase of 2 units from baseline on the BASDAI (Bath Ankylosing Spondylitis Disease Activity Index).

7. Has the patient achieved clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index of at least 50% or more?

   If yes, **APPROVE FOR 12 MONTHS FOR TWO KITS (#4 SYRINGES/PENS) PER MONTH.**
   APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

   If no, do not approve.
   DENIAL TEXT: Renewal requires that the patient has achieved clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more.

CONTINUED ON NEXT PAGE

RENEWAL CRITERIA (CONTINUED)

8. Is the patient taking methotrexate or does the patient have a contraindication to methotrexate?

   If yes, continue to #9.
   If no, do not approve.
   DENIAL TEXT: Renewal requires a diagnosis of rheumatoid arthritis, a 20% improvement in tender or swollen joint count, and concurrent methotrexate therapy or a contraindication to methotrexate.

9. Is the dose of Humira 40mg **every other week**?

   If yes, **APPROVE FOR 12 MONTHS FOR ONE KIT (#2 SYRINGES/PENS) PER MONTH.**
   APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

   If no, continue to #10.

10. Has the patient tried and failed at least a 3-month trial of Humira 40mg every other week?

    If yes, continue to #11.
    If no, do not approve. **ENTER A PROACTIVE AUTHORIZATION FOR 12 MONTHS FOR ONE KIT (#2 SYRINGES/PENS) PER MONTH.**
    DENIAL TEXT: Renewal of Humira at the dose requested requires at least a 3-month trial of Humira 40mg every other week. Consider trial of this agent at once every other week dosing. Please note that this drug has an important FDA safety warning. For more information please ask your doctor or pharmacist.

11. Is the prescribed dose of Humira 40mg **every week**?

    If yes, **APPROVE FOR 12 MONTHS FOR TWO KITS (#4 SYRINGES/PENS) PER MONTH.**
    APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

    If no, do not approve.
    DENIAL TEXT: The dosing schedule requested is not covered for the diagnosis provided.

RATIONALE
Ensure appropriate diagnostic, utilization and safety criteria are used for the management of requests for adalimumab.

FDA APPROVED INDICATIONS
HUMIRA is indicated for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage and improving physical function in adult patients with moderately to severely active rheumatoid arthritis and psoriatic arthritis. HUMIRA can be used alone or in combination with methotrexate or other DMARDs.

CONTINUED ON NEXT PAGE

ADALIMUMAB

FDA APPROVED INDICATIONS (CONTINUED)

HUMIRA is indicated for reducing signs and symptoms in patients with active ankylosing spondylitis.

HUMIRA is indicated for reducing signs and symptoms and inducing and maintaining clinical remission in adults with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy. HUMIRA is also indicated for reducing signs and symptoms and inducing clinical remission in these patients if they have also lost response to or are intolerant to infliximab.

HUMIRA is indicated for the treatment of adults with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate.

HUMIRA is indicated for reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical functions in patients with psoriatic arthritis. Humira can be used alone or in combination with DMARDs.

HUMIRA is indicated for reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patient 4 years of age and older. HUMIRA can be used alone or in combination with methotrexate.

HUMIRA is indicated for inducing and sustaining clinical remission in adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to immunosuppressants such as corticosteroids, azathioprine or 6-mercaptopurine (6-MP). The effectiveness of HUMIRA has not been established in patients who have lost response to or were intolerant to TNF blockers.

DOSING

Rheumatoid Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis
40 mg every other week. Some patients with RA not receiving methotrexate may benefit from increasing the frequency to 40 mg every week.

Juvenile Idiopathic Arthritis
15 kg (33 lbs) to <30 kg (66 lbs): 20 mg every other week ≥30 kg (66 lbs): 40 mg every other week.

Crohn's Disease and Ulcerative Colitis
Initial dose (Day 1) is 160 mg (four 40 mg injections in one day or two 40 mg injections per day for two consecutive days), followed by 80 mg two weeks later (Day 15). Two weeks later (Day 29) begin a maintenance dose of 40 mg every other week.

Plaque Psoriasis
80 mg initial dose followed by 40 mg every other week starting one week after initial dose.

DOSAGE FORMS AND STRENGTHS

40 mg/0.8 mL in a single-use prefilled pen (HUMIRA Pen)
40 mg/0.8 mL in a single-use prefilled glass syringe
20 mg/0.4 mL in a single-use prefilled glass syringe

CONTINUED ON NEXT PAGE

ADALIMUMAB

REFERENCES

- Abbott Laboratories. Humira product information. North Chicago, IL. September 2012.
- Bristol-Myers Squibb. Orencia product information. Princeton, NJ. November, 2009.
- Felson D, Anderson J, Boers M, et al. American College of Rheumatology preliminary definition of improvement in rheumatoid arthritis. Arthritis Rheum 1995;38:727-35
- Mease P, Gladman D, Ritchlin C, et al. Adalimumab for the treatment of patients with moderately to severely active psoriatic arthritis. Arthritis and Rheumatism 2005;52:3279-89.
- Braun J, Davis J et al. First update of the international ASAS consensus statement for the use of anti-TNF agents in patients with ankylosing spondylitis. Ann Rheum Dis. 2006;65(3):316-20.
- Hanauer SB, Sandborn WJ, Rutgeerts P, et al. Human Anti-Tumor Necrosis Factor Monoclonal Antibody (Adalimumab) in Crohn's Disease: the CLASSIC-I Trial. Gastroenterology. 2006; 130: 323-333.
- Colombel JF, Sandborn WJ, Rutgeerts P, et al. Adalimumab for Maintenance of Clinical Response and Remission in Patients With Crohn's Disease: The CHARM Trial. Gastroenterology. 2007; 132: 53-65.
- Papadakis KA, Shaye OA, Vasiliauskas EA, et al. Safety and Efficacy of Adalimumab (D2E7) in Crohn's Disease Patients with an Attenuated Response to Infliximab. Am J Gastro. 2005; 75-79.
- Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2009. Available at: http://www.clinicalpharmacology.com. [Accessed: June 22, 2010].

Created: 05/03
Effective: 03/25/13 Client Approval: 02/14/13

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

ALEFACEPT

Generic	Brand	HICL	GCN	Exception/Other
ALEFACEPT	AMEVIVE	24899		

NOTE: This request can only be reviewed by a Prior Authorization Coordinator (PAC). Please request your caller to submit a Medication Request Form (MRF) for review

GUIDELINES FOR USE

1. Is the prescription written by a dermatologist with experience using Amevive?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: This medication is not covered for patients not overseen by a dermatologist.

2. Is this the initial request for treatment with alefacept?

   If yes, continue to #6.
   If no, continue to #3.

3. Has the patient already received two 3-month courses of alefacept treatment?

   If yes, do not approve.
   DENIAL TEXT: This medication is not covered for patients who have received two 3-month courses of alefacept treatment.
   If no, continue to #4.

4. Has there been a 3-month interval since the end of the patient's previous 3-month course of treatment with alefacept?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: This medication is not covered for patients that have not had at least a 3-month interval since the last course of alefacept treatment.

5. Did the patient receive clinical benefit on alefacept therapy as measured by Psoriasis Area and Severity Index (PASI 50: ≥ 50% improvement in PASI score) or a significant improvement in Quality of Life observed by the physician and patient (i.e., Dermatology Life Quality Index)?

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: This medication is not covered for patients that have not experienced a clinical benefit on alefacept therapy as measured by PASI 50 or Quality of Life index score.

CONTINUED ON NEXT PAGE

ALEFACEPT

GUIDELINES FOR USE (CONTINUED)

6. Does the patient have chronic moderate to severe plaque psoriasis involving ≥ 10% body surface area (BSA)?

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: This medication is not covered for patients that have psoriatic lesions covering less than 10% of body surface area.

7. Has the patient failed or does the patient have a contraindication to one or more forms of preferred therapy (PUVA, UVB, acitretin, methotrexate or cyclosporine)?

   If yes, continue to #8.
   If no, do not approve.
   DENIAL TEXT: This medication is not covered for patients that have not tried/failed at least one form of preferred therapy agent.

8. Does the patient have an active infection (including, but not limited to histoplasmosis, cytomegalovirus, tuberculosis and human immunodeficiency virus infection), a history of recurring infections or a history of systemic malignancy, or is the patient currently receiving other immunosuppressive agents (i.e., cyclosporine, methotrexate, etanercept, alefacept, infliximab)?

   If yes, do not approve.
   DENIAL TEXT: This medication is not covered for patients that have active infection, history of recurring infections, history of systemic malignancy, or currently on immunosuppressive therapy.
   If no, continue to #9.

9. Are the patient's liver function tests (LFTs) within normal limits?

   If yes, continue to #10.
   If no, do not approve.
   DENIAL TEXT: This medication is not covered for patients who have abnormal liver function tests results.

10. Has the physician submitted documentation indicating that the CD4+ T-lymphocyte count is above 250 cells/uL?

    If yes, continue to #11.
    If no, do not approve.
    DENIAL TEXT: This medication is not covered for patients that have CD4+ counts below 250 cells/uL.

CONTINUED ON NEXT PAGE

GUIDELINES FOR USE (CONTINUED)

11. **APPROVE FOR 3 MONTHS, AND CONTINUE TO #12.**

12. **QUANTITY LIMIT: 4 VIALS PER MONTH/COPAY.**

RATIONALE
To ensure appropriate use of Amevive.

FDA APPROVED INDICATIONS
Amevive is indicated for the treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy.

REFERENCES

- Astellas Pharma, Inc. Amevive package insert. Deerfield, IL, October 2006.
- Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2008. Available at: http://www.clinicalpharmacology.com. [Accessed: January 29th, 2009].
- Micromedex® Healthcare Series [database online]. Greenwood Village, Colo: Thomson Healthcare. Available at: https://www.thomsonhc.com/hcs/librarian/PFDefaultActionId/pf.LoginAction. [Accessed: January 29th, 2009].

Created: 05/03
Effective: 10/15/09 Client Approval: 10/01/09

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

ALISKIREN AND ALISKIREN COMBINATION AGENTS

Generic	Brand	HICL	GCN	Exception/Other
ALISKIREN HEMIFUMARATE	TEKTURNA		98076, 98077	
ALISKIREN/AMLODIPINE	TEKAMLO		28974, 28975, 28976, 28977	
ALISKIREN/AMLODIPINE/ HCTZ	AMTURNIDE		29393, 29394, 29395, 29396, 29397	
ALISKIREN/HCTZ	TEKTURNA HCT		99310, 99311, 99312, 99313	
ALISKIREN/VALSARTAN	VALTURNA		27642, 27643	

GUIDELINES FOR USE

1. Has the patient had a trial of one generic ACE inhibitor (e.g., benazepril, captopril, enalapril, fosinopril, lisinopril, moexipril, quinapril, ramipril, or trandolapril) **AND** a generic ARB (e.g. losartan, losartan/hydrochlorothiazide, irbesartan, irbesartan/hydrochlorothiazide)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: Approval requires a trial of a generic ACE inhibitor such as lisinopril or benazepril AND a generic ARB such as losartan or losartan/hydrochlorothiazide.

2. Does the patient have a diagnosis of type 2 diabetes mellitus?

   If yes, continue to #3.
   If no, **APPROVE FOR 1 TABLET PER DAY FOR 12 MONTHS BY GCN.**
   APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information please ask your doctor or pharmacist.

3. Is the patient currently taking an ACE inhibitor (e.g., benazepril, captopril, enalapril, fosinopril, lisinopril, moexipril, quinapril, ramipril, or trandolapril) or an angiotensin receptor blocker (ARB) (e.g., azilsartan, candesartan, eprosartan, irbesartan, losartan, olmesartan, telmisartan, valsartan, or an ARB-HCTZ combination)?

   If yes, do not approve.
   DENIAL TEXT: Approval requires that the patient does not have a diagnosis of diabetes mellitus or is not currently taking an angiotensin converting enzyme inhibitor (ACE) or an angiotensin receptor blocker (ARB) medication.
   If no, **APPROVE 1 TABLET PER DAY FOR 12 MONTHS BY GCN.**
   APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information please ask your doctor or pharmacist.

CONTINUED ON NEXT PAGE

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

ALISKIREN AND ALISKIREN COMBINATION AGENTS

RATIONALE
To Promote use of Aliskiren in accordance with the FDA safety warning and package insert contraindications.

FDA APPROVED INDICATIONS
Tekturna, Tekamlo, Amturnide, and Tekturna HCT are indicated to treat hypertension.

OTHER INFORMATION
On April 20, 2012 the U.S. Food and Drug Administration (FDA) released a safety announcement regarding medications containing aliskiren when used in combination with angiotensin converting enzyme inhibitors (ACE) or angiotensin receptor blocker (ARB) therapy in diabetics or those with renal impairment.

A randomized, double-blind, placebo controlled, parallel-group clinical trial (Aliskiren Trial in Type 2 diabetes using Cardio-renal Endpoints (ALTITUDE)) examined aliskiren 300mg daily versus placebo in 8,606 high risk patients with type 2 diabetes already taking baseline ACE or ARB therapy. The trial was terminated in December 2011 due to increased adverse events in the group taking aliskiren. A higher incidence of certain adverse events was found in the aliskiren group versus the placebo group. Individuals in the aliskiren group were also at a slightly higher risk for death or stroke. However, at this time, the FDA has not reached a final conclusion regarding whether a link exists between aliskiren-containing drugs and death or stroke.

Adverse events in the ALTITUDE clinical trial		
	Aliskiren group	Placebo group
Decline in renal function	12.4%	10.4%
Hypotension	18.6%	14.8%
Hyperkalemia	36.9%	27.1%
Non-fatal stroke	2.7%	2.0%

Currently marketed medications containing aliskiren include Tekturna (aliskiren), Tekturna HCT (aliskiren/hctz), Amturnide (aliskiren/amlodipine/hctz), Tekamlo (aliskiren/amlodipine), and Valturna (aliskiren/valsartan). At this time, Novartis has planned to voluntarily withdraw Valturna from the market in July 2012. The labeling of other aliskiren-containing medications has been changed to reflect a contraindication for combination use of aliskiren with ARB or ACE inhibitors in patients with diabetes, and this combination should be avoided in patients with renal impairment (GFR<60mL/min).

REFERENCES

- Novartis. Amturnide prescribing information. East Hanover, NJ. March 2012. Accessed online May 2012: http://www.pharma.us.novartis.com/product/pi/pdf/amturnide.pdf
- Novartis. Tekamlo prescribing information. East Hanover, NJ. March 2012. Accessed online May 2012: http://www.pharma.us.novartis.com/product/pi/pdf/tekamlo.pdf
- Novartis. Tekturna prescribing information. East Hanover, NJ. March 2012. Accessed online May 2012: http://www.pharma.us.novartis.com/product/pi/pdf/tekturna.pdf
- Novartis. Tekturna HCT prescribing information. East Hanover, NJ. March 2012. Accessed online May 2012: http://www.pharma.us.novartis.com/product/pi/pdf/tekturna_hct.pdf
- U.S. Food and Drug Administration (FDA) Safety Warning. Accessed online April 2012: http://www.fda.gov/Drugs/DrugSafety/ucm300889.htm

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

ANAKINRA

Generic	Brand	HICL	GCN	Exception/Other
ANAKINRA	KINERET	22953		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Has the treatment been prescribed or is it currently being supervised by a rheumatologist?

   If yes, continue to #5.
   If no, continue to #2.

2. Does the patient have diagnosis of moderate to severe rheumatoid arthritis?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: Indicated for moderate to severe rheumatoid arthritis.

3. Is the patient 18 years of age or older?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: Indicated for use in adults only.

4. Has the patient tried and failed or experienced intolerable side effects to at least one of the following DMARD agents: methotrexate, leflunomide, azathioprine, cyclosporine, hydroxychloroquine, penicillamine, sulfasalazine, gold sodium thiomalate or auranofin?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: Indicated for use after failing therapy with a DMARD.

5. Is the baseline absolute neutrophil count (ANC) in the range of 2,500 to 10,000?

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: Drug causes neutropenia. Neutrophil count must be normal prior to starting therapy.

6. Is patient using Kineret with Enbrel, Remicade, Humira or Rituxan?

   If yes, do not approve.
   DENIAL TEXT: Not indicated for concomitant use with other biologics due to increased toxicity.
   If no, continue to #7.

7. **APPROVE FOR 3 MONTHS WITH A QUANTITY LIMIT OF 28 SYRINGES PER 28 DAYS.**

CONTINUED ON NEXT PAGE

ANAKINRA

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Has the patient experienced 20% or greater improvement in tender joint count and swollen joint count?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: Patient must have a positive response to continue therapy.

2. **APPROVE FOR 12 MONTHS WITH A QUANTITY LIMIT OF 28 SYRINGES PER 28 DAYS OR PER COPAY.**

RATIONALE
Ensure appropriate diagnostic, utilization, and safety criteria.

FDA APPROVED INDICATIONS
Moderate to severe rheumatoid arthritis in patients 18 years or older who have failed 1 or more DMARDs. Kineret can be used alone or in combination with DMARDs other than TNF blocking agents.

REFERENCES

- Amgen, Inc. Kineret package insert. Thousand Oaks, CA, October 2008.
- Cohen S, et al. Treatment of rheumatoid arthritis with anakinra, a recombinant human interleukin-1 receptor antagonist, in combination with methotrexate. Arthritis & Rheum 2002; 46(3):614-24.
- Nuki G et al. Long-term safety and maintenance of clinical improvement following treatment with anakinra (recombinant human interleukin-1 receptor antagonist) in patients with rheumatoid arthritis. Am College of Rheumatol. 2005; 46(11):2838-46.
- Clinical Pharmacology [database online]. Tampa, FL. Gold Standard, Inc.; 2008. Available at: http://www.clinical pharmacology.com. [Accessed: May 27, 2008].

Created: 02/03
Effective: 10/15/09 Client Approval: 10/01/09

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

ANTIHYPERTENSIVES

Generic	Brand	HICL	GCN	Exception/Other
AZILSARTAN	EDARBI	37444		
CANDESARTAN CANDESARTAN/HCTZ	ATACAND ATACAND HCT	16913 21280		
EPROSARTAN EPROSARTAN/HCTZ	TEVETEN TEVETEN HCT	16920 24744		
IRBESARTAN IRBESARTAN/HCTZ	AVAPRO AVALIDE	15576 18963		
LOSARTAN LOSARTAN/HCTZ	COZAAR HYZAAR	09829 09863		
OLMESARTAN OLMESARTAN/HCTZ	BENICAR BENICAR HCT	23490 25446		
OLMESARTAN/AMLODIPINE/HCTZ	TRIBENZOR	37089		
TELMISARTAN TELMISARTAN/HCTZ	MICARDIS MICARDIS HCT	18839 21873		
TELMISARTAN/AMLODIPINE	TWYNSTA	36697		
VALSARTAN VALSARTAN/HCTZ	DIOVAN DIOVAN HCT	12204 17084		

GUIDELINES FOR USE

1. Has the patient had a trial of one formulary ACE inhibitor (e.g. benazepril, captopril, enalapril, fosinopril, lisinopril, moexipril, quinapril, ramipril, or trandolapril) **AND** a generic ARB (e.g. losartan, losartan/hydrochlorothiazide)?

   If yes, **APPROVE FOR 12 MONTHS.**
   APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.
   If no, do not approve.
   DENIAL TEXT: Approval requires a trial of a formulary ACE inhibitor such as lisinopril or benazepril AND a generic ARB such as losartan or losartan/hydrochlorothiazide.

RATIONALE
Ensure use of single-source brand agents as second-line agents to ACE Inhibitors or generic ARBs for hypertension.

FDA APPROVED INDICATIONS
ATACAND, ATACAND HCT, EDARBI, TEVETEN, TEVETEN HCT, AVAPRO, AVALIDE, COZAAR, HYZAAR, MICARDIS, MICARDIS HCT, BENICAR, BENICAR HCT, DIOVAN, and DIOVAN HCT are indicated for treatment of hypertension alone or in combination with other antihypertensive agents. The fixed dose combinations are not indicated for initial therapy.

CONTINUED ON NEXT PAGE

ANTIHYPERTENSIVES

FDA APPROVED INDICATIONS (CONTINUED)

TRIBENZOR, and TWYNSTA are indicated for the treatment of hypertension.

COZAAR and AVAPRO are indicated for the treatment of diabetic nephropathy with an elevated serum creatinine and proteinuria in patients with Type 2 Diabetes and a history of hypertension.

DIOVAN is indicated in reducing cardiovascular mortality in clinically stable patients with left ventricular failure or left ventricular dysfunction following myocardial infarction. Diovan is indicated for the treatment of heart failure (NYHA Class II to IV).

EDARBI is indicated for the treatment of hypertension.

ATACAND is indicated for the treatment of hypertension in adults and children (1-17 years old) and for the treatment of heart failure (NYHA II-IV) in patients with left ventricular systolic dysfunction (ejection fraction ≤ 40%) to reduce cardiovascular deaths and to reduce heart failure hospitalization with or without concurrent use of an ACEI.

COZAAR and HYZAAR are indicated to reduce the risk of stroke in patients with hypertension and left ventricular hypertrophy, but there is evidence that this benefit does not apply to black patients.

AVALIDE may be used in patients whose blood pressure is not adequately controlled on monotherapy. May also be used as initial therapy in patients likely to need multiple drugs to achieve their blood pressure goals.

HYZAAR fixed dose combination is not indicated for initial therapy of hypertension except when hypertension is severe enough that value of achieving prompt blood pressure control exceeds risk of initiating combination therapy in these patients.

DIOVAN HCT is indicated for the treatment of hypertension in patients not adequately controlled with monotherapy or as initial therapy in patients likely to need multiple drugs to achieve their blood pressure goals.

MICARDIS is also indicated for cardiovascular (CV) risk reduction in patients unable to take ACE inhibitors.

CONTINUED ON NEXT PAGE

REFERENCES

- Cohn J, Tognoni G. for the Valsartan Heart Failure Trial Investigators. A randomized trial of the angiotensin-receptor blocker valsartan in chronic heart failure. NEJM 2001; 345:1667-75.
- Brenner B, Cooper M, Zeeuw D, Keane W, Mitch W, Parving H. et al. For the RENAL study investigators. Effects of losartan on renal and cardiovascular outcomes in patients with Type 2 Diabetes and Nephropathy. NEJM 2001; 345:861-9.
- Pitt B, Poole-Wilson A, Segal R, Martinez F, Dickstein K, Camm A, et al. Effect of losartan compared with captopril on mortality in patients with symptomatic heart failure: randomized trial-the Losartan Heart Failure Survival Study ELITE II. Lancet 2000; 355:1582-7.
- Lindholm L, Ibsen H, Dahlof B, Devereux R, Beevers G, de Faire U, et al.. Cardiovascular morbidity and mortality in patients with diabetes in the losartan intervention for endpoint reduction in hypertension study (LIFE): a randomized trial against atenolol. Lancet 2002; 359:1004-10.
- Dahlof B, Devereux R, Ekeldsen S, Julius S, Beevers G, de Faire U, et al. Cardiovascular morbidity and mortality in the losartan intervention for endpoint reduction in hypertension study (LIFE): a randomized trial against atenolol. Lancet 2002; 359:995-1003.
- Parving J, Lehnert H, Brochner-Mortensen J, Gomis R, Andersen S, Arner P for the Irbesartan in Patients with Type 2 Diabetes and Microalbuminuria Study Group. The effect of irbesartan on the development of diabetic nephropathy in patients with Type 2 Diabetes. NEJM 2001; 345:870-8.
- Lewis E, Hunsicker L, Clarke W, Berl T, Pohl M, Lewis J. et al. Renoprotective effect of the angiotensin-receptor antagonist irbesartan in patients with nephropathy due to Type 2 Diabetes. NEJM 2001; 345:851-60.
- Angiotensin Converting Enzyme Inhibitor and Angiotensin II Receptor Antagonists. MedImpact P&T Monograph, August, 2010.
- Astrazeneca Pharmaceuticals LP. Atacand package insert. Wilmington, DE. April 2011.
- Astrazeneca Pharmaceuticals LP. Atacand HCT package insert. Wilmington, DE. April 2011.
- Abbott Laboratories. Teveten package insert. North Chicago, IL. March 2011.
- Abbott Laboratories. Teveten HCT package insert. North Chicago, IL. March 2011.
- Bristol-Myers Squibb. Avapro package insert. New York, NY. April 2011.
- Bristol-Myers Squibb. Avalide package insert. New York, NY. December 2010.
- Merck & Co., Inc. Cozaar package insert. Whitehouse Station, NJ. June 2011.
- Merck & Co., Inc. Hyzaar package insert. Whitehouse Station, NJ. June 2011.
- Boehringer Ingelheim Pharmaceuticals, Inc. Micardis package insert. Ridgefield, CT. May 2011.
- Boehringer Ingelheim Pharmaceuticals, Inc. Micardis HCT package insert. Ridgefield, CT. April 2011.
- Daiichi Sankyo, Inc. Benicar package insert. Parsippanny, NJ. June 2011.
- Daiichi Sankyo, Inc. Benicar HCT package insert. Parsippanny, NJ. May 2011.
- Novartis Pharmaceuticals Corp. Diovan package insert. East Hanover, NJ. April 2011.
- Novartis Pharmaceuticals Corp. Diovan HCT package insert. East Hanover, NJ. February 2011.
- Micromedex® Healthcare Series [database online]. Greenwood Village, CO: Thomson Healthcare. Available at: https://www.thomsonhc.com/hcs/librarian/PFDefaultActionId/pf.LoginAction. [Accessed: June 30, 2011].

Created: 06/10
Effective: 10/01/12 Client Approval: 08/30/12

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

APPLICABLE TO ASC02-SETON FAMILY OF HOSPITALS, AUSTIN TX ONLY

ANTIHEMOPHILIC AGENTS (FACTOR VIIa, VIII, XI)

Generic	Brand	HICL	GCN	Exception/Other
ANTIHEMOPHILIC FACTOR				STC=0322
FACTOR IX PREPARATIONS				STC=0323

GUIDELINES FOR USE

1. Does the patient have a diagnosis of hemophilia A, hemophilia B, acquired hemophilia, congenital factor VII deficiency or Von Willebrand Disease?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: Approval for this medication requires that patients are diagnosed with hemophilia, congenital factor VII deficiency or Von Willebrand Disease.

2. Is this drug being prescribed for the treatment and/or management of acute bleeding in patients with severe hemophilia, or as maintenance therapy to maintain trough factor levels at 1% or greater?

   If yes, **APPROVE FOR ONE YEAR.**
   If no, continue to #3.

3. Is this drug being prescribed for treatment and/or management of acute bleeding episodes for patients with mild hemophilia (defined as factor levels >5% and <30%) or moderate hemophilia (defined as factor levels of 1% - 5%), such as bleeding episodes associated with surgery or trauma?

   If yes, **APPROVE FOR ONE YEAR.**
   If no, continue to #4.

4. Is this drug being prescribed for treatment and/or management of acute bleeding in patients with Von Willebrand Disease, and in clinical situations in which patients with Von Willebrand Disease are at increased risk of bleeding (i.e. surgery or trauma)?

   If yes, **APPROVE FOR ONE YEAR.**
   If no, continue to #5.

5. Is this drug being prescribed for the treatment and/or management of significant menorrhagia in women with Von Willebrand Disease?

   If yes, **APPROVE FOR ONE YEAR.**
   If no, do not approve.
   DENIAL TEXT: Approval for this medication requires that patients are diagnosed with hemophilia, congenital factor VII deficiency or Von Willebrand Disease.

CONTINUED ON NEXT PAGE

ANTIHEMOPHILIC AGENTS (FACTOR VIIa, VIII, XI)

RATIONALE

Ensure appropriate diagnostic, utilization and safety criteria are used for the management of prior authorization requests for blood factor products.

FDA APPROVED INDICATIONS

REFERENCES

- Tufts Health Plan. Pharmacy Medical Necessity Guidelines. Factor Products for the Treatment of Hemophilia, Congenital Factor VII Deficiency and Von Willebrand Disease. Effective Date September 2009.

Created: 01/10
Effective: 04/02/10 Client Approval: 01/29/10

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

ARMODAFINIL/MODAFINIL

Generic	Brand	HICL	GCN	Exception/Other
MODAFINIL	PROVIGIL	10865		
ARMODAFINIL	NUVIGIL	34868		

GUIDELINES FOR USE

1. Is the patient diagnosed with a shift work sleep disorder?

   If yes, continue to #6.
   If no, continue to #2.

2. Is the patient diagnosed with obstructive sleep apnea/hypopnea syndrome?

   If yes, continue to #3.
   If no, continue to #4.

3. Has the patient failed a trial of Continuous Positive Airway Pressure (CPAP)?

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: This medication is not covered for patients with obstructive sleep apnea or hypopnea syndrome who have not failed a trial of CPAP.

4. Is the patient diagnosed with narcolepsy?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: This medication is not covered for the requested indication.

5. Has the patient tried and failed or is there a contraindication to amphetamine, dextroamphetamine and/or methylphenidate?

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: This medication is not covered for patients with narcolepsy who have not tried/failed stimulant therapy.

6. **APPROVE FOR 12 MONTHS WITH A QUANTITY LIMIT OF #1 TABLET PER DAY.**

CONTINUED ON NEXT PAGE

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

ARMODAFINIL/MODAFINIL

RATIONALE
To promote the most cost-efficient and clinically appropriate utilization for Armodafinil/Modafinil.

FDA APPROVED INDICATIONS
Armodafinil and Modafinil are indicated to improve wakefulness in patients with excessive daytime sleepiness associated with narcolepsy, obstructive sleep apnea/hypopnea syndrome, and shift work sleep disorder.

REFERENCES

- Cephalon. Provigil product information. Frazer, PA. March, 2008.
- Stores, G. Recognition and Management of Narcolepsy. Arch Dis Child 1999; 81:519-524.
- Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2008. Available at: http://www.clinicalpharmacology.com. Updated August 2006. [Accessed: March 12, 2009].
- Thomson Healthcare. Modafinil. DRUGDEX® System [database online]. Greenwood Village, CO. Available at: https://www.thomsonhc.com/hcs/librarian/PFDefaultActionId/pf.LoginAction. [Accessed: March 12, 2009]
- Rammohan KW, Rosenberg JH, Lynn DJ, et al: Efficacy and safety of modafinil (Provigil(R)) for the treatment of fatigue in multiple sclerosis: a two centre phase 2 study. J Neurol Neurosurg Psychiatry 2002; 72:179-183.
- Wolters-Kluwer: Drug Facts and Comparisons. www.onlinefactsandcomparisons.com [Accessed: August 18, 2009]

Created: 05/99
Effective: 01/01/10 Client Approval: 08/24/09

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

BOCEPREVIR

Generic	Brand	HICL	GCN	Exception/Other
BOCEPREVIR	VICTRELIS	37609		

This drug requires a written request for prior authorization.

Boceprevir (Victrelis) is part of a three drug regimen for use with ribavirin and peginterferon alfa. Ribavirin and peginterferon alfa are started first in therapy. Boceprevir is added to peginterferon alfa and ribavirin regimen after 4 weeks of treatment (TW4).

GUIDELINES FOR USE

1. Is the requested medication being used with ribavirin **AND** peginterferon alfa?
   Note: The patient must have an active prior authorization for peginterferon alfa before proceeding.

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of chronic hepatitis C, genotype 1, minimum age of 18, current supervision by a gastroenterologist, infectious disease specialist, or a physician specializing in the treatment of hepatitis (e.g. hepatologist), and concurrent use of ribavirin and peginterferon alfa. Approval requires that the patient has a contraindication/intolerance to telaprevir (Incivek). Approval requires that the patient does not have coinfection with hepatitis B, or have a history of a previous solid organ transplant. Approval requires that the patient has not failed therapy with telaprevir (Incivek) or boceprevir (Victrelis) and is not a previous null responder. Approval requires that the patient is not concurrently taking carbamazepine, phenobarbital, phenytoin, or rifampin.

2. Is the patient currently taking the requested medication as indicated on the MRF, claims history, or prior authorization history?

   If yes, continue to #10.
   If no, continue to #3.

3. Does the patient have a contraindication to telaprevir or has previously failed a short trial with telaprevir (e.g. rash early in therapy or other intolerance)?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of chronic hepatitis C, genotype 1, minimum age of 18, current supervision by a gastroenterologist, infectious disease specialist, or a physician specializing in the treatment of hepatitis (e.g. hepatologist), and concurrent use of ribavirin and peginterferon alfa. Approval requires that the patient has a contraindication/intolerance to telaprevir (Incivek). Approval requires that the patient does not have coinfection with hepatitis B or have a history of a previous solid organ transplant. Approval requires that the patient has not failed previous therapy with telaprevir (Incivek) or boceprevir (Victrelis) and is not a previous null responder. Approval requires that the patient is not concurrently taking carbamazepine, phenobarbital, phenytoin, or rifampin.

CONTINUED ON NEXT PAGE

BOCEPREVIR

GUIDELINES FOR USE (CONTINUED)

4. Is the patient at least 18 years old with a diagnosis of chronic hepatitis C, genotype 1?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of chronic hepatitis C, genotype 1, minimum age of 18, current supervision by a gastroenterologist, infectious disease specialist, or a physician specializing in the treatment of hepatitis (e.g. hepatologist), and concurrent use of ribavirin and peginterferon alfa. Approval requires that the patient has a contraindication/intolerance to telaprevir (Incivek). Approval requires that the patient does not have coinfection with hepatitis B or have a history of a previous solid organ transplant. Approval requires that the patient has not failed previous therapy with telaprevir (Incivek) or boceprevir (Victrelis) and is not a previous null responder. Approval requires that the patient is not concurrently taking carbamazepine, phenobarbital, phenytoin, or rifampin.

5. Is the patient currently supervised by a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (e.g. hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model?

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of chronic hepatitis C, genotype 1, minimum age of 18, current supervision by a gastroenterologist, infectious disease specialist, or a physician specializing in the treatment of hepatitis (e.g. hepatologist), and concurrent use of ribavirin and peginterferon alfa. Approval requires that the patient has a contraindication/intolerance to telaprevir (Incivek). Approval requires that the patient does not have coinfection with hepatitis B or have a history of a previous solid organ transplant. Approval requires that the patient has not failed previous therapy with telaprevir (Incivek) or boceprevir (Victrelis) and is not a previous null responder. Approval requires that the patient is not concurrently taking carbamazepine, phenobarbital, phenytoin, or rifampin.

6. Has the patient failed a prior full course of triple therapy (with telaprevir [Incivek] or boceprevir [Victrelis])?

   If yes, do not approve.
   DENIAL TEXT: Approval requires that the patient has not failed a full course of therapy with telaprevir (Incivek) or boceprevir (Victrelis). Approval requires a diagnosis of chronic hepatitis C, genotype 1, minimum age of 18, current supervision by a gastroenterologist, infectious disease specialist, or a physician specializing in the treatment of hepatitis (e.g. hepatologist), and concurrent use of ribavirin and peginterferon alfa. Approval requires that the patient does not have coinfection with hepatitis B, or have a history of a previous solid organ transplant. Approval requires that the patient has not failed therapy with telaprevir (Incivek) or boceprevir (Victrelis) and is not a previous null responder. Approval requires that the patient is not concurrently taking carbamazepine, phenobarbital, phenytoin, or rifampin.
   If no, continue to #7.

CONTINUED ON NEXT PAGE

GUIDELINES FOR USE (CONTINUED)

7. Has the patient previously failed a prior course of peginterferon and ribavirin as a null responder (defined as less than 2 log reduction in HCV RNA at week 12)?

   If yes, do not approve.
   DENIAL TEXT: Approval requires that the patient is not a previous null responder to a course of peginterferon/ribavirin and has not failed a full course of therapy with telaprevir (Incivek) or boceprevir (Victrelis). Approval requires a diagnosis of chronic hepatitis C, genotype 1, minimum age of 18, current supervision by a gastroenterologist, infectious disease specialist or a physician specializing in the treatment of hepatitis (e.g. hepatologist), and concurrent use of ribavirin and peginterferon alfa. Approval requires that the patient does not have coinfection with hepatitis B, or have a history of a previous solid organ transplant. Approval requires that the patient has not failed therapy with telaprevir (Incivek) or boceprevir (Victrelis) and is not a previous null responder. Approval requires that the patient is not concurrently taking carbamazepine, phenobarbital, phenytoin, or rifampin.
   If no, continue to #8.

8. Is the patient currently taking carbamazepine, phenobarbital, phenytoin, or rifampin?

   If yes, do not approve.
   DENIAL TEXT: Approval requires that the patient is not currently taking carbamazepine, phenobarbital, phenytoin, or rifampin. Approval requires a diagnosis of chronic hepatitis C, genotype 1, minimum age of 18, current supervision by a gastroenterologist, infectious disease specialist, or a physician specializing in the treatment of hepatitis (e.g. hepatologist), and concurrent use of ribavirin and peginterferon alfa. Approval requires that the patient does not have coinfection with hepatitis B, or have a history of a previous solid organ transplant. Approval requires that the patient has not failed therapy with telaprevir (Incivek) or boceprevir (Victrelis) and is not a previous null responder. Approval requires that the patient is not concurrently taking carbamazepine, phenobarbital, phenytoin, or rifampin.
   If no, continue to #9.

CONTINUED ON NEXT PAGE

BOCEPREVIR

GUIDELINES FOR USE (CONTINUED)

9. Does the patient have a coinfection hepatitis B, or have a history of a previous solid organ transplant?

   If yes, do not approve.
   DENIAL TEXT: Approval requires that the patient does not have coinfection with hepatitis B, or have a history of a previous solid organ transplant. Approval requires a diagnosis of chronic hepatitis C, genotype 1, minimum age of 18, current supervision by a gastroenterologist, infectious disease specialist, or a physician specializing in the treatment of hepatitis (e.g. hepatologist), and concurrent use of ribavirin and peginterferon alfa. Approval requires that the patient has not failed therapy with telaprevir (Incivek) or boceprevir (Victrelis) and is not a previous null responder. Approval requires that the patient is not concurrently taking carbamazepine, phenobarbital, phenytoin, or rifampin.

   If no, **APPROVE THE FIRST FILL FOR #12 CAPSULES PER DAY FOR 12 WEEKS.**
   PAC: The days supply is based on the benefit structure. Enter the Maximum Daily Dose (MDD) = 12 capsules and a duration of 84 days (with start date 3 weeks after the start date of peginterferon PA).
   APPROVAL TEXT: Renewal requires HCV RNA levels at baseline and then at treatment weeks 4, 8, 12 and 24. Also the request must specify if the patient qualifies for 44 weeks of boceprevir treatment (for example one of the following: cirrhosis, poorly interferon responsive at treatment week 4 during current therapy, or less than 2-log HCV RNA decline by treatment week 12 during prior peginterferon/ribavirin therapy). Drugs that are contraindicated with Victrelis include alfuzosin, carbamazepine, phenobarbital, phenytoin, rifampin, ergot derivatives, cisapride, St John's Wort, lovastatin, simvastatin, drospirenone, sildenafil or tadalafil (at doses used to treat pulmonary arterial hypertension [PAH]), pimozide, triazolam, or orally administered midazolam.

10. **Renewal criteria for treatment week 16:** If the patient has received one previous boceprevir approval for 12 weeks of boceprevir (now at treatment week 16), continue to #11.

    Renewal criteria for treatment week 28: If the patient has received two previous approvals (now at treatment week 28), continue to #12.

CONTINUED ON NEXT PAGE

BOCEPREVIR

GUIDELINES FOR USE (CONTINUED)

11. **Renewal criteria for treatment week 16:** Did the patient have an HCV RNA level/viral load of ≥ 100 IU/mL at 8 weeks of boceprevir therapy (treatment week 12)?

    If yes, do not approve.
    CLINICAL SPECIALISTS: Triple therapy will be discontinued at this time. Review the prior authorization history and close peginterferon PA (and ribavirin PA, if applicable).
    DENIAL TEXT: Renewal requires HCV RNA level/viral load of less than 100 IU/mL at 8 weeks of boceprevir therapy (treatment week 12).

    If no, **APPROVE THE SECOND FILL FOR #12 CAPSULES PER DAY FOR 12 WEEKS.**
    PAC: The days supply is based on the benefit structure. Enter the Maximum Daily Dose (MDD) = 12 capsules and a duration of 84 days.
    APPROVAL TEXT: Renewal requires HCV RNA level at treatment week 24. Drugs that are contraindicated with Victrelis include alfuzosin, carbamazepine, phenobarbital, phenytoin, rifampin, ergot derivatives, cisapride, St John's Wort, lovastatin, simvastatin, drospirenone, sildenafil or tadalafil (at doses used to treat pulmonary arterial hypertension [PAH]), pimozide, triazolam, or orally administered midazolam.

12. **Renewal criteria for treatment week 28:** Did the patient have a detectable HCV RNA level/viral load at treatment week 24?

    If yes, do not approve.
    CLINICAL SPECIALISTS: Triple therapy will be discontinued at this time. Review the prior authorization history and close peginterferon PA (and ribavirin PA, if applicable).
    DENIAL TEXT: Renewal requires an undetectable HCV RNA level/viral load at 20 weeks of boceprevir therapy (treatment week 24).
    If no, continue to #13.

13. Is the patient one of the following:
    - a patient with cirrhosis,
    - a patient that was poorly interferon responsive at treatment week 4 during present therapy (less than 0.5 log HCV RNA decline at treatment week 4)?

    If yes, **APPROVE THE THIRD FILL FOR #12 CAPSULES PER DAY FOR 20 WEEKS.**
    PAC: The days supply is based on benefit structure. Enter the Maximum Daily Dose (MDD) = 12 capsules and a duration of 140 days.
    APPROVAL TEXT: Drugs that are contraindicated with Victrelis include alfuzosin, carbamazepine, phenobarbital, phenytoin, rifampin, ergot derivatives, cisapride, St John's Wort, lovastatin, simvastatin, drospirenone, sildenafil or tadalafil at doses used to treat pulmonary arterial hypertension (PAH), pimozide, triazolam, or orally administered midazolam.
    If no, continue to #14.

CONTINUED ON NEXT PAGE

GUIDELINES FOR USE (CONTINUED)

14. Did the patient have an undetectable HCV RNA level at both treatment week 8 and treatment week 24?

    If yes, continue to #16.
    If no, continue to #15.

15. Did the patient have a detectable level at treatment week 8 but an undetectable level at treatment week 24?

    If yes, **APPROVE THE THIRD FILL FOR #12 CAPSULES PER DAY FOR 8 WEEKS.**
    PAC: The days supply is based on the benefit structure. Enter the Maximum Daily Dose (MDD) = 12 capsules and a duration of 56 days.
    CLINICAL SPECIALISTS: Continue three medication regimens through treatment week 36 and the patient will receive peginterferon/ribavirin through treatment week 48.
    APPROVAL TEXT: Drugs that are contraindicated with Victrelis include alfuzosin, carbamazepine, phenobarbital, phenytoin, rifampin, ergot derivatives, cisapride, St John's Wort, lovastatin, simvastatin, drospirenone, sildenafil or tadalafil (at doses used to treat pulmonary arterial hypertension [PAH]), pimozide, triazolam, or orally administered midazolam.
    If no, do not approve.
    DENIAL TEXT: Approval requires a diagnosis of chronic hepatitis C, genotype 1, minimum age of 18, current supervision by a gastroenterologist, infectious disease specialist, or a physician specializing in the treatment of hepatitis (e.g. hepatologist), and concurrent use of ribavirin and peginterferon alfa. The patient must have an undetectable level at treatment week 24.

16. Did the patient fail (*partial responder* or *relapser*) a prior trial of ribavirin and peginterferon alfa therapy (does not include previous null responders, defined as less than 2 log reduction in HCV RNA at week 12)?

    - *Partial responder* is defined as 2 log or higher reduction in HCV RNA at week 12 but not undetectable HCV RNA at end of treatment;
    - *Relapser* is defined as undetectable HCV RNA at end of therapy but detectable during follow-up

    If yes, **APPROVE THE THIRD FILL FOR #12 CAPSULES PER DAY FOR 8 WEEKS.**
    PAC: The days supply is based on the benefit structure. Enter the Maximum Daily Dose (MDD) = 12 capsules and a duration of 56 days.
    APPROVAL TEXT: Drugs that are contraindicated with Victrelis include alfuzosin, carbamazepine, phenobarbital, phenytoin, rifampin, ergot derivatives, cisapride, St John's Wort, lovastatin, simvastatin, drospirenone, sildenafil or tadalafil (at doses used to treat pulmonary arterial hypertension [PAH]), pimozide, triazolam, or orally administered midazolam.
    If no, continue to #17.

CONTINUED ON NEXT PAGE

GUIDELINES FOR USE (CONTINUED)

17. Is the patient treatment naïve (previously untreated prior to current regimen)?

If yes, do not approve.
CLINICAL SPECIALISTS: Review prior authorization history, complete triple therapy at treatment week 28.
DENIAL TEXT: Previously untreated patients must complete triple therapy at treatment week 28. Twenty four weeks of boceprevir was previously approved; therefore no further boceprevir is approved after treatment week 28.

If no, do not approve.
DENIAL TEXT: Approval requires a diagnosis of chronic hepatitis C, genotype 1, minimum age of 18, current supervision by a gastroenterologist, infectious disease specialist, or a physician specializing in the treatment of hepatitis (e.g. hepatologist), and concurrent use of ribavirin and peginterferon alfa. Patient must have an undetectable level at treatment week 24.

CONTINUED ON NEXT PAGE

BOCEPREVIR

RATIONALE
Ensure appropriate utilization of boceprevir based on FDA approved indication.

FDA APPROVED INDICATIONS
Victrelis is indicated for the treatment of chronic hepatitis C genotype 1 infection, in combination with peginterferon alfa and ribavirin, in adult patients (=18 years of age) with compensated liver disease, including cirrhosis, who are previously untreated or who have failed previous interferon and ribavirin therapy.

FDA APPROVED DOSAGE
Victrelis 800mg (four 200mg capsules) orally three times daily is added to peginterferon alfa and ribavirin after 4 weeks of treatment. Duration of treatment is determined based on the patient's HCV-RNA levels at treatment week (TW) 8, 12, and 24. Patients with HCV RNA level greater than or equal to 100 IU/mL at TW 12 or any detectable HCV RNA level at treatment week 24 should discontinue the three medication regimen. Patients with compensated cirrhosis, patients with poor interferon response at TW 4 should receive 4 weeks of peginterferon alfa and ribavirin followed by 44 weeks of Victrelis in combination with peginterferon alfa and ribavirin.

OTHER INFORMATION
Currently AASLD treatment guidelines recommend that "any use of boceprevir in HIV-coinfected or transplant populations infected with HCV should be done with caution and under close clinical monitoring. A clinical trial evaluating use of boceprevir triple therapy in HCV/HIV co-infected patients showed significantly higher rates of SVR than in patients treated with peginterferon/ribavirin alone.

REFERENCES

- Arora S, Thornton K, Murata G, et al. Outcomes of Treatment for Hepatitis C Virus Infection by Primary Care Providers. NEJM 364;23: 2199-2207.
- Ghany M, Nelson D, Strader D, Thomas D, and Seeff L. An Update on Treatment of Genotype I Chronic Hepatitis C Virus Infection: 2011
- Practice Guidelines by the American Association for the Study of Liver Diseases. Hepatology 2011; 54 (4): 1433-1443. Accessed online March 9, 2012 at: http://www.aasld.org/practiceguidelines/Documents/2011UpdateGenotype1HCVbyAASLD24641.pdf
- Merck/Schering Corporation. Victrelis package insert. Whitehouse Station, NJ. May 2011.
- Poizant-Martin, I, Bellissant E, et al. Phase IIb trial results (http://clinicaltrials.gov/ct2/show/NCT01335529); presented at the 19th Conference on Retroviruses and Opportunistic Infections (CROI): Presented March 2012.

Created: 05/11
Effective: 10/01/12 Client Approval: 08/30/12

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

BOTULINUM NEUROTOXIN

Generic	Brand	HICL	GCN	Exception/Other
ONABOTULINUM TOXIN A	BOTOX	04867		BRAND ≠ BOTOX COSMETIC
ABOBOTULINUM TOXIN A	DYSPORT	36477		
RIMABOTULINUM TOXIN B	MYOBLOC	21869		
INCOBOTULINUM TOXIN A	XEOMIN	36687		

GUIDELINES FOR USE

1. Is the request for the improvement of appearance of glabellar lines in the face (i.e. wrinkles)?

   If yes, do not approve.
   BOTOX DENIAL TEXT: Approval requires a non-cosmetic diagnosis such as cervical dystonia also called spasmodic torticollis (involuntary contracting of the neck muscles) or blepharospasm (involuntary forcible closure of the eyelid), strabismus (cross-eyed), primary axillary hyperhidrosis (excessive underarm sweating), upper limb spasticity or migraine headache, or urinary incontinence due to detrusor overactivity associated with a neurologic condition [such as spinal cord injury (SCI), multiple sclerosis (MS)] and a trial of an anticholinergic medication such as oxybutynin, Ditropan XL, Detrol, Detrol LA, or Toviaz.

   DYSPORT DENIAL TEXT: Approval requires a non-cosmetic diagnosis such as cervical dystonia also called spasmodic torticollis (involuntary contracting of the neck muscles).

   MYOBLOC DENIAL TEXT: Approval requires a non-cosmetic diagnosis such as cervical dystonia also called spasmodic torticollis (involuntary contracting of the neck muscles).

   XEOMIN DENIAL TEXT: Approval requires a non-cosmetic diagnosis such as cervical dystonia also called spasmodic torticollis (involuntary contracting of the neck muscles) or blepharospasm (involuntary forcible closure of the eyelid).

   If no, continue to #2.

2. Does the patient have a diagnosis of migraine headache?

   If yes, continue to #3.
   If no, continue to #5.

CONTINUED ON NEXT PAGE

BOTULINUM NEUROTOXIN

GUIDELINES FOR USE (CONTINUED)

3. Is the request for Botox (onabotulinum toxin A)?

   If yes, continue to #4.
   If no, process as follows by drug:
   DYSPORT: Do not approve.
   DYSPORT DENIAL TEXT: Approval requires a diagnosis of cervical dystonia also called spasmodic torticollis (involuntary contracting of the neck muscles).

   MYOBLOC: Do not approve.
   MYOBLOC DENIAL TEXT: Approval requires a diagnosis of cervical dystonia also called spasmodic torticollis (involuntary contracting of the neck muscles).

   XEOMIN: Do not approve.
   XEOMIN DENIAL TEXT: Approval requires a diagnosis of cervical dystonia also called spasmodic torticollis (involuntary contracting of the neck muscles) or blepharospasm (involuntary forcible closure of the eyelid).

4. Has the patient tried or does the patient have a contraindication to 2 of the following: beta-blockers (e.g. propranolol, nadolol), tricyclic antidepressants (e.g. amitriptyline, nortriptyline, doxepin), **or** valproic acid?

   If yes, **APPROVE BOTOX FOR 12 MONTHS WITH THE FOLLOWING QUANTITY LIMITS: UP TO TWO 100 UNIT VIALS OR ONE 200 UNIT VIAL EVERY 3 MONTHS.**
   APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

   If no, do not approve.
   DENIAL TEXT: Approval requires a trial of 2 of the following: a beta-blocker (such as propranolol or nadolol), a tricyclic antidepressant (such as amitriptyline, nortriptyline or doxepin) or delayed-release valproic acid.

CONTINUED ON NEXT PAGE

BOTULINUM NEUROTOXIN

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have cervical dystonia also called spasmodic torticollis (involuntary contracting of the neck muscles)?

   If yes, **APPROVE FOR 12 MONTHS OR LENGTH OF THERAPY, (WHICHEVER IS LESS) WITH THE FOLLOWING QUANTITY LIMITS:**
   BOTOX: UP TO THREE 100 UNIT VIALS OR ONE 200 UNIT VIAL EVERY 3 MONTHS.
   DYSPORT: UP TO TWO 500 UNIT VIALS OR ONE 300 UNIT VIAL EVERY 3 MONTHS.
   MYOBLOC: UP TO TWO 2,500 UNIT VIALS, ONE 5,000 UNIT VIAL OR ONE 10,000 UNIT VIAL EVERY 3 MONTHS.
   XEOMIN: UP TO THREE 50 UNIT VIALS OR TWO 100 UNIT VIALS EVERY 3 MONTHS.
   APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

   If no, continue to #6.

6. Does the patient have primary axillary hyperhidrosis (excessive underarm sweating)?

   If yes, process as follows by drug:
   BOTOX: APPROVE FOR 12 MONTHS OR LENGTH OF THERAPY, (WHICHEVER IS LESS) WITH THE FOLLOWING QUANTITY LIMITS: UP TO THREE 100 UNIT VIALS OR ONE 200 UNIT VIAL EVERY 3 MONTHS.
   APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

   DYSPORT: Do not approve.
   DYSPORT DENIAL TEXT: Approval requires a diagnosis of cervical dystonia also called spasmodic torticollis (involuntary contracting of the neck muscles).

   MYOBLOC: Do not approve.
   MYOBLOC DENIAL TEXT: Approval requires a diagnosis of cervical dystonia also called spasmodic torticollis (involuntary contracting of the neck muscles).

   XEOMIN: Do not approve.
   XEOMIN DENIAL TEXT: Approval requires a diagnosis of cervical dystonia also called spasmodic torticollis (involuntary contracting of the neck muscles) or blepharospasm (involuntary forcible closure of the eyelid).

   If no, continue to #7.

CONTINUED ON NEXT PAGE

BOTULINUM NEUROTOXIN

GUIDELINES FOR USE (CONTINUED)

7. Is the patient being treated for upper limb spasticity involving muscles of the elbow, wrist, and fingers?

   If yes, process as follows by drug:
   BOTOX: APPROVE FOR 12 MONTHS OR LENGTH OF THERAPY, (WHICHEVER IS LESS) WITH THE FOLLOWING QUANTITY LIMITS: UP TO FOUR 100 UNIT VIALS OR TWO 200 UNIT VIAL EVERY 3 MONTHS.
   BOTOX APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information please ask your doctor or pharmacist.

   DYSPORT: Do not approve.
   DYSPORT DENIAL TEXT: Approval requires a diagnosis of cervical dystonia also called spasmodic torticollis (involuntary contracting of the neck muscles).

   MYOBLOC: Do not approve.
   MYOBLOC DENIAL TEXT: Approval requires a diagnosis of cervical dystonia also called spasmodic torticollis (involuntary contracting of the neck muscles).

   XEOMIN: Do not approve.
   XEOMIN DENIAL TEXT: Approval requires a diagnosis of cervical dystonia also called spasmodic torticollis (involuntary contracting of the neck muscles) or blepharospasm (involuntary forcible closure of the eyelid).

   If no, continue to #8.

CONTINUED ON NEXT PAGE

GUIDELINES FOR USE (CONTINUED)

8. Does the patient have strabismus (cross-eyed)?

   If yes, process as follows by drug:
   BOTOX: APPROVE FOR 12 MONTHS OR LENGTH OF THERAPY, (WHICHEVER IS LESS) WITH THE FOLLOWING QUANTITY LIMITS: UP TO THREE 100 UNIT VIALS OR ONE 200 UNIT VIAL EVERY 3 MONTHS.
   APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

   DYSPORT: Do not approve.
   DYSPORT DENIAL TEXT: Approval requires a diagnosis of cervical dystonia also called spasmodic torticollis (involuntary contracting of the neck muscles).

   MYOBLOC: Do not approve.
   MYOBLOC DENIAL TEXT: Approval requires a diagnosis of cervical dystonia also called spasmodic torticollis (involuntary contracting of the neck muscles).

   XEOMIN: Do not approve.
   XEOMIN DENIAL TEXT: Approval requires a diagnosis of cervical dystonia also called spasmodic torticollis (involuntary contracting of the neck muscles) or blepharospasm (involuntary forcible closure of the eyelid).

   If no, continue to #9.

9. Does the patient have blepharospasm (involuntary forcible closure of the eyelid)?

   If yes, continue to #10.
   If no, process as follows by drug:
   BOTOX: continue to #13.

   DYSPORT: Do not approve.
   DYSPORT DENIAL TEXT: Approval requires a diagnosis of cervical dystonia also called spasmodic torticollis (involuntary contracting of the neck muscles).

   MYOBLOC: Do not approve.
   MYOBLOC DENIAL TEXT: Approval requires a diagnosis of cervical dystonia also called spasmodic torticollis (involuntary contracting of the neck muscles).

   XEOMIN: Do not approve.
   XEOMIN DENIAL TEXT: Approval requires a diagnosis of cervical dystonia also called spasmodic torticollis (involuntary contracting of the neck muscles) or blepharospasm (involuntary forcible closure of the eyelid).

CONTINUED ON NEXT PAGE

BOTULINUM NEUROTOXIN

GUIDELINES FOR USE (CONTINUED)

10. Is the request for Botox (onabotulinum toxin A)?

    If yes, **APPROVE BOTOX FOR 12 MONTHS OR LENGTH OF THERAPY, (WHICHEVER IS LESS) WITH THE FOLLOWING QUANTITY LIMITS: UP TO THREE 100 UNIT VIALS OR ONE 200 UNIT VIAL EVERY 3 MONTHS.**
    APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

    If no, continue to #11.

11. Is the request for Xeomin (incobotulinum toxin A)?

    If yes, continue to #12.
    If no, do not approve.
    DENIAL TEXT: Approval requires a diagnosis of cervical dystonia also called spasmodic torticollis (involuntary contracting of the neck muscles).

12. Has the patient been previously treated with Botox (onabotulinum toxin A)?

    If yes, **APPROVE XEOMIN FOR 12 MONTHS OR LENGTH OF THERAPY, (WHICHEVER IS LESS) WITH THE FOLLOWING QUANTITY LIMITS: UP TO THREE 50 UNIT VIALS OR TWO 100 UNIT VIALS EVERY 3 MONTHS.**
    APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

    If no, do not approve.
    XEOMIN DENIAL TEXT: Approval requires a trial of Botox (onabotulinum toxin A), which may also require prior authorization.

13. Does the patient have a diagnosis of urinary incontinence due to detrusor overactivity associated with a neurologic condition [such as spinal cord injury (SCI), multiple sclerosis (MS)]?

    If yes, continue to #14.
    If no, do not approve.
    BOTOX DENIAL TEXT: Approval requires a non-cosmetic diagnosis such as cervical dystonia also called spasmodic torticollis (involuntary contracting of the neck muscles) or blepharospasm (involuntary forcible closure of the eyelid), strabismus (cross-eyed), primary axillary hyperhidrosis (excessive underarm sweating), or upper limb spasticity or migraine headache, or urinary incontinence due to detrusor overactivity associated with a neurologic condition [such as spinal cord injury (SCI), multiple sclerosis (MS)] and a trial of an anticholinergic medication such as oxybutynin, Ditropan XL, Detrol, Detrol LA, or Toviaz.

CONTINUED ON NEXT PAGE

BOTULINUM NEUROTOXIN

GUIDELINES FOR USE (CONTINUED)

14. Has the patient tried or have a contraindication to the use of an anticholinergic medication (such as oxybutynin, Ditropan XL, Detrol, Detrol LA, Enablex, Toviaz, VESIcare, or Sanctura)?

    If yes, **APPROVE BOTOX FOR 12 MONTHS OR LENGTH OF THERAPY, (WHICHEVER IS LESS) WITH THE FOLLOWING QUANTITY LIMITS: UP TO TWO 100 UNIT VIALS OR ONE 200 UNIT VIAL EVERY 3 MONTHS.**
    APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

    If no, do not approve.
    BOTOX DENIAL TEXT: Approval requires a non-cosmetic diagnosis such as cervical dystonia also called spasmodic torticollis (involuntary contracting of the neck muscles) or blepharospasm (involuntary forcible closure of the eyelid), strabismus (cross-eyed), primary axillary hyperhidrosis (excessive underarm sweating), or upper limb spasticity or migraine headache, or of urinary incontinence due to detrusor overactivity associated with a neurologic condition [such as spinal cord injury (SCI), multiple sclerosis (MS)] and a trial of an anticholinergic medication such as oxybutynin, Ditropan XL, Detrol, Detrol LA, or Toviaz.

RATIONALE
Ensure botulinum neurotoxin is used for non-cosmetic use.

FDA APPROVED INDICATIONS
BOTOX is approved for the treatment cervical dystonia in adults. It is also approved for blepharospasm and strabismus in patients' ≥ 12 years of age. Botox is also indicated for adults in the treatment of severe primary axillary hyperhidrosis that is inadequately managed with topical agents and for the treatment of upper limb spasticity involving muscles in the elbow, wrist, and finger. Botox is indicated for the prophylaxis of headaches in adult patients with chronic migraine (≥ 15 days per month with headache lasting 4 hours a day or longer). Botox is indicated for the treatment of urinary incontinence due to detrusor overactivity associated with a neurologic condition [e.g. spinal cord injury (SCI), multiple sclerosis (MS)] in adults who have an inadequate response to or are intolerant of an anticholinergic medication.

DYSPORT is approved for adults with cervical dystonia and for the temporary improvement in moderate to severe glabellar lines in adults < 65 years of age.

MYOBLOC is only approved for cervical dystonia.

XEOMIN is approved for adults with cervical dystonia, to decrease the severity of abnormal head position and neck pain in both botulinum toxin-naïve and previously treated patients. Xeomin is also approved for blepharospasm in adults previously treated with onabotulinum toxin A

CONTINUED ON NEXT PAGE

BOTULINUM NEUROTOXIN

REFERENCES

- Solstice Neurosciences, Inc. Myobloc package insert. South San Francisco, CA. July 2009.
- Allergan Pharmaceuticals. Botox package insert. Irvine, CA. August 2011.
- Tercica, Inc. Dysport package insert. Brisbane, CA. May 2009.
- Merz Pharmaceuticals, LLC. Xeomin package insert. Greensboro, NC. July 2010.
- Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2008. Available at: http://www.clinicalpharmacology.com. [Accessed: July 21, 2011]
- Micromedex® Healthcare Series [database online].Greenwood Village, Colo: Thomson Healthcare. Available at https://www.thomsonhc.com/hcs/librarian. [Accessed: July 21, 2011]
- Silberstein SD. Practice parameter: Evidence-Based guidelines for migraine headache (an evidence-based review): Report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology 2000; 55; 754-762.

Created: 12/27/12
Effective: 01/23/13 Client Approval: 11/29/12

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

CAPSAICIN

Generic	Brand	HICL	GCN	Exception/Other
CAPSAICIN 8% PATCH	QUTENZA	36916		

GUIDELINES FOR USE

1. Does the patient have neuropathic pain associated with postherpetic neuralgia?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of neuropathic pain associated with postherpetic neuralgia.

2. Has the patient failed a trial of 2 or more agents, given 30 days apart, for treatment of post-herpetic neuralgia?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: Approval requires trial and failure of 2 or more agents for treatment of pain associated with post-herpetic neuralgia given 30 days apart.

3. **Approve for 6 months with the quantity limit below:**
   - **Up to 4 patches every 3 months or copay.**

RATIONALE
To ensure appropriate utilization of Qutenza.

FDA APPROVED INDICATIONS
Qutenza is indicated for the treatment of neuropathic pain associated with postherpetic neuralgia.

REFERENCES

- NeurogesX, Inc. Qutenza package insert. San Mateo, CA. November 2009.
- Dubinsky RM, Kabbani H, El-Chami Z, et al. Practice parameter: treatment of postherpetic neuralgia: an evidence-based report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology. 2004; 63(6):959-965.
- Micromedex® Healthcare Series [database online]. Greenwood Village, CO: Thomson Healthcare. Available at: www.thomsonhc.com/hcs/librarian/. [Accessed: May 6, 2010.]

Created: 09/10
Effective: 10/01/10 Client Approval: 09/20/10

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

CERTOLIZUMAB PEGOL

Generic	Brand	HICL	GCN	Exception/Other
CERTOLIZUMAB PEGOL	CIMZIA	35554		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe Crohn's Disease?

   If yes, continue to #2.
   If no, continue to #4.

2. Has the drug been prescribed or is the patient currently being supervised by a gastroenterologist?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: Approval requires supervision by a gastroenterologist, a diagnosis of moderate to severe Crohn's disease and trial of one or more conventional therapies (corticosteroids, azathioprine, mercaptopurine, methotrexate, or mesalamine).

3. Has the patient tried one or more conventional therapies for Crohn's Disease such as: corticosteroids, azathioprine, mercaptopurine, methotrexate, or mesalamine?

   If yes, **APPROVE ONE STARTER KIT (#6 PREFILLED SYRINGES) X 1 OR #3 KITS (#2 VIALS OR PREFILLED SYRINGES) X 1 FOR THE FIRST MONTH, THEN APPROVE ONE KIT (#2 VIALS OR PREFILLED SYRINGES) PER MONTH X 2 MONTHS.**
   APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.
   If no, do not approve.
   DENIAL TEXT: Approval requires supervision by a gastroenterologist, a diagnosis of moderate to severe Crohn's disease and a trial of one or more conventional therapies (corticosteroids, azathioprine, mercaptopurine, methotrexate, or mesalamine).

4. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of moderate to severe rheumatoid arthritis, supervision by a rheumatologist, a trial of at least one recommended DMARD agent (disease-modifying antirheumatic drug), and concurrent methotrexate or a contraindication to methotrexate.

CONTINUED ON NEXT PAGE

CERTOLIZUMAB PEGOL

INITIAL CRITERIA (CONTINUED)

5. Has the drug been prescribed by or is the patient currently being supervised by a rheumatologist?

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of moderate to severe rheumatoid arthritis, supervision by a rheumatologist, a trial of at least one recommended DMARD agent (disease-modifying antirheumatic drug), and concurrent methotrexate or a contraindication to methotrexate.

6. Has the patient tried and failed, or experienced intolerable side effects to at least one of the following DMARD agents: methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine?

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of moderate to severe rheumatoid arthritis, supervision by a rheumatologist, a trial of at least one recommended DMARD agent (disease-modifying antirheumatic drug), and concurrent methotrexate or a contraindication to methotrexate.

7. Is the patient taking methotrexate or does the patient have a contraindication to methotrexate?

   If yes, **APPROVE ONE STARTER KIT (#6 PREFILLED SYRINGES) X 1 OR #3 KITS (#2 VIALS OR PREFILLED SYRINGES) X 1 FOR THE FIRST MONTH, THEN APPROVE ONE KIT (#2 VIALS OR PREFILLED SYRINGES) PER MONTH X 2 MONTHS.**
   APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of moderate to severe rheumatoid arthritis, supervision by a rheumatologist, a trial of at least one recommended DMARD agent (disease-modifying antirheumatic drug), and concurrent methotrexate or a contraindication to methotrexate.

RENEWAL CRITERIA

1. Does the patient have Crohn's disease or rheumatoid arthritis?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: Approval requires supervision by a gastroenterologist or a rheumatologist and a diagnosis of moderate to severe Crohn's disease or moderate to severe rheumatoid arthritis.

CONTINUED ON NEXT PAGE

CERTOLIZUMAB PEGOL

RENEWAL CRITERIA (CONTINUED)

2. Has the drug been prescribed by or is the patient currently being supervised by a gastroenterologist or rheumatologist?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: Approval requires supervision by a gastroenterologist or a rheumatologist and a diagnosis of moderate to severe Crohn's disease or moderate to severe rheumatoid arthritis.

3. Does the patient have Crohn's disease?

   If yes, **APPROVE ONE KIT (#2 VIALS OR PREFILLED SYRINGES) PER MONTH X 12 MONTHS.**
   APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information please ask your doctor or pharmacist.
   If no, continue to #4.

4. Does the patient have rheumatoid arthritis?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: Approval requires supervision by a gastroenterologist or a rheumatologist and a diagnosis of moderate to severe Crohn's disease or moderate to severe rheumatoid arthritis.

5. Has the patient experienced or maintained a 20% or greater improvement in tender joint count and swollen joint count?

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: Approval requires supervision by a rheumatologist, a diagnosis of moderate to severe rheumatoid arthritis, that patient has experienced or maintained a 20% improvement in tender or swollen joint count while on therapy, and that the patient is currently taking methotrexate or has a contraindication to methotrexate.

CONTINUED ON NEXT PAGE

CERTOLIZUMAB PEGOL

RENEWAL CRITERIA (CONTINUED)

6. Is the patient currently taking methotrexate or does the patient have a contraindication to methotrexate?

   If yes, **APPROVE ONE KIT (#2 VIALS OR PREFILLED SYRINGES) PER MONTH X 12 MONTHS.**
   APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information please ask your doctor or pharmacist.
   If no, do not approve.
   DENIAL TEXT: Approval requires supervision by a rheumatologist, a diagnosis of moderate to severe rheumatoid arthritis, that patient has experienced or maintained a 20% improvement in tender or swollen joint count while on therapy, and that the patient is currently taking methotrexate or has a contraindication to methotrexate.

RATIONALE
Ensure appropriate diagnostic, utilization and safety criteria are used for the management of prior authorization requests for certolizumab pegol.

FDA APPROVED INDICATIONS
CIMZIA is indicated for reducing signs and symptoms of Crohn's disease and maintaining clinical response in adult patients with moderately to severely active disease that have had an inadequate response to conventional therapy.

CIMZIA is also indicated for the treatment of moderately to severely active rheumatoid arthritis.

REFERENCES

- UCB, Inc. Cimzia product information, Smyrna, GA. May 2009.
- Bristol-Myers Squibb. Orencia product information. Princeton, NJ. August 2009.
- Amgen. Kineret product information. Thousand Oaks, CA. December 2009.
- Micromedex® Healthcare Series [database online]. Greenwood Village, Colo: Thomson Healthcare. Available at https://www.thomsonhc.com/hcs/librarian. [Accessed: June 7, 2010].

Created: 08/09 Revised: 02/16/12
Effective: 03/20/12 Client Approval: 02/16/12

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

CLOMIPHENE

Generic	Brand	HICL	GCN	Exception/Other
CLOMIPHENE CITRATE	CLOMID SEROPHENE	02821		

GUIDELINES FOR USE

1. Is the patient using clomiphene for infertility purposes?

   If yes, continue to #4.
   If no, continue to #2.

2. Is the patient using clomiphene for diagnostic purposes (e.g. clomiphene challenge test)?

   If yes, continue to #3.
   If no, continue to #4.

3. **APPROVE WITHOUT LIMITS.**

4. **DO NOT APPROVE.**

RATIONALE
To assure the use of clomiphene per Ascension Policy

FDA APPROVED INDICATIONS
Treatment of ovulatory dysfunction

REFERENCES
Clomid Prescribing Information: www.sanofi-aventis.com

Created: 12/17/08
Effective: 01/01/09 Client Approval 12/10/08

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

CONTRACEPTIVES

Generic	Brand	HICL	GCN	Exception/Other
ETHINYL ESTRADIOL, MESTRANOL = ESTROGENIC COMPONENT DESOGESTREL, DROSPIRENONE, ETHYNODIOL DIACETATE, LEVONORGESTREL, NORETHINDRONE, NORGESTREL, NORGESTIMATE, LEVONORGESTREL = PROGESTIN COMPONENT				TCC = G8A
	NUVARING	23721	17528	
	ORTHO EVRA	23235	15524	
PROGESTERONE	DEPO-PROVERA LUNELLE			TCC=G8C

GUIDELINES FOR USE

<u>NOTE</u>: NuvaRing and Depo-Provera are excluded for ASC02.

1. Does the patient have one of the following documented conditions?

    a. Recalcitrant acne
    b. Amenorrhea
    c. Dysfunctional uterine bleeding
    d. Dysmenorrhea
    e. Endometriosis
    f. Hirsutism secondary to ovarian dysfunction
    g. Irregular menses such as hypermenorrhea or menorrhagia
    h. Ovarian cyst
    i. Pelvic inflammatory disease
    j. Polycystic ovary syndrome
    k. Perimenopausal symptoms
    l. Premenstrual dysphoric disorder
    m. Migraine prophylaxis

    If yes, continue to #2.
    If no, continue to #3.

2. **APPROVE WITH NO END DATE.**

3. **DO NOT APPROVE.**

CONTINUED ON NEXT PAGE

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

CONTRACEPTIVES

RATIONALE
To ensure use of oral contraceptives are within Ascension Health's policies on contraception.

FDA APPROVED INDICATIONS
Oral contraceptives are used to prevent pregnancy and to treat other medical conditions.

REFERENCES
Drug Facts and Comparisons on-line. (www.drugfacts.com), Wolters Kluwer Health, St. Louis, MO

Created: 11/17/08 Revised: 8/25/09
Effective: 04/02/10 Client Approval: 07/31/09

COSMETIC MEDICATIONS

Generic	Brand	HICL	GCN	Exception/Other
TRETINOIN	AVITA ALTINAC RETIN-A ATRALIN	02468		ROUTE = TOPICAL
TRETINOIN MICROSPHERES	RETIN-A MICRO, RETIN-A MICRO PUMP	32888		
TRETINOIN/EMOLLIENT	RENOVA	10245		
ADAPALENE	DIFFERIN	11233		
AZELAIC ACID	AZELEX FINACEA	07471		
TAZAROTENE	AVAGE TAZORAC	13315		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have:

    a. acne vulgaris
    b. psoriasis
    c. rosacea
    d. cancerous lesions
    e. actinic keratosis
    f. dysplastic nevi/nevus
    g. acne scars
    h. epidermolysis bullosa
    i. verruca plana
    j. verruca plantaris
    k. hypertrophic scars
    l. folliculitis
    m. cutaneous lichen planus
    n. solar lentigo, or
    o. Other indication not associated with cosmetic use?

    If yes, continue to #2.
    If no, do not approve.

2. **APPROVE FOR 1 YEAR.**

CONTINUED ON NEXT PAGE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Has the patient shown an improvement in condition?

   If yes, continue to #2.
   If no, do not approve.

2. **APPROVE FOR 1 YEAR.**

RATIONALE
To ensure use of topical agents according to Ascension policy.

FDA APPROVED INDICATIONS
- Adapalene is indicated for the topical treatment of acne vulgaris
- Azelaic acid cream is indicated for the topical treatment of inflammatory acne vulgaris
- Azelaic acid gel is indicated for topical treatment of inflammatory papules and pustules of mild to moderate rosacea
- Tazarotene 0.05% and 0.1% cream and gel are indicated for topical treatment of patients with stable plaque psoriasis of up to 20% body surface area involvement. Tazarotene 0.1% cream and gel are indicated as topical treatment for patients with acne vulgaris
- Retin-A and Retin-A Micro are approved for the treatment of acne vulgaris

REFERENCES
Package inserts

Created: 1/12/09
Effective: 08/01/12 Client Approval: 01/26/09

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

DABIGATRAN

Generic	Brand	HICL	GCN	Exception/Other
DABIGATRAN	PRADAXA	35604		

This drug requires a written request for prior authorization

GUIDELINES FOR USE

1. Does the patient have a diagnosis of atrial fibrillation?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of atrial fibrillation.

2. **Approve for one year (maximum of #2 capsules per day or #60 capsules per month).**

RATIONALE
To ensure appropriate use of dabigatran for the indication of prevention of stroke or systemic embolism in atrial fibrillation.

FDA APPROVED INDICATIONS
Reduction of risk of stroke or systemic embolism in atrial fibrillation.

REFERENCE

- Boehringer Ingelheim Pharmaceuticals, Inc. Pradaxa package insert. Ridgefield, CT. October 2010.

Created: 02/08/11
Effective: 06/28/11 Client Approval: 02/02/11

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

DALFAMPRIDINE

Generic	Brand	HICL	GCN	Exception/Other
DALFAMPRIDINE	AMPYRA	13907		

GUIDELINES FOR USE

1. Does the patient have multiple sclerosis?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: Approval for dalfampridine requires the patient has a diagnosis of multiple sclerosis.

2. **Approve #2 tablets per day per month for 12 months.**

RATIONALE
Ensure appropriate utilization for dalfampridine.

FDA APPROVED INDICATIONS
Dalfampridine is approved in patients with multiple sclerosis to improve walking.

REFERENCES

- Acorda Therapeutics. Ampyra package insert. Hawthorne, NY. January 2010.
- Goodman AD, Brown TR, Krupp LB, et al. Sustained-release oral fampridine in multiple sclerosis: a randomized, double-blind, controlled trial. Lancet. 2009;373:732-738.
- Kachuck, NJ. Sustained release oral fampridine in the treatment of multiple sclerosis. Expert Opin Pharmacother. 2009;10:2025-2035.
- Bever CT, Judge S. Sustained-release fampridine for multiple sclerosis. Expert Opin Investig Drugs. 2009;18:1013-1024.
- Micromedex® Healthcare Series [database online]. Greenwood Village, Colo: Thomson Healthcare. Available at: https://www.thomsonhc.com/hcs/librarian/PFDefaultActionId/pf.LoginAction. [Accessed: February 16, 2010].

Created: 09/10
Effective: 10/01/10 Client Approval: 09/20/10

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

ERECTILE DYSFUNCTION AGENTS

Generic	Brand	HICL	GCN	Exception/Other
SILDENAFIL	VIAGRA	18084		GCN ≠ 28273, 24758
TADALAFIL	CIALIS	24859		GCN ≠ 26587
VARDENAFIL	LEVITRA STAXYN	25035		

GUIDELINES FOR USE

1. Is the member being treated for erectile dysfunction?

   If yes, continue to #2.
   If no, continue to #6.

2. Does the patient have panhypopituitarism, hypogonadism, or hypothyroidism?

   If yes, do not approve.
   CIALIS DENIAL TEXT: Approval requires that the member is not taking nitrates and is being treated for erectile dysfunction due to spinal cord injury, diabetes, peripheral vascular disease, hypertension, hyperlipidemia, or a history of prostate surgery or rectal surgery, and has no history of panhypopituitarism, hypogonadism, or hypothyroidism OR has a diagnosis of Benign Prostatic Hyperplasia (BPH) and a trial of a formulary alpha blocker (e.g., doxazosin, prazosin, terazosin, or tamsulosin) AND finasteride.

   VIAGRA - LEVITRA - STAXYN DENIAL TEXT: Approval requires that the member is not taking nitrates and is being treated for erectile dysfunction due to spinal cord injury, diabetes, peripheral vascular disease, hypertension, hyperlipidemia, or history of prostate surgery, or rectal surgery, and has no history of panhypopituitarism, hypogonadism, or hypothyroidism.
   If no, continue to #3.

3. Does the patient have a history of spinal cord injury, diabetes, peripheral vascular disease, hypertension, hyperlipidemia, prostate, or rectal surgery?

   If yes, continue to #4.
   If no, do not approve.
   CIALIS DENIAL TEXT: Approval requires that the member is not taking nitrates and is being treated for erectile dysfunction due to spinal cord injury, diabetes, peripheral vascular disease, hypertension, hyperlipidemia, or a history of prostate surgery or rectal surgery, and has no history of panhypopituitarism, hypogonadism, or hypothyroidism OR has a diagnosis of Benign Prostatic Hyperplasia (BPH) and a trial of a formulary alpha blocker (e.g., doxazosin, prazosin, terazosin, or tamsulosin) AND finasteride.

   VIAGRA - LEVITRA - STAXYN DENIAL TEXT: Approval requires that the member is not taking nitrates and is being treated for erectile dysfunction due to spinal cord injury, diabetes, peripheral vascular disease, hypertension, hyperlipidemia, or history of prostate surgery, or rectal surgery, and has no history of panhypopituitarism, hypogonadism, or hypothyroidism.

CONTINUED ON NEXT PAGE

ERECTILE DYSFUNCTION AGENTS

GUIDELINES FOR USE (CONTINUED)

4. Is the member taking nitrates?

   If yes, do not approve.
   CIALIS DENIAL TEXT: Approval requires that the member is not taking nitrates and is being treated for erectile dysfunction due to spinal cord injury, diabetes, peripheral vascular disease, hypertension, hyperlipidemia, or a history of prostate surgery or rectal surgery, and has no history of panhypopituitarism, hypogonadism, or hypothyroidism OR has a diagnosis of Benign Prostatic Hyperplasia (BPH) and a trial of a formulary alpha blocker (e.g., doxazosin, prazosin, terazosin, or tamsulosin) AND finasteride.

   VIAGRA - LEVITRA - STAXYN DENIAL TEXT: Approval requires that the member is not taking nitrates and is being treated for erectile dysfunction due to spinal cord injury, diabetes, peripheral vascular disease, hypertension, hyperlipidemia, or history of prostate surgery, or rectal surgery, and has no history of panhypopituitarism, hypogonadism, or hypothyroidism.
   If no, continue to #5.

5. Is the prescription for Cialis (tadalafil) 2.5mg or 5mg strengths?

   If yes, **APPROVE FOR 12 MONTHS BY GPID WITH A QUANTITY LIMIT OF 1 TABLET PER DAY.**
   If no, **APPROVE FOR 12 MONTHS BY HICL WITH A QUANTITY LIMIT OF 6 TABLETS PER MONTH.**

6. Does the patient have a diagnosis of Benign Prostatic Hyperplasia (BPH)?

   If yes, continue to #7.
   If no, do not approve.
   CIALIS DENIAL TEXT: Approval requires that the member is not taking nitrates and is being treated for erectile dysfunction due to spinal cord injury, diabetes, peripheral vascular disease, hypertension, hyperlipidemia, or a history of prostate surgery or rectal surgery, and has no history of panhypopituitarism, hypogonadism, or hypothyroidism OR has a diagnosis of Benign Prostatic Hyperplasia (BPH) and a trial of a formulary alpha blocker (e.g., doxazosin, prazosin, terazosin, or tamsulosin) AND finasteride.

   VIAGRA - LEVITRA - STAXYN DENIAL TEXT: Approval requires that the member is not taking nitrates and is being treated for erectile dysfunction due to spinal cord injury, diabetes, peripheral vascular disease, hypertension, hyperlipidemia, or history of prostate surgery, or rectal surgery, and has no history of panhypopituitarism, hypogonadism, or hypothyroidism.

CONTINUED ON NEXT PAGE

ERECTILE DYSFUNCTION AGENTS

GUIDELINES FOR USE (CONTINUED)

7. Is the member currently taking a non-selective alpha blocker (doxazosin, prazosin, terazosin, or tamsulosin) AND finasteride?

   If yes, continue to #8.
   If no, do not approve. .
   DENIAL TEXT: Approval requires a diagnosis of Benign Prostatic Hyperplasia (BPH) and a trial of a formulary alpha blocker (e.g. doxazosin, prazosin, terazosin, or tamsulosin) AND finasteride.

8. Is the prescription for Cialis (tadalafil) 2.5mg or 5mg strengths?

   If yes, **APPROVE FOR 12 MONTHS BY GPID WITH A QUANTITY LIMIT OF #30 PER MONTH.**
   If no, do not approve.
   CIALIS DENIAL TEXT: Requested dosage is not approved for the treatment of benign Prostatic Hyperplasia (BPH). Consider a trial of Cialis 2.5mg or 5mg which also requires prior authorization.

   VIAGRA - LEVITRA - STAXYN DENIAL TEXT: Approval requires that the member is not taking nitrates and is being treated for erectile dysfunction due to spinal cord injury, diabetes, peripheral vascular disease, hypertension, hyperlipidemia, or history of prostate surgery, or rectal surgery, and has no history of panhypopituitarism, hypogonadism, or hypothyroidism.

RATIONALE

To limit the coverage of impotent medications to men with documented ED not due to an endogenic cause e.g. hypothyroidism. Also allow treatment of BPH with Cialis following a trial of generic therapies. The recommended Cialis dose for the treatment of BPH is 5mg daily. A starting dose of 2.5mg daily is recommended for patients with a creatinine clearance of 30 to 50mL/min.

FDA APPROVED INDICATIONS

Levitra, Staxyn and Viagra are approved for the treatment of erectile dysfunction.

Cialis is indicated for the treatment of ED, the signs and symptoms of BPH and ED, and symptoms of BPH. Cialis may be administered once daily or on an as-needed basis for the treatment of ED. For the treatment of BPH, Cialis is recommended to be administered on a daily basis.

CONTINUED ON NEXT PAGE

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

ERECTILE DYSFUNCTION AGENTS

REFERENCES

- Clinical Pharmacology [database online]. Tampa, FL: Gold Standard Inc.; 2010. Available at http://www.clinicalpharmacology.com. [Accessed June 8, 2010].
- Eli Lilly and Company. Cialis package insert. Indianapolis, IN. October 2011.
- GlaxoSmithKline. Staxyn package insert. Research Triangle Park. June 2010.
- Gresser U, Gleiter CH. Erectile dysfunction: comparison of efficacy and side effects of the PDE-5 inhibitors sildenafil, vardenafil and tadalafil--review of the literature. Eur J Med Res. 2002 Oct 29; 7(10):435-446.
- MICROMEDEX® Healthcare Series [database online]. Greenwood Village, CO: Thomson Healthcare; Available at: https://www.thomsonhc.com/hcs/librarian/PFDefaultActionId/pf.LoginAction. [Accessed: June 8, 2010].
- Pfizer Laboratories. Viagra package insert. New York, NY. January 2010.
- Schering-Plough Corporation. Levitra package insert. Kenilworth, NJ. December 2008.

- Pfizer Laboratories. Viagra package insert. New York, NY. January 2010.
- Schering-Plough Corporation. Levitra package insert. Kenilworth, NJ. December 2008.

Created: 01/03/06 Revised: 02/16/12
Effective: 03/20/12 Client Approval: 02/16/12

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

ERYTHROPOIESIS STIMULATING AGENTS

Generic	Brand	HICL	GCN	Exception/Other
DARBEPOETIN	ARANESP	22890 22889		
EPOETIN ALFA	EPOGEN PROCRIT	04553		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Is the patient being treated for anemia associated with chronic renal failure?

   If yes, continue to #2.
   If no, continue to #6.

2. Is the patient currently taking the requested agent?

   If yes, continue to #3.
   If no, continue to #5.

3. Does the patient have a hemoglobin level less than 11g/dL if on dialysis or less than 10g/dL if not on dialysis?

   If yes, **APPROVE FOR 12 MONTHS WITH THE FOLLOWING QUANTITY LIMITS:**
   - **Aranesp: Approve 4 vials or syringes per 28 days**
   - **Epogen:**
     - **2,000U/mL, 3,000U/mL, 4,000U/mL and 10,000U/mL vials: 12 vials per 28 days**
     - **20,000U/2mL vials: 8 vials per 28 days**
     - **20,000U/mL and 40,000U/mL vials: 4 vials per 28 days**
   - **Procrit:**
     - **2,000U/mL, 3,000U/mL, 4,000U/mL and 10,000U/mL vials: 12 vials per 28 days**
     - **20,000U/mL and 40,000U/mL vials: 4 vials per 28 days**

   APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

   If no, continue to #4.

CONTINUED ON NEXT PAGE

ERYTHROPOIESIS STIMULATING AGENTS

GUIDELINES FOR USE (CONTINUED)

4. Is the request for one of the following reasons?

   - Hemoglobin has reached 11g/dL if on dialysis and dose reduction/dose interruption required to reduce the need for blood transfusions.
   - Hemoglobin has reached 10g/dL for patient not on dialysis and dose reduction/dose interruption is required to reduce the need for blood transfusions.

   If yes, **APPROVE FOR 12 MONTHS WITH THE FOLLOWING QUANTITY LIMITS:**
   - **Aranesp: Approve 4 vials or syringes per 28 days**
   - **Epogen:**
     - **2,000U/mL, 3,000U/mL, 4,000U/mL and 10,000U/mL vials: 12 vials per 28 days**
     - **20,000U/2mL vials: 8 vials per 28 days**
     - **20,000U/mL and 40,000U/mL vials: 4 vials per 28 days**
   - **Procrit:**
     - **2,000U/mL, 3,000U/mL, 4,000U/mL and 10,000U/mL vials: 12 vials per 28 days**
     - **20,000U/mL and 40,000U/mL vials: 4 vials per 28 days**

   If no, do not approve.
   DENIAL TEXT: Approval for reauthorization requires a level less than 11g/dL if on dialysis or less than 10g/dL if not on dialysis or the need for dose reduction required to reduce the need for blood transfusions for dialysis patients reaching Hgb of 11g/DL and patients not on dialysis who have reached a hemoglobin of 10g/dL.

5. Does the patient have a hemoglobin level of less than 10g/dL?

   If yes, **APPROVE FOR 12 MONTHS WITH THE FOLLOWING QUANTITY LIMITS:**
   - **Aranesp: Approve 4 vials or syringes per 28 days**
   - **Epogen:**
     - **2,000U/mL, 3,000U/mL, 4,000U/mL and 10,000U/mL vials: 12 vials per 28 days**
     - **20,000U/2mL vials: 8 vials per 28 days**
     - **20,000U/mL and 40,000U/mL vials: 4 vials per 28 days**
   - **Procrit:**
     - **2,000U/mL, 3,000U/mL, 4,000U/mL and 10,000U/mL vials: 12 vials per 28 days**
     - **20,000U/mL and 40,000U/mL vials: 4 vials per 28 days**

   APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

   If no, do not approve.
   DENIAL TEXT: Approval requires a hemoglobin level of less than 10g/dL prior to initiating therapy for patients with anemia associated with chronic renal failure.

CONTINUED ON NEXT PAGE

ERYTHROPOIESIS STIMULATING AGENTS

GUIDELINES FOR USE (CONTINUED)

6. Is the patient being treated for anemia due to the effect of concomitantly administered cancer chemotherapy?

   If yes, continue to #7.
   If no, continue to #9.

7. Is the patient currently taking the requested agent and has a hemoglobin level between 10g/dL and 12g/dL?

   If yes, **APPROVE FOR 12 MONTHS WITH THE FOLLOWING QUANTITY LIMITS:**
   - **Aranesp: Approve 4 vials or syringes per 28 days**
   - **Epogen:**
     - **2,000U/mL, 3,000U/mL, 4,000U/mL and 10,000U/mL vials: 12 vials per 28 days**
     - **20,000U/2mL vials: 8 vials per 28 days**
     - **20,000U/mL and 40,000U/mL vials: 4 vials per 28 days**
   - **Procrit:**
     - **2,000U/mL, 3,000U/mL, 4,000U/mL and 10,000U/mL vials: 12 vials per 28 days**
     - **20,000U/mL and 40,000U/mL vials: 4 vials per 28 days**

   APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

   If no, continue to #8.

8. Does the patient have a hemoglobin level of less than 11g/dL or has the patient's hemoglobin decreased at least 2g/dL below their baseline level?

   If yes, **APPROVE FOR 12 MONTHS WITH THE FOLLOWING QUANTITY LIMITS:**
   - **Aranesp: Approve 4 vials or syringes per 28 days**
   - **Epogen:**
     - **2,000U/mL, 3,000U/mL, 4,000U/mL and 10,000U/mL vials: 12 vials per 28 days**
     - **20,000U/2mL vials: 8 vials per 28 days**
     - **20,000U/mL and 40,000U vials: 4 vials per 28 days**
   - **Procrit:**
     - **2,000U/mL, 3,000U/mL, 4,000U/mL and 10,000U/mL vials: 12 vials per 28 days**
     - **20,000U/mL and 40,000U/mL vials: 4 vials per 28 days**

   APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

   If no, do not approve.
   DENIAL TEXT: Approval requires a hemoglobin level of less than 11g/dL or a decrease at least 2g/dL from baseline level.

CONTINUED ON NEXT PAGE

ERYTHROPOIESIS STIMULATING AGENTS

GUIDELINES FOR USE (CONTINUED)

9. Does the patient have anemia related to zidovudine therapy?

   If yes, continue to #10.
   If no, continue to #12

10. Is the patient currently taking the requested agent and has a hemoglobin level between 10g/dL and 12g/dL?

    If yes, **APPROVE FOR 12 MONTHS WITH THE FOLLOWING QUANTITY LIMITS:**
    - **Aranesp: Approve 4 vials or syringes per 28 days**
    - **Epogen:**
      - **2,000U/mL, 3,000U/mL, 4,000U/mL and 10,000U/mL vials: 12 vials per 28 days**
      - **20,000U/2mL vials: 8 vials per 28 days**
      - **20,000U/mL and 40,000U/mL vials: 4 vials per 28 days**
    - **Procrit:**
      - **2,000U/mL, 3,000U/mL, 4,000U/mL and 10,000U/mL vials: 12 vials per 28 days**
      - **20,000U/mL and 40,000U/mL vials: 4 vials per 28 days**

    APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

    If no, continue to #11.

11. Does the patient have a hemoglobin level of less than 10g/dL?

    If yes, **APPROVE FOR 12 MONTHS WITH THE FOLLOWING QUANTITY LIMITS:**
    - **Aranesp: Approve 4 vials or syringes per 28 days**
    - **Epogen:**
      - **2,000U/mL, 3,000U/mL, 4,000U/mL and 10,000U/mL vials: 12 vials per 28 days**
      - **20,000U/2mL vials: 8 vials per 28 days**
      - **20,000U/mL and 40,000U/mL vials: 4 vials per 28 days**
    - **Procrit:**
      - **2,000U/mL, 3,000U/mL, 4,000U/mL and 10,000U/mL vials: 12 vials per 28 days**
      - **20,000U/mL and 40,000U/mL vials: 4 vials per 28 days**

    APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

    If no, do not approve.
    DENIAL TEXT: Approval requires a hemoglobin level of less than 10g/dL prior to initiating therapy.

12. Is the patient scheduled for elective, noncardiac, nonvascular surgery?

    If yes, continue to #13.
    If no, continue to #14.

CONTINUED ON NEXT PAGE

ERYTHROPOIESIS STIMULATING AGENTS

GUIDELINES FOR USE (CONTINUED)

13. Does the patient have a hemoglobin level of less than or equal to 13g/dL?

    If yes, **APPROVE FOR 1 MONTH WITH THE FOLLOWING QUANTITY LIMITS:**
    - **Aranesp: Approve 4 vials or syringes per 28 days**
    - **Epogen:**
      - **2,000U/mL, 3,000U/mL, 4,000U/mL and 10,000U/mL vials: 12 vials per 28 days**
      - **20,000U/2mL vials: 8 vials per 28 days**
      - **20,000U/mL and 40,000U/mL vials: 4 vials per 28 days**
    - **Procrit:**
      - **2,000U/mL, 3,000U/mL, 4,000U/mL and 10,000U/mL vials: 12 vials per 28 days**
      - **20,000U/mL and 40,000U/mL vials: 4 vials per 28 days**

    APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

    If no, do not approve.
    DENIAL TEXT: Approval requires a hemoglobin level of less than 13g/dL prior to initiating therapy.

14. Does patient have anemia due to concurrent hepatitis C treatment?

    If yes, continue to #15.
    If no, do not approve.
    DENIAL TEXT: Approval requires a diagnosis of anemia related to chronic kidney disease, elective, noncardiac, nonvascular surgery, concomitant zidovudine, cancer, or hepatitis C therapy.

15. Is the patient currently taking the requested agent and has a hemoglobin level between 10g/dL and 12g/dL?

    If yes, **APPROVE FOR 6 MONTHS WITH THE FOLLOWING QUANTITY LIMITS:**
    - **Aranesp: Approve 4 vials or syringes per 28 days**
    - **Epogen:**
      - **2,000U/mL, 3,000U/mL, 4,000U/mL and 10,000U/mL vials: 12 vials per 28 days**
      - **20,000U/2mL vials: 8 vials per 28 days**
      - **20,000U/mL and 40,000U/mL vials: 4 vials per 28 days**
    - **Procrit:**
      - **2,000U/mL, 3,000U/mL, 4,000U/mL and 10,000U/mL vials: 12 vials per 28 days**
      - **20,000U/mL and 40,000U/mL vials: 4 vials per 28 days**

    APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

    If no, continue to #16.

CONTINUED ON NEXT PAGE

ERYTHROPOIESIS STIMULATING AGENTS

GUIDELINES FOR USE (CONTINUED)

16. Has the patient tried or does the patient have a contraindication to ribavirin dose reduction?

    If yes, continue to #17.
    If no, do not approve.
    DENIAL TEXT: Approval requires ribavirin dose reduction prior to receiving an erythropoiesis-stimulating agent.

17. Does the patient have a hemoglobin level of less than 10g/dL?

    If yes, **APPROVE FOR 6 MONTHS WITH THE FOLLOWING QUANTITY LIMITS:**
    - **Aranesp: Approve 4 vials or syringes per 28 days**
    - **Epogen:**
      - **2,000U/mL, 3,000U/mL, 4,000U/mL and 10,000U/mL vials: 12 vials per 28 days**
      - **20,000U/2mL vials: 8 vials per 28 days**
      - **20,000U/mL and 40,000U/mL vials: 4 vials per 28 days**
    - **Procrit:**
      - **2,000U/mL, 3,000U/mL, 4,000U/mL and 10,000U/mL vials: 12 vials per 28 days**
      - **20,000U/mL and 40,000U/mL vials: 4 vials per 28 days**

    APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

    If no, do not approve.
    DENIAL TEXT: Approval requires a hemoglobin level of less than 10g/dL prior to initiating therapy.

RATIONALE

Ensure appropriate utilization based on FDA approved indications and treatment guidelines and promote use of preferred ESA treatment.
Anemia due to hepatitis C therapy is not an FDA approved indication for any ESA. AASLD does not recommend the use of ESAs, NIH/DHHS/NIDDKD state that the proper role and dose of ESAs has yet to be defined, and the AGA consider either ribavirin dose reduction or ESA use as viable options for managing treatment-related anemia. None of these guidelines provide specific hemoglobin levels at which to initiate or maintain hemoglobin levels for this patient population, so the hemoglobin levels selected for this diagnosis are based off of the recommendations for zidovudine therapy.

FDA APPROVED INDICATIONS

CHRONIC KIDNEY DISEASE: the prescribing information of the ESAs and an FDA safety update recommend initiation of therapy only for patients with a hemoglobin of less than 10g/dL. They recommend reducing or interrupting the dose of ESA and using the lowest dose of an ESA sufficient to reduce the need for blood transfusions at a hemoglobin of 11g/dL for patients on dialysis or a hemoglobin of 10g/dL for patients not on dialysis.

CONTINUED ON NEXT PAGE

ERYTHROPOIESIS STIMULATING AGENTS

FDA APPROVED INDICATIONS (CONTINUED)

ANEMIA RELATED TO CANCER CHEMOTHERAPY: ASCO recommends initiating ESA therapy at hemoglobin levels at less than 10g/dL while NCCN recommends initiation at or below hemoglobin levels of 11g/dL. ASCO recommends maintaining hemoglobin levels between 10 and 12d/gL, while NCCN does not comment on a maintenance hemoglobin range.

ANEMIA RELATED TO ZIDOVUDINE THERAPY: the clinical trials contained within the prescribing information of the ESAs recommend initiating therapy at a hemoglobin of less than 10g/dL and maintaining between 10 and 12g/dL.

PATIENTS SCHEDULED FOR ELECTIVE, NONCARDIAC, NONVASCULAR SURGERY: the prescribing information of the ESAs recommends therapy only for those patients with a hemoglobin level at or below 13g/dL.

DARBEPOETIN is indicated for the treatment of anemia associated with chronic renal failure including patients on and not on dialysis and for anemia due to the effect of concomitantly administered chemotherapy in patients with non-myeloid malignancies.

EPOETIN ALFA is indicated for the treatment of anemia of chronic renal failure patients, including patients on dialysis and patients not on dialysis; treatment of anemia in zidovudine-treated HIV infected patients; treatment of anemia in cancer patients with metastatic, non-myeloid malignancies receiving chemotherapy; and reduction of allogenic blood transfusions in patients undergoing elective, noncardiac, nonvascular surgery.

REFERENCES

- American Gastroenterological Association Medical Position Statement on the Management of Hepatitis C. *Gastroenterology* 2006; 130:225-230.
- Amgen, Aranesp product information. Thousand Oaks, CA, June 2011.
- Amgen. Epogen product information. Thousand Oaks, CA, June 2011.
- CMS Part C & D User Call: December 1, 2010, 3:30 PM ET. Available at: http://www.mscginc.com/materials/12_1_2010/CMSPartCDUserCallDec12010.pdf [Accessed December 22, 2010].
- Ghany MG, Strader DB et al. AASLD Practice Guidelines: Diagnosis, Management, and Treatment of Hepatitis C: An Update. *Hepatology* 2009:49 (4): 1335-1374.
- Locatelli F, Nissenson AR, et al. Clinical practice guidelines for anemia in chronic kidney disease: problems and solutions. A position statement from Kidney Disease: Improving Global Outcomes (KDIGO). Available at: www.kidney-international.org. [Accessed January 12, 2011].
- Micromedex® Healthcare Series [database online]. Greenwood Village, CO: Thomson Healthcare. Available at: http://www.thomsonhc.com/hcs/librarian/. [Accessed July 15 2011].
- National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology. Cancer- and Chemotherapy- Induced Anemia. Version 2.2011.
- National Kidney Foundation: Kidney Disease Outcomes Quality Initiative (KDOQI). KDOQI Clinical Practice Recommendations for Anemia in Chronic Kidney Disease: 2007 Update of Hemoglobin Target.
- Ortho Biotech. Procrit product information. Raritan, New Jersey, June 2011.

CONTINUED ON NEXT PAGE

REFERENCES (CONTINUED)

- Rizzo JD, Brouwers M, et al. American Society of Clinical Oncology / American Society of Hematology Clinical Practice Guideline Update on the Use of Epoetin and Darbepoetin in Adult Patients With Cancer. Available at www.ASCO.org. [Accessed January 12, 2011].
- Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Department of Health and Human Services. January 10, 2011; 1–166. Available at: http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf. [Accessed January 13, 2011].
- Practice Guidelines for Perioperative Blood Transfusion and Adjuvant Therapies: An Updated Report by the American Society of Anesthesiologists Task Force on Perioperative Blood Transfusion and Adjuvant Therapies. Anesthesiology 2006; 105:198-208.
- U.S. Department of Health and Human Services, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases. Chronic Hepatitis C: Current Disease Management 2010. Available at: www.digestive.niddk.nih.gov. [Accessed January 13, 2011].
- U.S. Food and Drug Administration. FDA Drug Safety Communication: Modified dosing recommendations to improve the safe use of Erythropoiesis-Stimulating Agents (ESAs) in chronic kidney disease. Available at: http://www.fda.gov/Drugs/DrugSafety/ucm259639.htm. [Accessed July 8 2011].

Created: 08/02
Effective: 12/14/11 Client Approval: 11/07/11 P&T Approval: 08/11

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

DENOSUMAB

Generic	Brand	HICL	GCN	Exception/Other
DENOSUMAB	PROLIA XGEVA	37012		

GUIDELINES FOR USE

1. Is the prescription for Prolia?

   If yes, continue to #3.
   If no, continue to #2.

2. Does the patient have a diagnosis of multiple myeloma?

   If yes, do not approve.
   DENIAL TEXT: Xgeva approval requires a diagnosis of cancer with bone metastases from solid tumors.
   If no, continue to #6.

3. Does the patient have osteoporosis?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of osteoporosis.

4. Does the patient have a history of osteoporotic fracture(s) or ≥ 2 risk factors for fracture (e.g. history of multiple recent low trauma fractures, BMD T-score ≤ -2.5, corticosteroid use, or use of GnRH analogs such as nafarelin, etc.)?

   If yes, continue to #7.
   If no, continue to #5.

5. Has the patient tried and is intolerant to bisphosphonates (Fosamax, Actonel, Boniva) or does the patient have a contraindication(s) to these medications?

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of osteoporosis with history of fragility fracture, or multiple risk factors for fracture, or that the patient has tried and is intolerant to or contraindicated to the use of bisphosphonates.

6. Is Xgeva being used to treat skeletal-related events (e.g., bone fractures or bone pain requiring radiation) in a patient with a diagnosis of cancer with bone metastases from solid tumors?

   If yes, continue to #8.
   If no, do not approve.
   DENIAL TEXT: Xgeva approval is for prevention of skeletal related events in patients with a diagnosis of cancer with bone metastases from solid tumors.

CONTINUED ON NEXT PAGE

DENOSUMAB

GUIDELINES FOR USE (CONTINUED)

7. **APPROVE 2 FILLS BY GCN FOR ONE PRE-FILLED SYRINGE PER FILL WITH AN END DATE OF 12 MONTHS.**

8. **APPROVE 12 FILLS BY GCN FOR ONE VIAL PER MONTH WITH AN END DATE OF 12 MONTHS.**

RATIONALE

To ensure appropriate use of denosumab: Prolia is for the treatment of osteoporosis in high-risk patients who have failed or are intolerant to anti-resorptive agents and Xgeva is for the treatment of skeletal related events in patients with bone metastases from solid tumors. A subgroup analysis within the Xgeva clinical trials revealed a higher mortality risk for patients with multiple myeloma.

FDA APPROVED INDICATIONS

Prolia: Treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.

Xgeva is indicated for the treatment of skeletal-related events in patients with bone metastases from solid tumors. Xgeva is not indicated for the treatment of skeletal-related events in patients with multiple myeloma.

REFERENCES

- Amgen. Prolia package insert. Thousand Oaks, CA. June 2010.
- Amgen. Xgeva package insert. Thousand Oaks, CA. December 2010.

Created: 07/10
Effective: 08/01/11 Client Approval: 11/01/10

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

DESIRUDIN

Generic	Brand	HICL	GCN	Exception/Other
DESIRUDIN	IPRIVASK	19072	94098	

GUIDELINES FOR USE

1. Is the request for Iprivask for the prevention (prophylaxis) of deep vein thrombosis (DVT) for a patient undergoing elective hip replacement surgery?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: Approval requires that the patient is receiving Iprivask for the prevention of deep vein thrombosis (DVT) undergoing elective hip replacement surgery.

2. Does the patient have a contraindication to a low molecular weight heparin, warfarin, or fondaparinux?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: Patient should try a low molecular weight heparin, Coumadin, or fondaparinux prior to receiving desirudin.

3. **Approve for 12 days for 24 vials (maximum quantity 24 vials). Also enter one fill for 23 days for 46 vials (maximum quantity 46) with a start date of 7 days following the initial approval (for a total max of 70 vials for 35 days of treatment).**

   APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

RATIONALE

To ensure appropriate use of desirudin for the prevention of deep vein thrombosis (DVT) in patients undergoing hip replacement surgery. Desirudin prescribing information states that the average duration of treatment is 9 to 12 days. The 2008 ACCP guidelines recommend venous thromboembolism treatment of up to 35 days.

FDA APPROVED INDICATIONS

Prophylaxis of deep vein thrombosis (DVT) in elective hip replacement surgery.

REFERENCES

- Canyon Pharmaceuticals, Inc. Iprivask package insert. Hunt Valley, MD. January 2010.
- MICROMEDEX® Healthcare Series [database online]. Greenwood Village, CO: Thomson Healthcare. Available at https://www.thomsonhc.com/hcs/librarian/PFDefaultActionId/pf.LoginAction. [Accessed: August 19, 2010].
- Geerts W, Bergquist D, and Pineo G et al. Prevention of Venous Thromboembolism supplement; the eighth ACCP conference on antithrombotic and thrombolytic therapy. *Chest* 2008; 133 (6 Suppl)

Created: 02/11
Effective: 06/28/11 Client Approval: 06/13/11

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

DEXTROMETHORPHAN WITH QUINIDINE

Generic	Brand	HICL	GCN	Exception/Other
DEXTROMETHORPHAN/ QUINIDINE	NUEDEXTA	37278		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of multiple sclerosis (MS) or amyotrophic lateral sclerosis (ALS)?

   If yes, continue to #2
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of pseudobulbar affect (PBA) in patients with a diagnosis of multiple sclerosis or amyotrophic lateral sclerosis (ALS).

2. Does patient have a diagnosis of pseudobulbar affect (PBA)?

   If yes, **APPROVE FOR 12 MONTHS WITH A QUANTITY LIMIT OF #2 CAPSULES PER DAY PER MONTH BY HICL.**
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of pseudobulbar affect (PBA).

RATIONALE
Ensure that Nuedexta is used solely for its FDA approved indication and in patients for whom it has been determined to be safe and efficacious. Clinical trials for Nuedexta examined efficacy of Nuedexta in patients with underlying multiple sclerosis (MS) or amyotrophic lateral sclerosis (ALS). The product prescribing information states that Nuedexta has not been shown to be safe or effective in patients with other causes of emotional liability, for example dementia due to Alzheimer's disease or other types of dementia.

FDA APPROVED INDICATIONS
Nuedexta is indicated for treatment of pseudobulbar affect.

REFERENCES

- Avanir Pharmaceuticals, Inc. Nuedexta package insert. Aliso Viejo, CA. October 2010.
- Miller A, Pratt H, and Schiffer R. Pseudobulbar affect: the spectrum of clinical presentations, etiologies and treatments. Expert Rev Neurother. 2011; 11(7) 1077-1088.
- National Stroke Association. Pseudobulbar affect and stroke. Stroke Clinical Updates. Volume XV, Issue 1: January/February 2005.
- Pioro E. Current concepts in pharmacotherapy of pseudobulbar affect. Drugs 2004; 71 (9): 1192-1207.

Created: 06/11
Effective: 12/14/11 Client Approval: 11/07/11 P&T Approval: 02/11

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

DPP-IV INHIBITORS

Generic	Brand	HICL	GCN	Exception/Other
SITAGLIPTIN	JANUVIA	34126		
SITAGLIPTIN/METFORMIN	JANUMET	34665		
SAXAGLIPTIN	ONGLYZA	36471		
LINAGLIPTIN	TRADJENTA	37576		

GUIDELINES FOR USE

1. Does the patient have Type 2 Diabetes?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of Type 2 Diabetes and a trial of, or a contraindication to the use of metformin.

2. Has the patient tried, or does the patient have a contraindication to the use of one of the following: metformin (e.g. Glucophage), metformin ER, glyburide/metformin (e.g. Glucovance) or glipizide/metformin (e.g. Metaglip)?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of Type 2 Diabetes and a trial or contraindication to the use of metformin.

3. **APPROVE BY HICL FOR 12 MONTHS WITH THE FOLLOWING QUANTITY LIMITS:**

   - **JANUMET 50/1,000mg or 50mg/500mg: up to #2 tablets per day per month/copay.**
   - **JANUVIA 25, 50mg or 100mg: #1 tablet per day per month/copay.**
   - **ONGLYZA 2.5 or 5mg: #1 tablet per day per month/copay.**
   - **TRADJENTA 5mg: #1 tablet per day per month/copay.**

   APPROVAL TEXT for Januvia and Janumet: Please note that these drugs have an important FDA safety warning. For more information please ask your doctor or pharmacist.

RATIONALE
Ensures that Januvia/Janumet/Onglyza/Tradjenta is not used for Type 1 Diabetics and ensure use as a second-line agent (after metformin) for Type 2 Diabetes.

FDA APPROVED INDICATIONS
- Januvia is indicated as an adjunct to diet and exercise to improve glycemic control in adults with Type 2 Diabetes mellitus.
- Janumet is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both sitagliptin and metformin is appropriate.
- Onglyza is indicated as an adjunct to diet and exercise to improve glycemic control in adults with Type 2 Diabetes mellitus in multiple clinical settings.
- Tradjenta is indicated as an adjunct to diet and exercise to improve glycemic control in adults with Type 2 Diabetes Mellitus.

CONTINUED ON NEXT PAGE

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

DPP-IV INHIBITORS

REFERENCES

- AACE Diabetes Mellitus Guidelines, Endoc Pract. 2007; 13 (Suppl 1) 2007.
- AACE/ACE Consensus Statement: Glycemic Control Algorithm, Endocr Pract. 2009; 15 (no.6) 541.
- DIABETES CARE, Standards of Medical Care in Diabetes -2010, Volume 33, Supplement 1, January 2010.
- Bristol-Myers Squibb Company. Onglyza package insert. Princeton, NJ. February 2011.
- Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2008. Available at: http://www.clinicalpharmacology.com. [Accessed: June 7, 2010].
- Merck & Co., Inc. Januvia™ package insert. Whitehouse Station, NJ. February 2010.
- Merck & Co., Inc. Janumet package insert. Whitehouse Station, NJ. February 2010.
- Boehringer Ingelheim Pharmaceuticals, Inc. Tradjenta package insert. Ridgefield, CT. May 2011.

Created: 08/10
Effective: 12/14/11 Client Approval: 11/07/11

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

DULOXETINE

Generic	Brand	HICL	GCN	Exception/Other
DULOXETINE	CYMBALTA	26521		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of depression or generalized anxiety disorder?

   If yes, continue to #2.
   If no, continue to #3.

2. Has the patient tried or does the patient have a contraindication to a preferred formulary antidepressant such as fluoxetine, paroxetine, citalopram, sertraline, bupropion, mirtazapine, or venlafaxine/venlafaxine ER?

   If yes, continue to #8.
   If no, do not approve.
   DENIAL TEXT: Approval requires a trial of or a contraindication to fluoxetine, paroxetine, citalopram, sertraline, bupropion, mirtazapine, or venlafaxine/venlafaxine ER.

3. Does the patient have a diagnosis of fibromyalgia or neuropathic pain (including diabetic peripheral neuropathy) WITHOUT a concurrent diagnosis of chronic musculoskeletal pain (e.g., osteoarthritis or chronic lower back pain)?

   If yes, continue to #4.
   If no, continue to #6.

4. Is this medication prescribed in order to treat trigeminal neuralgia?

   If yes, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of depression, generalized anxiety disorder, fibromyalgia, pain that is neuropathic in nature other than trigeminal neuralgia, or chronic musculoskeletal pain.
   If no, continue to #5.

5. Has the patient tried or does the patient have a contraindication to a tricyclic antidepressant (e.g., amitriptyline, nortriptyline, doxepin) or gabapentin?

   If yes, continue to #9.
   If no, do not approve.
   DENIAL TEXT: Approval requires a trial of or a contraindication to a tricyclic antidepressant (e.g., amitriptyline, nortriptyline, doxepin) or gabapentin.

CONTINUED ON NEXT PAGE

DULOXETINE

GUIDELINES FOR USE (CONTINUED)

6. Does the patient have a diagnosis of chronic musculoskeletal pain, including discomfort from osteoarthritis or chronic lower back pain?

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of depression, generalized anxiety disorder, fibromyalgia, neuropathic pain including diabetic neuropathy, or chronic musculoskeletal pain.

7. Has the patient tried or does the patient have a contraindication to at least 2 of the following: tricyclic antidepressant (e.g., amitriptyline, nortriptyline, or doxepin), oral NSAID (e.g., diclofenac, ibuprofen, nabumetone, naproxen, or meloxicam), short-acting opioids (e.g., hydrocodone/acetaminophen, oxycodone/acetaminophen, or oxycodone IR), tramadol, or a skeletal muscle relaxant (e.g., cyclobenzaprine, metaxalone, methocarbamol, or tizanidine)?

   If yes, continue to #9.
   If no, do not approve.
   DENIAL TEXT: Approval requires a trial of or a contraindication to at least 2 of the following: tramadol, oral NSAID, tricyclic antidepressant, skeletal muscle relaxant, or short-acting opioid.

8. **APPROVE FOR 12 MONTHS WITH A QUANTITY LIMIT AS FOLLOWS:**
   20MG STRENGTH: #2 per day per month or per copay
   30MG STRENGTH: #1 per day per month or per copay
   60MG STRENGTH: #2 per day per month or per copay

   APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

9. **APPROVE FOR 12 MONTHS BY HICL WITH A QUANTITY LIMIT OF #1 PER DAY PER MONTH OR PER COPAY.**

   APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

CONTINUED ON NEXT PAGE

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

DULOXETINE

RATIONALE
Ensure appropriate use of Cymbalta.

EFNS guidelines confirm tricyclic antidepressants and gabapentin should be used as first line for various neuropathic conditions except trigeminal neuralgia.

FDA APPROVED INDICATIONS
Cymbalta is indicated for the treatment of major depressive disorder, diabetic peripheral neuropathic pain, generalized anxiety disorder, fibromyalgia, and chronic musculoskeletal pain.

REFERENCES

- Arnold LM, Lu Y, et al. A Double-Blind, Multicenter Trial Comparing Duloxetine With Placebo in the Treatment of Fibromyalgia Patients With or Without Major Depressive Disorder. *Arthritis & Rheumatism*. 2004; 50(9):2974-84.
- Arnold LM, Rosen A, et al. A randomized, double-blind, placebo-controlled trial of duloxetine in the treatment of women with fibromyalgia with or without major depressive disorder. *Pain*. 2005; 119:5-15.
- Attal N, Cruccu G et al. EFNS guidelines on pharmacological treatment of neuropathic pain. *European Journal of Neurology*. 2010; April 9. [epub ahead of print].
- Backonja MM. Gabapentin monotherapy for the symptomatic treatment of painful neuropathy: a multicenter, double-blind, placebo-controlled trial in patients with diabetes mellitus. *Epilepsia*. 1999; 40 Suppl 6:S57-9; discussion S73-4.
- Backonja M, Beydoun A, et al. Gabapentin for the symptomatic treatment of painful neuropathy in patients with diabetes mellitus: a randomized controlled trial. *JAMA*. 1998 Dec 2; 280(21):1831-6.
- Chou R, Fanciuollo G, Fine P, et al. Clinical Guidelines for use of chronic opioid therapy in chronic noncancer Pain. *Journal of Pain*. 2009. 10(2): 113-130.
- Chou R and Hoyt-Huffman L. Diagnosis and Treatment of Low Back Pain: A Joint Clinical Practice Guideline from the American College of Physicians and the American Pain Society, *Annals of Internal Medicine.* 2007. 147(7): 478-491.
- Eli Lilly. Cymbalta package insert. Indianapolis, IN. November 2010.
- Max MB, Lynch SA, et al. Effects of desipramine, amitriptyline, and fluoxetine on pain in diabetic neuropathy. *N Engl J Med*. 1992 May 7; 326(19):1250-6.
- Morello CM, Leckband SG, et al. Randomized double-blind study comparing the efficacy of gabapentin with amitriptyline on diabetic peripheral neuropathy pain. *Arch Intern Med*. 1999 Sep 13; 159(16):1931-7.

Created: 10/10/11
Effective: 01/01/12 Client Approval: 08/05/11 P&T Approval: 05/11

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

ELTROMBOPAG

Generic	Brand	HICL	GCN	Exception/Other
ELTROMBOPAG	PROMACTA	35989		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the patient being treated for chronic immune (idiopathic) thrombocytopenia purpura (ITP)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: This medication is not covered for the diagnosis provided.

2. Has the patient tried and failed corticosteroids or immunoglobulins, or has had an insufficient response to a splenectomy?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: This medication is covered only after a trial of corticosteroids or immunoglobulins or if the patient has undergone a splenectomy.

3. **APPROVE 1 TAB (25MG OR 50MG) PER DAY X 1 MONTH.**

RENEWAL CRITERIA

1. Is the patient being treated for chronic immune (idiopathic) thrombocytopenia purpura (ITP)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: This medication is not covered for the diagnosis provided.

2. Did the patient receive the maximum dose of 75mg for 4 consecutive weeks?

   If yes, continue to #6.
   If no, continue to #3.

3. Did the patient have a clinical response, as defined by an increase in platelet count to ≥ $50X10^9$/L (≥ 50,000 per µl)?

   If yes, continue to #4.
   If no, continue to #5.

4. **APPROVE 1 TAB (25MG OR 50MG) PER DAY PER MONTH X 12 MONTHS.**

5. **APPROVE 1 TAB (25MG) AND 1 TAB (50MG) PER DAY X 1 MONTH.**

CONTINUED ON NEXT PAGE

ELTROMBOPAG

RENEWAL CRITERIA (CONTINUED)

6. Did the patient have a clinical response, as defined by an increase in platelet count to ≥ $50X10^9$/L (≥ 50,000 per µl)?

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: This medication is only covered in patients who have had a clinical response after 4 weeks at maximum dose.

7. **APPROVE 1 TAB (25MG) AND 1 TAB (50MG) PER DAY PER MONTH X 12 MONTHS.**

RATIONALE
To ensure safe and appropriate utilization of Promacta.

FDA APPROVED INDICATION
Promacta is indicated for the treatment of thrombocytopenia in patients with chronic immune thrombocytopenic purpura (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy.

REFERENCES
- GlaxoSmithKline. Promacta package insert. Research Triangle Park, NC. October 2008.
- Thomson Healthcare. Eltrombopag. DRUGDEX® System [database online]. Greenwood Village, CO. Available at: https://www.thomsonhc.com/hcs/librarian/PFDefaultActionId/pf.LoginAction. [Accessed: December 2008].

Created: 01/09
Effective: 05/02/12 Client Approval: 04/18/12

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

ENDOTHELIN RECEPTOR ANTAGONISTS

Generic	Brand	HICL	GCN	Exception/Other
BOSENTAN	TRACLEER	22990		
AMBRISENTAN	LETAIRIS	34849		

GUIDELINES FOR USE

1. Is the prescribing physician a cardiologist or pulmonologist?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: Approval requires supervision by a cardiologist or a pulmonologist.

2. Does the patient have a diagnosis of pulmonary arterial hypertension NYHA/WHO Functional Class II or greater?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of pulmonary arterial hypertension.

3. **TRACLEER: Approve for one year by HICL #2 tablets/day.**
   LETAIRIS: Approve for one year by HICL #1 tablet/day.

RATIONALE
Ensure appropriate utilization of Tracleer and Letairis.

FDA APPROVED INDICATIONS
LETAIRIS is an endothelin receptor antagonist indicated for the treatment of pulmonary arterial hypertension (WHO group I) in patients with NYHA/WHO Class II or III symptoms to improve exercise capacity and delay worsening.

TRACLEER is an endothelin receptor antagonist indicated for the treatment of pulmonary arterial hypertension (WHO group I) in patients with NYHA/WHO Class II or IV symptoms to improve exercise ability and decrease the rate of clinical worsening. TRACLEER is contraindicated for use with cyclosporine and glyburide.

REFERENCES

- Actelion Pharmaceuticals US, Inc. Tracleer package insert. South San Francisco, CA. August 2009.
- Gilead Sciences, Inc., Letairis package insert. Foster City, CA. August 2009.

Created: 11/17/08
Effective: 06/28/11 Client Approval: 06/13/11

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

ENFUVIRTIDE

Generic	Brand	HICL	GCN	Exception/Other
ENFUVIRTIDE	FUZEON	25044		

GUIDELINES FOR USE

1. Is the patient greater than or equal to 6 years of age?

   If yes, continue to #2.
   If no, do not approve.

2. Is the prescriber a physician specializing in the treatment of HIV infection?

   If yes, continue to #3.
   If no, do not approve.

3. Does the patient have documented HIV viremia (2 consecutive RNA measures > 200 copies/ml) despite either:

   a. At least 3 months therapy with a nucleoside reverse transcriptase inhibitor (NRTI), non-nucleoside reverse transcriptase inhibitor (NNRTI), and a protease inhibitor (PI), or
   b. Viremia and documented resistance to or intolerance to at least one member in each of the NRTI, NNRTI, and PI classes?

   If yes, continue to #4.
   If no, do not approve.

4. Is enfuvirtide prescribed in combination with an optimized antiviral regimen (determine by viral resistance testing: genotypic or phenotypic) including at least 3 HIV drugs?

   If yes, continue to #5.
   If no, do not approve.

5. **APPROVE 1 KIT PER MONTH FOR 6 MONTHS.**

CONTINUED ON NEXT PAGE

ENFUVIRTIDE

RATIONALE
To ensure Fuzeon is used as a second-line agent in combination with other antiretroviral medication to treat experienced patients with evidence of viral replication despite ongoing therapy.

FDA APPROVED INDICATIONS
Fuzeon is indicated to treat HIV-1 infection in treatment-experienced patients with evidence of viral replication despite continuing anti-retroviral therapy. Fuzeon is to be used in combination with other antiretroviral agents.

REFERENCES

- Roche Laboratories Inc. Fuzeon product information. Nutley, NJ. January 2007.
- Lalezari JP, Henry K, O'Hearn M, Montaner JSG, Piliero PJ, Trottier B et al. Lazzarin A, Clotet B, Cooper D, Reynes J, Arasteh K, Nelson M et al. Enfuvirtide, an HIV-1 fusion inhibitor, for drug-resistant HIV infection in North and South America. N Engl J Med 2003; 348(22)2175-2185.
- Department of Health and Human Services. Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Revised on October 6, 2005. Available at: http://AIDSinfo.nih.gov.
- Yeni PG et al. Treatment for Adult HIV Infection 2004 Recommendations of the International AIDS Society-USA Panel. JAMA, July 14, 2004; 292:2, 251-265.
- Clotet B et al. Clinical management of treatment-experienced, HIV-infected patients with the fusion inhibitor enfuvirtide: consensus recommendations. AIDS 2004; 18:1137-1146.

Created: 08/03
Effective: 10/15/09 Client Approval: 10/01/09

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

ERLOTINIB

Generic	Brand	HICL	GCN	Exception/Other
ERLOTINIB HCL	TARCEVA	26745		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Metastatic Non-Small Cell Lung Cancer (NSCLC)?

   If yes, continue to #2.
   If no, continue to #3.

2. Has the disease progressed despite treatment with another antineoplastic agent (i.e., cisplatin, carboplatin, paclitaxel, or gemcitabine)?

   If yes, continue to #5.
   If no, continue to #6.

3. Does the patient have a diagnosis of pancreatic cancer?

   If yes, continue to #4.
   If no, continue to #6.

4. Will the patient be using Tarceva in combination with Gemzar (gemcitabine)?

   If yes, continue to #5.
   If no, continue to #6.

5. **APPROVE FOR ONE YEAR.**

6. **DO NOT APPROVE.**

RATIONALE

To assure safe and appropriate use of erlotinib.

FDA APPROVED INDICATIONS

Tarceva is a kinase inhibitor indicated for the treatment of:

- Locally advanced or metastatic non-small cell lung cancer (NSCLC) after failure of at least one prior chemotherapy regimen
- First-line treatment of patients with locally advanced, unresectable, or metastatic pancreatic cancer, in combination with gemcitabine.

REFERENCES

Tarceva prescribing information available at: www.gene.com/gene/products/information/pdf/tarceva-prescribing.pdf

Created: 11/17/08
Effective: 01/01/09 Client Approval 12/10/08

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

ETANERCEPT

Generic	Brand	HICL	GCN	Exception/Other
ETANERCEPT	ENBREL	18830		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Has this drug been prescribed by or is it currently being supervised by a rheumatologist or dermatologist?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: Approval requires supervision by a rheumatologist or dermatologist; and a diagnosis of rheumatoid arthritis, juvenile idiopathic arthritis; psoriatic arthritis, ankylosing spondylitis or plaque psoriasis.

2. Does the patient have active rheumatoid arthritis?

   If yes, continue to #3.
   If no, continue to #5.

3. Has the patient previously tried at least one of the following DMARD agents: methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: Approval requires supervision by a rheumatologist; a trial of one of the following DMARD (disease-modifying antirheumatic drug) agents: methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine; and that the patient is currently taking or has a contraindication to methotrexate.

4. Is the patient taking methotrexate or does the patient have a contraindication to methotrexate?

   If yes, for active rheumatoid arthritis, **APPROVE INITIALLY FOR 3 MONTHS FOR #8 OF THE 25MG SYRINGES/VIALS (2 KITS) PER MONTH OR #4 OF THE 50MG SYRINGES/VIALS (1 KIT) PER MONTH.**
   APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.
   If no, do not approve.
   DENIAL TEXT: Approval requires supervision by a rheumatologist; a trial of one of the following DMARD (disease-modifying antirheumatic drug) agents: methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine; and that the patient is currently taking or has a contraindication to methotrexate.

CONTINUED ON NEXT PAGE

ETANERCEPT

INITIAL CRITERIA (CONTINUED)

5. Does the patient have active juvenile idiopathic arthritis?

   If yes, continue to #6.
   If no, continue to #8.

6. Has the patient previously tried at least one of the following DMARD agents: methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine?

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: Approval requires supervision by a rheumatologist; a trial of at least one DMARD (disease-modifying antirheumatic drug) agents: methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine; and that patient is currently taking or has a contraindication to methotrexate.

7. Is the patient taking methotrexate or does the patient have a contraindication to methotrexate?

   If yes, for juvenile idiopathic arthritis, **APPROVE INITIALLY FOR 3 MONTHS FOR #8 OF THE 25MG SYRINGES/VIALS (2 KITS) PER MONTH OR #4 OF THE 50MG SYRINGES/VIALS (1 KIT) PER MONTH.**
   APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.
   If no, do not approve.
   DENIAL TEXT: Approval requires supervision by a rheumatologist; a trial of at least one DMARD (disease-modifying antirheumatic drug) agents: methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine; and that patient is currently taking or has a contraindication to methotrexate.

8. Does the patient have ankylosing spondylitis?

   If yes, for ankylosing spondylitis, **APPROVE INITIALLY 3 MONTHS FOR #8 OF THE 25MG SYRINGES/VIALS (2 KITS) PER MONTH OR #4 OF THE 50MG SYRINGES/VIALS (1 KIT) PER MONTH.**
   If no, continue to #9.

9. Does the patient have active psoriatic arthritis?

   If yes, continue to #10.
   If no, continue to #11.

CONTINUED ON NEXT PAGE

ETANERCEPT

INITIAL CRITERIA (CONTINUED)

10. Has the patient previously tried at least one of the following DMARD agents: methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine?

    If yes, for psoriatic arthritis, **APPROVE INITIALLY FOR 3 MONTHS FOR #8 OF THE 25MG SYRINGES/VIALS (2 KITS) PER MONTH OR #4 OF THE 50MG SYRINGES/VIALS (1 KIT) PER MONTH.**
    APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.
    If no, do not approve.
    DENIAL TEXT: Approval requires supervision by a rheumatologist; a trial of at least one DMARD agents (disease-modifying antirheumatic drug): methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine.

11. Does the patient have chronic moderate to severe plaque psoriasis?

    If yes, continue to #12.
    If no, do not approve.
    DENIAL TEXT: Approval requires a diagnosis of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, or moderate to severe plaque psoriasis.

12. Does the plaque psoriasis involve greater than or equal to10% body surface area (BSA) or do the psoriatic lesions affect the hands, feet, or genital area?

    If yes, continue to #13.
    If no, do not approve.
    DENIAL TEXT: Approval requires supervision by a dermatologist, diagnosis of plaque psoriasis, psoriatic lesions covering greater than 10% of BSA (Body Surface Area) or lesions on the hands, feet, or genital area; a trial of or contraindication to one or more forms of preferred therapy (e.g., PUVA, UVB, methotrexate, or cyclosporine).

13. Has the patient tried or does the patient have a contraindication to one or more forms of preferred therapy (PUVA, UVB, methotrexate or cyclosporine)?

    If yes, for plaque psoriasis, **APPROVE INITIALLY FOR 3 MONTHS FOR #16 OF THE 25MG SYRINGES/VIALS (4 KITS) PER MONTH OR #8 OF THE 50MG SYRINGES/VIALS (2 KITS) PER MONTH.**

    APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.
    If no, do not approve.
    DENIAL TEXT: Approval requires supervision by a dermatologist, diagnosis of plaque psoriasis, psoriatic lesions covering greater than 10% of BSA (Body Surface Area) or lesions on the hands, feet, or genital area; a trial of or contraindication to one or more forms of preferred therapy (e.g., PUVA, UVB, methotrexate or cyclosporine).

CONTINUED ON NEXT PAGE

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

ETANERCEPT

RENEWAL CRITERIA

1. Does the patient have active rheumatoid arthritis, psoriatic arthritis, or juvenile idiopathic arthritis?

   If yes, continue to #2.
   If no, continue to #4.

2. Has the patient experienced or maintained a 20% or greater improvement in tender joint count and swollen joint count?

   If yes, process as follows:
   - For rheumatoid arthritis or juvenile idiopathic arthritis, continue to #3.
   - For psoriatic arthritis, **APPROVE FOR 12 MONTHS #8 OF THE 25MG SYRINGES/VIALS (2 KITS) PER MONTH OR #4 OF THE 50MG SYRINGES/VIALS (1 KIT) PER MONTH.**
     APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

   If no, do not approve.
   DENIAL TEXT: Renewal requires a diagnosis of rheumatoid arthritis, psoriatic arthritis, or juvenile idiopathic arthritis and that the patient has experienced or maintained a 20% or greater improvement in tender joint count and swollen joint count while on therapy.

3. Is the patient taking methotrexate or does the patient have a contraindication to methotrexate?

   If yes, for rheumatoid arthritis or juvenile idiopathic arthritis, **APPROVE FOR 12 MONTHS #8 OF THE 25MG SYRINGES/VIALS (2 KITS) PER MONTH OR #4 OF THE 50MG SYRINGES/VIALS (1 KIT) PER MONTH.**
   APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.
   If no, do not approve.
   DENIAL TEXT: Renewal requires a diagnosis of rheumatoid arthritis or juvenile idiopathic arthritis, and that the patient has experienced or maintained a 20% or greater improvement in tender joint count and swollen joint count and that the patient is currently taking or has a contraindication to methotrexate.

4. Does the patient have chronic plaque psoriasis?

   If yes, continue to #5.
   If no, continue to #6.

CONTINUED ON NEXT PAGE

ETANERCEPT

RENEWAL CRITERIA (CONTINUED)

5. Has the patient achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more?

   If yes, for chronic plaque psoriasis, **APPROVE FOR 12 MONTHS #8 OF THE 25MG SYRINGES/VIALS (2 KITS) PER MONTH OR #4 OF THE 50MG SYRINGES/VIALS (1 KIT) PER MONTH.**
   APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.
   If no, do not approve.
   DENIAL TEXT: Renewal requires a diagnosis of chronic plaque psoriasis and that the patient has achieved clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more.

6. Does the patient have ankylosing spondylitis?

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: Renewal requires a diagnosis of ankylosing spondylitis, and that the patient has experienced an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI).

7. Has the patient experienced an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI)?

   If yes, for ankylosing spondylitis, **APPROVE FOR 12 MONTHS #8 OF THE 25MG SYRINGES/VIALS (2 KITS) PER MONTH OR #4 OF THE 50MG SYRINGES/VIALS (1 KIT) PER MONTH.**
   APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.
   If no, do not approve.
   DENIAL TEXT: Renewal requires a diagnosis of ankylosing spondylitis, and that the patient has experienced an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI).

CONTINUED ON NEXT PAGE

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

ETANERCEPT

RATIONALE
Ensure that appropriate diagnostic, utilization, and safety criteria are utilized for the management of requests for etanercept.

FDA APPROVED INDICATIONS
Rheumatoid arthritis, psoriatic arthritis, chronic moderate to severe plaque psoriasis, ankylosing spondylitis, and juvenile rheumatoid arthritis.

REFERENCES

- Immunex Corporation. Enbrel product information. Thousand Oaks, CA. April 2009.
- Braun J, Davis J et al. First update of the international ASAS consensus statement for the use of anti-TNF agents in patients with ankylosing spondylitis. Ann Rheum Dis. 2006; 65(3):316-20.
- Micromedex® Healthcare Series [database online]. Greenwood Village, Colo: Thomson Healthcare. Available at: https://www.thomsonhc.com/hcs/librarian/PFDefaultActionId/pf.LoginAction. [Accessed: June 18, 2009].
- Smith CH, Anstey AV, et al. British association of dermatologists' guidelines for use of biological interventions in psoriasis 2005. Br J Dermatol 2005; 153:486-497.

Created: 02/03 Revised: 02/16/12
Effective: 03/20/12 Client Approval: 02/16/12

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

EZOGABINE

Generic	Brand	HICL	GCN	Exception/Other
EZOGABINE	POTIGA	37667		

GUIDELINES FOR USE

1. Is patient at least 18 years old?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of partial-onset seizures in patients at least 18 years old and a trial of at least two of the following: carbamazepine, gabapentin, lamotrigine, levetiracetam, levetiracetam ER, oxcarbazepine, valproic acid, valproate, topiramate, or zonisamide.

2. Does patient have a diagnosis of partial-onset seizures?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of partial-onset seizures in patients at least 18 years old and a trial of at least two of the following: carbamazepine, gabapentin, lamotrigine, levetiracetam, levetiracetam ER, oxcarbazepine, valproic acid, valproate, topiramate, or zonisamide.

3. Did the patient have a trial of or contraindication to at least two of the following: carbamazepine, gabapentin, lamotrigine, levetiracetam, levetiracetam ER, oxcarbazepine, valproic acid, valproate, topiramate, or zonisamide?

   If yes**, APPROVE FOR 12 MONTHS AS FOLLOWS:**
   - **50mg tablet: 270 per 30 days**
   - **200mg tablet: 90 per 30 days**
   - **300mg tablet: 90 per 30 days**
   - **400mg tablet: 90 per 30 days**

   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of partial-onset seizures in patients at least 18 years old and a trial of at least two of the following: carbamazepine, gabapentin, lamotrigine, levetiracetam, levetiracetam ER, oxcarbazepine, valproic acid, valproate, topiramate, or zonisamide.

RATIONALE
To allow for appropriate utilization based on FDA approved indication following trial of at least two generically available alternatives.

CONTINUED ON NEXT PAGE

EZOGABINE

RATIONALE (CONTINUED)

Potiga offers a new option for partial seizures with a novel mechanism of action and may benefit patients with seizures refractory to other therapies. Other options with an FDA-approved indication as adjunctive therapy to treat partial seizures include gabapentin, oxcarbazepine, topiramate, levetiracetam /levetiracetam extended release, zonisamide, and lamotrigine (all available as generics), as well as lacosamide, tiagabine, and lamotrigine extended release (all available as single source brands). Additionally, carbamazepine and valproate are indicated for therapy of complex partial seizures (available as generics).

Premarketing clinical trials evaluated Potiga in 1365 patients with epilepsy. Three randomized, double-blind, placebo-controlled clinical trials examined the use of Potiga in patients with partial seizures already on 1-3 concomitant antiepileptic drugs (AED) with or without vagus nerve stimulator. The majority of patients enrolled were on 2 AEDs with a median of 8-12 seizures per month. Daily dosages of 600mg, 900mg and 1200mg demonstrated a statistically significant reduction in median seizure frequency over 28 days when compared to placebo. Of those who tolerated initial titration and entered maintenance phase in the third clinical trial, Potiga-treated patients (1200mg/day) had a 54.5% median reduction in seizure frequency versus 18.9% for placebo-treated patients. More than 30% on Potiga 1200mg/day had more than 75% reduction in seizures from baseline, but only 3.3% of patients became seizure-free.

Common adverse events occurring in clinical trials included dizziness, somnolence, vertigo, tremor, abnormal coordination/gait disturbances, diplopia, disturbance in attention, memory impairment, aphasia, and asthenia. Serious, dose-related neuropsychiatric adverse effects, including confusion, hallucinations, and psychosis, occurred more often in clinical trials in the Potiga-treated group (9% - confusion, 2% - hallucinations, 1% - psychosis) than in the placebo-treated group (3%, <1% and 0%, respectively). Symptoms typically occurred within the first 8 weeks of treatment, and hospitalization was required for 50% of patients discontinuing Potiga due to severe neuropsychiatric effects. Patients on concurrent carbamazepine or phenytoin may require higher doses of Potiga. Patients taking digoxin must have digoxin levels monitored closely while on Potiga. Potiga is pregnancy category C and a schedule V controlled substance.

Dosage: The initial dose should be started at 100mg orally three times daily with or without food. The dose may be increased at weekly intervals, with a daily dose increase of no more than 150mg/day per week, up to a maintenance dose of 200 to 400mg three times daily. If discontinuation of therapy is required, the dosage should be tapered gradually over at least 3 weeks.

FDA APPROVED INDICATIONS

Potiga is indicated for adjunctive treatment of partial-onset seizures in patients aged 18 and older.

REFERENCES

- French J, Abou-Khalil B, Leroy R, et al. Randomized, double-blind, placebo-controlled trial of ezogabine (retigabine) in partial epilepsy. Neurology 2011; 76: 1555-1563.
- Potiga [Prescribing Information]. Research Triangle Park, NC: GlaxoSmithKline; March 2012.
- Wilner, Andrew. Ezogabine: A new drug for seizure control. Medscape Neurology; available online at http://www.medscape.com/viewarticle/745271; accessed April 2012.

Created: 09/12
Effective: 10/01/12 Client Approval: 08/30/12

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

FENTANYL TRANSMUCOSAL

Generic	Brand	HICL	GCN	Exception/Other
FENTANYL CITRATE TRANSMUCOSAL	ACTIQ FENTORA ONSOLIS	01747		ROUTE = BUCCAL OR SUBLINGUAL
FENTANYL SUBLINGUAL	ABSTRAL			

GUIDELINES FOR USE

1. Does the patient have a diagnosis of cancer?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of cancer-related pain, and concurrent use with a controlled-release pain medication (MS Contin, Oxycontin, Oramorph SR, Duramorph, Roxanol SR, Duragesic, Kadian, Avinza or the generic forms of any of these drugs), a trial of an oral immediate-release pain medication (morphine sulfate immediate-release [MSIR], Percodan, Percocet, Vicodin, Tylenol with Codeine, Dilaudid, Demerol or the generic forms of any of these), AND a trial of generic fentanyl citrate lozenge.

2. Is the patient on a maintenance dose of controlled-release pain medication (MS Contin, Oxycontin, Oramorph SR, Duramorph, Roxanol SR, Duragesic, Kadian, Avinza or the generic forms of any of these drugs)?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of cancer-related pain, and concurrent use with a controlled-release pain medication (MS Contin, Oxycontin, Oramorph SR, Duramorph, Roxanol SR, Duragesic, Kadian, Avinza or the generic forms of any of these drugs), a trial of an oral immediate-release pain medication (morphine sulfate immediate-release [MSIR], Percodan, Percocet, Vicodin, Tylenol with Codeine, Dilaudid, Demerol or the generic forms of any of these), AND a trial of generic fentanyl citrate lozenge.

3. Has the patient tried or does the patient have a contraindication to at least one immediate-release oral pain agent (morphine sulfate immediate-release [MSIR], Percodan, Percocet, Vicodin, Tylenol with Codeine, Dilaudid, Demerol or the generic forms of any of these)?

   If yes, continue to #5.
   If no, continue to #4.

CONTINUED ON NEXT PAGE

FENTANYL TRANSMUCOSAL

GUIDELINES FOR USE (CONTINUED)

4. Does the patient have difficulty swallowing tablets or capsules?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of cancer-related pain, and concurrent use with a controlled-release pain medication (MS Contin, Oxycontin, Oramorph SR, Duramorph, Roxanol SR, Duragesic, Kadian, Avinza or the generic forms of any of these drugs), a trial of an oral immediate-release pain medication (morphine sulfate immediate-release [MSIR], Percodan, Percocet, Vicodin, Tylenol with Codeine, Dilaudid, Demerol or the generic forms of any of these), AND a trial of generic fentanyl citrate lozenge.

5. Is the request for generic fentanyl citrate lozenge?

   If yes, **APPROVE FOR 6 MONTHS WITH A QUANTITY LIMIT OF 120 PER MONTH.**
   APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.
   If no, continue to #6.

6. Has the patient tried or does the patient have a contraindication to generic fentanyl citrate lozenge?

   If yes, **APPROVE FOR 6 MONTHS WITH A QUANTITY LIMIT OF 120 PER MONTH.**
   APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of cancer-related pain, and concurrent use with a controlled-release pain medication (MS Contin, Oxycontin, Oramorph SR, Duramorph, Roxanol SR, Duragesic, Kadian, Avinza or the generic forms of any of these drugs), a trial of an oral immediate-release pain medication (morphine sulfate immediate-release [MSIR], Percodan, Percocet, Vicodin, Tylenol with Codeine, Dilaudid, Demerol or the generic forms of any of these), AND a trial of generic fentanyl citrate lozenge.

CONTINUED ON NEXT PAGE

FENTANYL TRANSMUCOSAL

RATIONALE
To assure the safe and appropriate use of transmucosal fentanyl.

FDA APPROVED INDICATIONS

ABSTRAL is an opioid analgesic indicated only for the management of breakthrough pain in patients with cancer, 18 years of age and older, who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.

ACTIQ is indicated for breakthrough cancer pain in patients 16 years and older with malignancies who are already receiving and who are tolerant to opioid therapy for persistent cancer pain. Patients must remain on around-the-clock opioids when taking Actiq.

FENTORA is indicated for breakthrough pain in patients with cancer who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. Patients considered opioid tolerant are those who are taking around-the-clock medicine consisting of at least 60 mg of oral morphine daily, at least 25 mcg of transdermal fentanyl/hour, at least 30 mg of oxycodone daily, at least 8 mg of oral hydromorphone daily or an equianalgesic dose of another opioid daily for a week or longer. This product must not be used in opioid non-tolerant patients because life-threatening hypoventilation and death could occur at any dose in patients not on a chronic regimen of opioids.

FENTORA is contraindicated in the management of acute or postoperative pain. Fentora is intended to be used only in the care of opioid tolerant cancer patients and only by healthcare professionals who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.

ONSOLIS is indicated for the management of breakthrough pain in patients with cancer, 18 years of age and older, who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.

REFERENCES
- Cephalon, Inc. Actiq package insert. Frazer, PA. September 2009.
- Cephalon, Inc. Fentora package insert. Frazer, PA. January 2011.
- Meda Pharmaceuticals, Inc. Onsolis package insert. Somerset, NJ July 2009.
- ProStrakan Inc. Abstral package insert. Bedminster, NJ. January 2011.

Created: 12/10/08
Effective: 10/01/12 Client Approval: 08/30/12

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

FIDAXOMICIN

Generic	Brand	HICL	GCN	Exception/Other
FIDAXOMICIN	DIFICID	37674		

GUIDELINES FOR USE

1. Is the patient at least 18 years old?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: Approval requires that patient is at least 18 years old, has a diagnosis of *Clostridium difficile*-associated diarrhea along with labs documenting white blood cell count, and has previously tried metronidazole and vancomycin for mild to moderate cases or vancomycin (which may require prior authorization) for severe cases.

2. Does the patient have a diagnosis of mild or moderate *Clostridium difficile*-associated diarrhea (mild or moderate infection defined as leukocytosis with a white blood cell count of 15,000 cells/μL or lower)?

   If yes, continue to #3.
   If no, continue to #5.

3. Has the patient tried or does the patient have a contraindication to oral vancomycin?

   If yes, **APPROVE FOR ONE FILL FOR #20 TABLETS PER 10 DAYS.**
   If no, continue to #4.

4. Has the patient tried or does the patient have a contraindication to oral metronidazole?

   If yes, do not approve. **Enter an authorization for oral vancomycin for one fill by HICL, #40 capsules per 10 day supply.**
   DENIAL TEXT: Approval requires that patient is at least 18 years old, has a diagnosis of *Clostridium difficile*-associated diarrhea along with labs documenting white blood cell count, and has previously tried metronidazole and vancomycin for mild to moderate cases or vancomycin (which may require prior authorization) for severe cases.

   If no, do not approve.
   DENIAL TEXT: Approval requires that patient is at least 18 years old, has a diagnosis of *Clostridium difficile*-associated diarrhea along with labs documenting white blood cell count, and has previously tried metronidazole and vancomycin for mild to moderate cases or vancomycin (which may require prior authorization) for severe cases.

CONTINUED ON NEXT PAGE

FIDAXOMICIN

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a diagnosis of severe *Clostridium difficile*-associated diarrhea (severe infection defined as leukocytosis with a white blood cell count higher than 15,000 cells/µL)?

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: Approval requires that patient is at least 18 years old, has a diagnosis of *Clostridium difficile*-associated diarrhea along with labs documenting white blood cell count, and has previously tried metronidazole and vancomycin for mild to moderate cases or vancomycin (which may require prior authorization) for severe cases.

6. Has the patient tried or does the patient have a contraindication to oral vancomycin?

   If yes, **APPROVE FOR ONE FILL FOR #20 TABLETS PER 10 DAYS.**
   If no, do not approve. **Enter an authorization for oral vancomycin for one fill by HICL, #40 capsules per 10 day supply.**
   DENIAL TEXT: Approval requires that patient is at least 18 years old, has a diagnosis of *Clostridium difficile*-associated diarrhea along with labs documenting white blood cell count, and has previously tried metronidazole and vancomycin for mild to moderate cases or vancomycin (which may require prior authorization) for severe cases.

RATIONALE
Ensure appropriate use of fidaxomicin aligned with the FDA approved indication of *Clostridium difficile*-associated diarrhea and dosage of 200mg twice daily for 10 days. Prefer use of metronidazole for mild or moderate cases and vancomycin for severe cases based on the SHEA/IDSA 2010 Clinical Practice Guidelines.

FDA APPROVED INDICATIONS
Dificid is indicated in adults (≥18 years of age) for the treatment of *Clostridium difficile*-associated diarrhea.

REFERENCES
- Optimer Pharmaceuticals, Inc. Dificid package insert. San Diego, CA. May 2011.
- Cohen SH, Gerding DN, Johnson S et al. Clinical Practice Guidelines for *Clostridium difficile* Infection in Adults: 2010 Update by the Society for Healthcare Epidemiology of America (SHEA) and the Infectious Diseases Society of America (IDSA). *Infect Control Hosp Epidemiol* 2010; 31(5):431-455.

Created: 08/11
Effective: 12/14/11 Client Approval: 11/07/11 P&T Approval: 11/11

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

FINGOLIMOD

Generic	Brand	HICL	GCN	Exception/Other
FINGOLIMOD	GILENYA	37180		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of multiple sclerosis?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of multiple sclerosis.

2. Has the patient tried or does the patient have a contraindication to interferon therapy (Avonex, Betaseron, Extavia, or Rebif) **AND** Copaxone?

   If yes, **APPROVE FOR 12 MONTHS WITH A QUANTITY LIMIT OF #28 CAPSULES PER 28 DAYS SUPPLY.**
   If no, do not approve.
   DENIAL TEXT: Approval requires a trial of both Rebif and Copaxone.

RATIONALE
To prevent inappropriate utilization of fingolimod for clinically isolated syndrome (CIS) and encourage the use of Copaxone and preferred interferons.

FDA APPROVED INDICATIONS
Fingolimod is indicated for the treatment of patients with relapsing forms of multiple sclerosis to reduce the frequency of clinical exacerbations and to delay the accumulation of physical disability.

REFERENCES
Novartis Pharmaceutical Corporation. Gilenya package insert. East Hanover, NJ. September 2010.

Created: 02/08/11
Effective: 11/23/11 Client Approval: 02/02/11

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

GEFITINIB

Generic	Brand	HICL	GCN	Exception/Other
GEFITINIB	IRESSA	25178		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC)?

   If yes, continue to #2.
   If no, continue to #4.

2. Has the patient previously received chemotherapy or is the patient not suitable for chemotherapy?

   If yes, continue to #3.
   If no, continue to #4.

3. **APPROVE FOR ONE YEAR.**

4. **DO NOT APPROVE.**

RATIONALE
To assure safe and appropriate use of Iressa

FDA APPROVED INDICATIONS
Treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) who have previously received chemotherapy or who are not suitable for chemotherapy.

REFERENCES
Iressa prescribing information available at:
www.iressa.com/iressaHCP/9898_20846_0_0_0.aspx?mid=39

Created: 11/17/08
Effective: 01/01/09 Client Approval 12/10/08

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

GLATIRAMER ACETATE

Generic	Brand	HICL	GCN	Exception/Other
GLATIRAMER ACETATE	COPAXONE	12810		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsing-remitting MS?

   If yes, continue to #2.
   If no, continue to #3.

2. **APPROVE FOR ONE YEAR.**

3. **DO NOT APPROVE.**

RATIONALE
To assure safe and appropriate use of Glatiramer acetate.

FDA APPROVED INDICATIONS
COPAXONE® Injection is indicated for reduction of the frequency of relapses in patients with Relapsing-Remitting Multiple Sclerosis.

REFERENCES
Copaxone prescribing information available at www.copaxone.com

Created: 11/17/08
Effective: 01/01/09 Client Approval 12/10/08

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

GLP-1 ANALOGS

Generic	Brand	HICL	GCN	Exception/Other
EXENATIDE	BYETTA	32893		
EXENATIDE MICROSPHERES	BYDUREON	38451		
LIRAGLUTIDE	VICTOZA	36436		

GUIDELINES FOR USE

1. Does the patient have Type 2 Diabetes?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of Type 2 Diabetes and documentation that the patient has failed to reach treatment goals with either metformin; a sulfonylurea agent such as glyburide or glipizide; or a thiazolidinedione such as pioglitazone or rosiglitazone.

2. Has the patient failed to reach treatment goals with either metformin, a sulfonylurea agent (e.g., glyburide, glipizide), or a thiazolidinedione (e.g., pioglitazone, rosiglitazone)?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of Type 2 Diabetes and documentation that the patient has failed to reach treatment goals with either metformin; a sulfonylurea agent such as glyburide or glipizide; or a thiazolidinedione such as pioglitazone or rosiglitazone.

3. **BYETTA: APPROVE FOR 12 MONTHS FOR 1 PEN (1.2ML OR 2.4ML) PER MONTH.**
   BYDUREON: APPROVE FOR 12 MONTHS FOR 4 VIALS PER 28 DAYS.
   VICTOZA: APPROVE FOR 12 MONTHS FOR UP TO 3 PENS PER MONTH.

   BYDUREON AND VICTOZA APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

RATIONALE
Ensure appropriate use of Byetta, Bydureon and Victoza.

FDA APPROVED INDICATIONS
BYDUREON: As adjunct to diet and exercise to improve glycemic control in adults with Type 2 Diabetes Mellitus in multiple clinical settings.

BYETTA: As adjunct to diet and exercise to improve glycemic control in adults with Type 2 diabetes mellitus.

VICTOZA: As adjunctive therapy to improve glycemic control in patients with Type 2 diabetes mellitus who are taking metformin, a sulfonylurea, a thiazolidinedione, a combination of metformin and a sulfonylurea, or a combination of metformin and a thiazolidinedione, but have not achieved adequate glycemic control. Not recommended as first-line therapy for patients inadequately controlled on diet and exercise.

CONTINUED ON NEXT PAGE

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

GLP-1 ANALOGS

REFERENCES

- Amylin Pharmaceuticals. Bydureon package insert. San Diego, CA. January 2012.
- Amylin Pharmaceuticals. Byetta package insert. San Diego, CA. September 2010.
- Novo Nordisk. Victoza package insert. Princeton, NJ. January 2010.
- AACE Diabetes Mellitus Guidelines, Endoc Pract. 2007; 13(Suppl 1) 2007.
- AACE/ACE Consensus Statement: Glycemic Control Algorithm, Endocr Pract. 2009;15(no.6) 541
- DIABETES CARE, Standards of Medical Care in Diabetes -2010, Volume 33, Supplement 1, January 2010.

Created: 05/05 Revised: 03/14/12
Effective: 03/20/12 Client Approval: 03/14/12

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

GOLIMUMAB

Generic	Brand	HICL	GCN	Exception/Other
GOLIMUMAB	SIMPONI	36278		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Has this drug been prescribed by or is it currently being supervised by a rheumatologist or dermatologist?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: Approval requires supervision by a rheumatologist or dermatologist, that the patient is at least 18 years of age, a diagnosis of rheumatoid arthritis, psoriatic arthritis or ankylosing spondylitis.

2. Is the patient at least 18 years of age?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: Approval requires supervision by a rheumatologist or dermatologist, that the patient is at least 18 years of age, a diagnosis of rheumatoid arthritis, psoriatic arthritis or ankylosing spondylitis.

3. Does the patient have active rheumatoid arthritis?

   If yes, continue to #4.
   If no, continue to #6.

4. Has the patient tried, or does the patient have a contraindication to at least one of the following DMARDs: methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: Approval requires supervision by a rheumatologist or dermatologist, that the patient is at least 18 years of age, a trial of one of the following DMARDS (disease-modifying antirheumatic drug): methotrexate, leflunomide, hydroxychloroquine, sulfasalazine; and that patient is currently taking or has a contraindication to methotrexate and a diagnosis of rheumatoid arthritis, psoriatic arthritis or ankylosing spondylitis.

CONTINUED ON NEXT PAGE

GOLIMUMAB

INITIAL CRITERIA (CONTINUED)

5. Is the patient currently taking methotrexate or has a contraindication to methotrexate?

   If yes, for rheumatoid arthritis, **APPROVE FOR 3 MONTHS FOR ONE PREFILLED SMARTJECT AUTOINJECTOR OR SYRINGE PER MONTH.**
   If no, do not approve.
   DENIAL TEXT: Approval requires supervision by a rheumatologist or dermatologist, that the patient is at least 18 years of age, a trial of one of the following DMARDS (disease-modifying antirheumatic drug): methotrexate, leflunomide, hydroxychloroquine, sulfasalazine; and that patient is currently taking or has a contraindication to methotrexate and a diagnosis of rheumatoid arthritis, psoriatic arthritis or ankylosing spondylitis.

6. Does the patient have active psoriatic arthritis?

   If yes, continue to #7.
   If no, continue to #8.

7. Has the patient tried, or does the patient have a contraindication to at least one of the following DMARDs: methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine?

   If yes, **APPROVE FOR 3 MONTHS FOR ONE PREFILLED SMARTJECT AUTOINJECTOR OR SYRINGE PER MONTH.**
   If no, do not approve.
   DENIAL TEXT: Approval requires supervision by a rheumatologist; that the patient is at least 18 years of age; diagnosis of active psoriatic arthritis and has tried at least one DMARD (disease-modifying antirheumatic drug): methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine.

8. Does the patient have active ankylosing spondylitis?

   If yes, for ankylosing spondylitis, **APPROVE FOR 3 MONTHS FOR ONE PREFILLED SMARTJECT AUTOINJECTOR OR SYRINGE PER MONTH.**
   If no, do not approve.
   DENIAL TEXT: This medication is not covered for the requested indication.

RENEWAL CRITERIA

1. Does the patient have active rheumatoid arthritis?

   If yes, continue to #4.
   If no, continue to #2.

CONTINUED ON NEXT PAGE

GOLIMUMAB

RENEWAL CRITERIA (CONTINUED)

2. Does the patient have ankylosing spondylitis?

   If yes, continue to #6.
   If no, continue to #3.

3. Does the patient have psoriatic arthritis?

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of active rheumatoid arthritis, psoriatic arthritis or ankylosing spondylitis.

4. Has the patient experienced or maintained a 20% or greater improvement in tender joint count and swollen joint count?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of psoriatic arthritis; that the patient has experienced or maintained a 20% improvement in tender or swollen joint count while on therapy; and that the patient is currently taking or has a contraindication to methotrexate.

5. Is the patient on concurrent methotrexate therapy, or does the patient have a contraindication to methotrexate?

   If yes, for rheumatoid arthritis, **APPROVE FOR 12 MONTHS FOR ONE PREFILLED SMARTJECT AUTOINJECTOR OR SYRINGE PER MONTH.**
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of active rheumatoid arthritis; that the patient has experienced or maintained a 20% improvement in tender or swollen joint count while on therapy and that the patient is currently taking or has a contraindication to methotrexate.

6. Has the patient experienced or maintained an improvement of 20% or greater in the assessment in Ankylosing Spondylitis (ASAS20) criteria?

   If yes, for ankylosing spondylitis, **APPROVE FOR 12 MONTHS FOR ONE PREFILLED SMARTJECT AUTOINJECTOR OR SYRINGE PER MONTH.**
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of ankylosing spondylitis and that the patient has experienced at least a 20% improvement from baseline on the Ankylosing Spondylitis (ASAS20) criteria.

CONTINUED ON NEXT PAGE

RENEWAL CRITERIA (CONTINUED)

7. Has the patient experienced or maintained a 20% or greater improvement in tender joint count and swollen joint count?

   If yes, for psoriatic arthritis, **APPROVE FOR 12 MONTHS FOR ONE PREFILLED SMARTJECT AUTOINJECTOR OR SYRINGE PER MONTH.**
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of psoriatic arthritis; that the patient has experienced or maintained a 20% improvement in tender or swollen joint count while on therapy; and that the patient is currently taking or has a contraindication to methotrexate.

RATIONALE
Ensure appropriate diagnostic, utilization and safety criteria are used for the management of prior authorization requests for golimumab.

FDA APPROVED INDICATIONS
SIMPONI, in combination with methotrexate, is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis.

Simponi, alone or in combination with methotrexate, is also indicated for adult patients with active psoriatic arthritis.

Simponi has a third indication for the treatment of adult patients with active ankylosing spondylitis.

REFERENCES

- Centocor Ortho Biotech, Inc. Simponi package insert. Horsham, PA. March 2011.
- Inman RD, Davis JC, Heijde D, et al. Efficacy and safety of golimumab in patients with ankylosing spondylitis. Arthritis & Rheumatism. 2008; 58(11): 3402-3412.
- Kavanaugh A, McInnes I, Mease P, et al. Golimumab, a new human tumor necrosis factor α antibody administered every four weeks as a subcutaneous injection in psoriatic arthritis. Arthritis & Rheumatism. 2009; 60(4): 976-986.
- Keystone EC, Genovese MC, Klareskog L, et al. Golimumab, a human antibody to tumor necrosis factor α antibody given by monthly subcutaneous injections, in active rheumatoid arthritis despite methotrexate therapy: the GO-FORWARD study. Ann Rheum. 2009:68: 789-796.

Created: 08/09 Revised: 02/16/12
Effective: 03/20/12 Client Approval: 02/16/12

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

GRANISETRON TRANSDERMAL (SANCUSO)

Generic	Brand	HICL	GCN	Exception/Other
GRANISETRON TRANSDERMAL	SANCUSO	35877		ROUTE = TRANSDERMAL

GUIDELINES FOR USE

1. Has the patient had a previous trial of ondansetron ODT, oral ondansetron, oral granisetron or oral dolasetron?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: This medication is covered only for patients who have had a previous trial of ondansetron ODT.

2. Is the patient unable to tolerate oral medications?

   If yes, **APPROVE ONE PATCH PER CHEMO CYCLE.**
   If no, do not approve.
   DENIAL TEXT: This medication is covered only for patients who are physically unable to tolerate oral medications.

RATIONALE
Ensure use of Sancuso consistent with indication.

REFERENCES
ProStrakan Inc. Sancuso® prescribing information. Bedminster, NJ. Aug 2008.

Created: 01/09
Effective: 05/15/09 Client Approval: 04/15/09

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

GRANULOCYTE COLONY-STIMULATING FACTORS

Generic	Brand	HICL	GCN	Exception/Other
FILGRASTIM	NEUPOGEN	06070		
PEGFILGRASTIM	NEULASTA	23255		

GUIDELINES FOR USE

1. Is the prescription written or currently being supervised by a Hematologist or Oncologist?

   If yes, continue to #4.
   If no, continue to #2.

2. Is the patient being treated for febrile neutropenia, associated with the administration of cancer chemotherapy?

   If yes, continue to #4.
   If no, continue to #3.

3. Is the patient receiving cancer chemotherapy and being treated prophylactically for the prevention of febrile neutropenia associated with cancer chemotherapy?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: The medication is not approved for the requested indication.

4. **APPROVE FOR 3 MONTHS OR COURSE OF TREATMENT BASED UPON CHEMOTHERAPY CYCLE.**

CONTINUED ON NEXT PAGE

GRANULOCYTE COLONY-STIMULATING FACTORS

RATIONALE
Ensure proper utilization and appropriate place in therapy according to FDA Approved Indications.

FDA APPROVED INDICATIONS
Neupogen is indicated for treatment of Chronic idiopathic neutropenia, Congenital neutropenia, Cyclic neutropenia, Idiopathic neutropenia, Mobilization: Peripheral blood stem cells, Neutropenia: Bone Marrow Transplant, Neutropenia: Chemotherapy induced, severe chronic neutropenia.

Neulasta is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

REFERENCES
Amgen Inc. Neupogen product information. Thousand Oaks, CA. September 2007.
Amgen Inc. Neulasta product information. Thousand Oaks, CA. April 2008.

Created: 02/03
Effective: 10/15/09 Client Approval: 10/01/09

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

GROWTH HORMONE

Generic	Brand	HICL	GCN	Exception/Other
SOMATROPIN	HUMATROPE NUTROPIN NUTROPIN AQ NUTROPIN DEPOT GENOTROPIN NORDITROPIN NORDIFLEX SAIZEN SEROSTIM TEV-TROPIN ZORBTIVE OMNITROPE	02824		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Idiopathic Short Stature (not growth hormone-deficient short stature), or is somatropin being prescribed for athletic enhancement or anti-aging purposes?

   If yes, do not approve.
   DENIAL TEXT: Use of somatropin for idiopathic short stature, athletic enhancement or anti-aging purposes is not covered.
   If no, continue to #2.

2. Is the medication being prescribed by an endocrinologist?

   If yes, **APPROVE FOR 12 MONTHS UP TO THE MAXIMUM LIMITS NOTED IN #16.**
   If no, continue to #3.

3. Does the patient have one of the following:

   - Growth failure due to chronic renal insufficiency (CRI), **continue to #4.**
   - HIV/AIDS-wasting syndrome, **continue to #9.**
   - Short-bowel syndrome, **continue to #14.**

   If yes, continue as indicated above.
   If no, do not approve.
   DENIAL TEXT: Approval requires diagnosis of growth failure due to chronic renal insufficiency, (CRI), HIV/AIDS-wasting syndrome or short-bowel syndrome and for patients with growth hormone deficiency(GHD) small for gestational age (SGA), Turner Syndrome, Prader-Willi, or intrauterine growth retardation (IUGR) supervised by an endocrinologist.

4. Is the medication being prescribed by a nephrologist?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: Approval requires supervision by an endocrinologist or nephrologist.

CONTINUED ON NEXT PAGE

GUIDELINES FOR USE (CONTINUED)

5. Has the patient undergone renal transplantation?

   If yes, do not approve.
   DENIAL TEXT: Somatropin is recommended for chronic renal insufficiency up to the time of renal transplantation.
   If no, continue to #6.

6. Is the patient's epiphysis closed (as confirmed by radiograph of the wrist and hand)?

   If yes, do not approve.
   DENIAL TEXT: Somatropin is contraindicated in pediatric patients with closed epiphyses.
   If no and induction, continue to #7.
   If no and renewing, continue to #8.

7. Is the patient's height at ≥2 standard-deviation (SD) below the mean height for normal children of the same age and gender?

   If yes, **APPROVE FOR 12 MONTHS UP TO THE MAXIMUM LIMITS NOTED IN #16.**
   If no, do not approve.
   DENIAL TEXT: Approval requires the height standard deviation score is -2 or lower.

8. Does the patient have one or more of the following?

   - A lack of response defined as gain of growth velocity by ≤2cm compared with that observed during the previous year;
   - Patient has reached 50th percentile for target height following growth hormone therapy.

   If yes, do not approve.
   DENIAL TEXT: Renewal requires a gain of growth velocity by greater than or equal to 2cm or the patient has not reached a target height within the 50th percentile.
   If no, **APPROVE FOR 12 MONTHS UP TO THE MAXIMUM LIMITS NOTED IN #16.**

9. Is the patient on antiviral therapy?

   If yes, continue to #10.
   If no, do not approve.
   DENIAL TEXT: Somatropin is covered for HIV wasting if the member is being treated with HIV antiviral therapy.

CONTINUED ON NEXT PAGE

GROWTH HORMONE

GUIDELINES FOR USE (CONTINUED)

10. Does the patient meet one of the following criteria:

    - 10% unintentional weight loss over 12 months
    - 7.5% unintentional weight loss over 6 months
    - 5% body cell mass (BCM) loss within 6 months
    - In men: BCM <35% of total body weight and body mass index (BMI) <27kg/m2
    - In women: BCM <23% of total body weight and BMI <27kg/m2
    - BMI <20kg/m2

    If yes, continue to #11.
    If no, do not approve.
    DENIAL TEXT: Approval requires that the patient must have exhibited signs of HIV wasting.

11. Is the patient currently using this drug?

    If yes, continue to #13.
    If no, continue to #12.

12. Has the patient had an inadequate response to previous therapy (i.e., exercise training, nutritional supplements, appetite stimulants, or anabolic steroids)?

    If yes, **APPROVE FOR 3 MONTHS UP TO MAXIMUM LIMITS NOTED IN #16.**
    If no, do not approve.
    DENIAL TEXT: Approval requires an inadequate response to previous therapy such as nutritional supplements, appetite stimulants, exercise training, and/or anabolic steroids.

13. Has the patient shown clinical benefits by an increase in muscle mass and weight from growth hormone replacement?

    If yes, **APPROVE FOR ADDITIONAL 3 MONTHS THERAPY UP TO THE MAXIMUM LIMITS NOTED IN #16.**
    If no, do not approve.
    DENIAL TEXT: Approval requires an increase in clinical benefits such as an increase in muscle mass and weight.

14. Is the patient currently on specialized nutritional support? (i.e., consisting of a high carbohydrate, low-fat diet)

    If yes, continue to #15.
    If no, do not approve.
    DENIAL TEXT: Approval requires concurrent specialized nutritional support (i.e., high carbohydrate, low fat diet).

CONTINUED ON NEXT PAGE

GROWTH HORMONE

GUIDELINES FOR USE (CONTINUED)

15. Is this an initial therapy for the patient or renewal?

    If initial therapy, **APPROVE FOR 4 WEEKS UP TO THE MAXIMUM LIMITS NOTED IN #16.**
    If renewal, do not approve.
    DENIAL TEXT: Approval requires that somatropin not be administered for more than 4 weeks in patients with short bowel syndrome because it has not been adequately studied.

16. **MAXIMUM QUANTITY LIMITS:**
    Genotropin: 2.5mg per 1 day supply
    Humatrope: 2mg per 1 day supply
    Norditropin: 2.5mg per 1 day supply
    Norditropin FlexPro: 2.5mg per 1 day supply
    Norditropin Nordiflex: 2.5mg per 1 day supply
    Nutropin: 7.2mg per 1 day supply
    Nutropin AQ: 7.2mg per 1 day supply
    Nutropin AQ NuSpin: 7.2mg per 1 day supply
    Omnitrope: 1.5mg per 1 day supply
    Saizen: 1mg per 1 day supply
    Serostim: 1 vial per 1 day supply (maximum dosage of Serostim not to exceed 6mg per day)
    Tev-Tropin: 1.5mg per 1 day supply
    Zorbtive: 1 vial per 1 day supply (maximum dosage of Zorbtive not to exceed 8mg per day)

RATIONALE
Ensure appropriate use of growth hormones with respect to evidence based guidelines.

FDA APPROVED INDICATIONS
GENOTROPIN is indicated in the replacement of endogenous growth hormone in adults with growth hormone deficiency in of either adult or child onset. Adult Onset: Patients who have growth hormone deficiency, either alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases, hypothalamic disease, surgery, radiation therapy, or trauma. Childhood Onset: Patients who were growth hormone deficient during childhood as a result of congenital, genetic, acquired or idiopathic causes. Genotropin is also indicated for pediatric patients for the treatment of inadequate secretion of endogenous growth hormone, growth failure due to Prader-Willi syndrome, growth failure in children born small for gestational age who fail to manifest catch-up growth by the age of 2, for growth failure associated with Turner syndrome in patients with open epiphyses and for idiopathic short stature (ISS).

HUMATROPE is indicated for Pediatric Patients: Treatment of children with short stature or growth failure associated with growth hormone (GH) deficiency, Turner syndrome, idiopathic short stature, SHOX deficiency, and failure to catch up in height after small for gestational age birth. Adult Patients: Treatment of adults with either childhood-onset or adult-onset GH deficiency.

CONTINUED ON NEXT PAGE

GROWTH HORMONE

FDA APPROVED INDICATIONS (CONTINUED)

NORDITROPIN, FLEXPRO AND NORDIFLEX are indicated for the treatment of children with growth failure due to inadequate secretion of endogenous growth hormone, the treatment of children with short stature associated with Noonan syndrome and Turner syndrome, the treatment of children with short stature born small for gestational age (SGA) with no catch up growth by age 2-4 years and for the replacement of endogenous growth hormone in adults with growth hormone deficiency, either alone, or associated with multiple hormone deficiencies (hypopituitarism) as a result of pituitary disease, hypothalamic disease, surgery, radiation therapy, or trauma; or childhood onset: patients who were growth hormone deficient during childhood as a result of congenital, genetic, acquired, or idiopathic causes.

NUTROPIN, NUTROPIN AQ, NUTROPIN AQ NUSPIN are indicated in the replacement of endogenous growth hormone in adults with growth hormone deficiency in either adult or child onset. Adult Onset: Patients who have growth hormone deficiency, either alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases, hypothalamic disease, surgery, radiation therapy, or trauma. Childhood Onset: Patients who were growth hormone deficient during childhood as a result of congenital, genetic, acquired or idiopathic causes. These are also indicated in pediatric patients for the treatment of pediatric patients who have growth failure due to an inadequate secretion of normal endogenous growth hormone for the treatment of short stature associated with Turner syndrome, for the treatment of idiopathic short stature, and for the treatment of growth failure associated with chronic renal insufficiency up to the time of renal transplantation

OMNITROPE is indicated for the treatment of pediatric and adult growth hormone deficiency

SAIZEN is indicated for the treatment of pediatric and adult growth hormone deficiency.

SEROSTIM is indicated in the treatment of HIV patients with wasting or cachexia to increase lean body mass and body weight and improve physical endurance with concomitant antiretroviral therapy.

TEV-TROPIN is indicated for the long term treatment of children who have growth hormone failure due to an inadequate secretion of normal endogenous growth hormone.

ZORBTIVE is indicated for the treatment of Short Bowel Syndrome in patients receiving specialized nutritional support.

CONTINUED ON NEXT PAGE

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

GROWTH HORMONE

REFERENCES

- American Association of Clinical Endocrinologists medical guidelines for clinical practice for growth hormone use in adults and children – 2003 update. Endocr Pract 2003; 9(1):64-76.
- Consensus guidelines for the diagnosis and treatment of growth hormone (GH) deficiency in childhood and adolescence: summary statement of the GH Research Society. JCE & M 2000; 85(11):3990-3.
- Bengtsson B, et al. Treatment of Growth Hormone Deficiency in Adults. JCE & M 2000; 85(3): 933-42.
- Wilson, T et al. Update of Guidelines for the Use of Growth Hormone in Children: The Lawson Wilkins Pediatric Endocrinology Society Drug and Therapeutics Committee. J Pediatr 2003; 143:314-21.
- National Kidney Foundation (2000). Clinical practice guidelines for nutrition in chronic renal failure. Available at: www.kidney.org/professionals/kdoqi/guidelines_updates/nut_p10.html. [Accessed July 21, 2009].
- Vance M, Mauras N. Growth hormone therapy in adults and children. NEJM 1999; 341(16):1206-16.
- Grinspoon S, Mulligan K. Weight loss and wasting in patients infected with human immunodeficiency virus. Clinical Infectious Disease 2003; 36:S69-78.
- Corcoran C, Grinspoon S. Treatments for Wasting in Patients with the Acquired Immunodeficiency Syndrome. NEJM 1999; 340:1740-50.
- Hintz R, et al. Effect of Growth Hormone Treatment on Adult Height of Children with idiopathic Short Stature. NEJM 1999; 340:502-7.
- Haffner D, et al. Effect of Growth Hormone Treatment on the Adult Height of Children with Chronic Renal Failure. NEJM 2000; 343:923-30.
- Weiming Z, Ning L, Jieshou L. Effect of Recombinant Human Growth Hormone and Enteral Nutrition on Short Bowel Syndrome. JPEN 2004; 28(6): 377-81.
- Vetter Pharma-Fertigung GmBH & Co. KG. Genotropin package insert. Ravensburg, Germany. August 2009.
- Eli Lilly and Company. Humatrope package insert. Indianapolis, IN. August 2009.
- Novo Nordisk, Inc. Norditropin package insert. Princeton, NJ. March 2010.
- Genentech, Inc. Nutropin package insert. South San Francisco, CA. June 2006.
- Genentech, Inc. Nutropin AQ package insert. South San Francisco, CA. January 2008.
- EMD Serono, Inc. Saizen package insert. Rockland, MA. September 2007.
- EMD Serono, Inc. Serostim package insert. Rockland, MA. September 2007.
- Bio-Technology General (Israel) LTD. Tev-Tropin package insert. Be'er Tuvia, Israel. October 2007.
- EMD Serono, Inc. Zorbtive package insert. Rockland, MA. March 2009.
- Sandoz GmbH. Omnitrope package insert. Austria. June 2010.

Created: 05/04
Effective: 12/14/11 Client Approval: 11/07/11

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

IMATINIB MESYLATE

Generic	Brand	HICL	GCN	Exception/Other
IMATINIB MESYLATE	GLEEVEC	22096		

GUIDELINES FOR USE

1. Has the patient been diagnosed with Philadelphia chromosome positive (Ph+) chronic myeloid leukemia (CML)?

   If yes, continue to #8.
   If no, continue to #2.

2. Has the patient been diagnosed with Philadelphia chromosome positive (Ph+) acute lymphoblastic leukemia (ALL)?

   If yes, continue to #8.
   If no, continue to #3.

3. Does the patient have a diagnosis of gastrointestinal stromal tumors (GIST)?

   If yes, continue to #8.
   If no, continue to #4.

4. Does the patient have dermatofibrosarcoma protuberans tumors?

   If yes, continue to #8.
   If no, continue to #5.

5. Does the patient have hypereosinophilic syndrome?

   If yes, continue to #8.
   If no, continue to #6.

6. Does the patient have aggressive systemic mastocytosis?

   If yes, continue to #8.
   If no, continue to #7.

7. Does the patient have myeloproliferative disorders?

   If yes, continue to #8.
   If no, continue to #9.

8. **APPROVE FOR ONE YEAR.**

9. **DO NOT APPROVE.**

CONTINUED ON NEXT PAGE

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

IMATINIB MESYLATE

RATIONALE
To assure safe and appropriate use of imatinib.

FDA APPROVED INDICATIONS
Gleevec is a kinase inhibitor indicated for the treatment of:

- Newly diagnosed adult patients with Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase. Follow-up is limited to 5 years
- Patients with Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in blast crisis (BC), accelerated phase (AP), or in chronic phase (CP) after failure of interferon-alpha therapy
- Pediatric patients with Ph+ CML in chronic phase who are newly diagnosed or whose disease has recurred after stem cell transplant or who are resistant to interferon-alpha therapy. There are no controlled trials in pediatric patients demonstrating a clinical benefit, such as improvement in disease-related symptoms or increased survival
- Adult patients with relapsed or refractory Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL)
- Adult patients with myelodysplastic/ myeloproliferative diseases (MDS/MPD) associated with PDGFR (platelet-derived growth factor receptor) gene re-arrangements
- Adult patients with aggressive systemic mastocytosis (ASM) without the D816V c-Kit mutation or with c-Kit mutational status unknown
- Adult patients with hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (CEL) who have the FIP1L1-PDGFRα fusion kinase (mutational analysis or FISH demonstration of CHIC2 allele deletion) and for patients with HES and/or CEL who are FIP1L1- PDGFRα fusion kinase negative or unknown
- Adult patients with unresectable, recurrent and/or metastatic dermatofibrosarcoma protuberans (DFSP)
- Patients with Kit (CD117) positive unresectable and/or metastatic malignant gastrointestinal stromal tumors (GIST).

REFERENCES

- Gleevec Prescribing Information available at http://www.pharma.us.novartis.com/product/pi/pdf/gleevec_tabs.pdf.

Created: 11/17/08
Effective: 01/01/09 Client Approval 12/10/08

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

INTERFERON AGENTS

Generic	Brand	HICL	GCN	Exception/Other
INTERFERON ALFACON-1	INFERGEN	15707		
PEGINTERFERON ALFA-2A	PEGASYS	24035		
PEGINTERFERON ALFA-2B	PEGINTRON PEGINTRON REDIPEN	21367		GPID ≠ 29809, 29811, 29812
INTERFERON ALFA-2B	INTRON A	04528		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Is the request for continuation of current therapy (also consider continuation if member has a claim for the currently requested interferon in past 120 days) or a renewal?

   If yes, continue to #16.
   If no, continue to #2.

2. Is the request for Intron A?

   If yes, continue to #3.
   If no, continue to #4.

3. Is the patient being treated for one of the following?
   a. hairy cell leukemia, or
   b. condylomata acuminate, or
   c. AIDS-related Kaposi's sarcoma, or
   d. Chronic hepatitis B, or
   e. Non-Hodgkin's lymphoma, or
   f. Malignant melanoma, or
   g. Chronic phase, Philadelphia chromosome (Ph) positive chronic myelogenous leukemia (CML) patients who are minimally treated (within 1 year of diagnosis), or
   h. Follicular lymphoma, or
   i. Angioblastoma, or
   j. Carcinoid tumor, or
   k. Chronic myeloid leukemia, or
   l. Laryngeal papillomatosis, or
   m. Multiple myeloma, or
   n. Neoplasm of conjunctiva-neoplasm of cornea, or
   o. Ovarian cancer, or
   p. Polycythemia vera, or
   q. Renal cell carcinoma, or
   r. Skin cancer, or
   s. Thrombocytosis, or
   t. Vulvar vestibulitis

   If yes, continue to #15.
   If no, continue to #9.

CONTINUED ON NEXT PAGE

INTERFERON AGENTS

GUIDELINES FOR USE (CONTINUED)

4. Is the request for PegIntron or PegIntron Redipen?

   If yes, continue to #8.
   If no, continue to #5.

5. Is the request for Pegasys vial or kit AND is the patient 18 years of age or older?

   If yes, continue to #6.
   If no, continue to #7.

6. Is the patient being treated for chronic hepatitis B and currently supervised by a gastroenterologist, infectious disease specialist or a physician specializing in the treatment of hepatitis (e.g. hepatologist)?

   If yes, continue to #15.
   If no, continue to #9.

7. Is the request for Infergen AND the patient is 18 years of age or older?

   If yes, continue #9.
   If no, do not approve.
   DENIAL TEXT: Approval requires age of 18 years or older.

8. Is the patient 3 years of age or older?

   If yes, continue to #9.
   If no, do not approve.
   DENIAL TEXT: Approval requires an age of 3 years or older.

9. Is the patient being treated for chronic hepatitis C and currently supervised by a gastroenterologist, infectious disease specialist or a physician specializing in the treatment of hepatitis (e.g. hepatologist)?

   If yes, continue to #10.
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of chronic hepatitis C and therapy is being supervised by a gastroenterologist, infectious disease specialist, or a physician specializing in the treatment of hepatitis (e.g. hepatologist).

10. Is the request being used with ribavirin or does the patient have a contraindication to ribavirin?

    If yes, continue to #11.
    If no, do not approve.
    DENIAL TEXT: Approval requires combination therapy with ribavirin.

CONTINUED ON NEXT PAGE

INTERFERON AGENTS

GUIDELINES FOR USE (CONTINUED)

11. Does the patient have a detectable pretreatment HCV RNA level/viral load of ≥ 50 IU/mL?

    If yes, continue to #12.
    If no, do not approve.
    DENIAL TEXT: Approval requires a detectable pretreatment HCV RNA level/viral load of greater than or equal to 50 IU/mL.

12. Is the patient infected with genotype 1, 4, 5, or 6 hepatitis C?

    If yes, continue to #14.
    If no, continue to #13.

13. Is the patient infected with genotype 2 or 3 hepatitis C?

    If yes, continue to #15.
    If no, do not approve.
    DENIAL TEXT: Approval requires a diagnosis of hepatitis C with genotype 1, 2, 3, 4, 5, or 6.

14. **APPROVE FOR 16 WEEKS (4 MONTHS).**

    Recommend obtaining HCV RNA level at 12 weeks of treatment to determine if the patient has achieved at least a 2 log reduction (100 fold decrease) in HCV RNA.

15. **APPROVE FOR 24 WEEKS (6 MONTHS).**

16. Is the request for Intron A?

    If yes, continue to #25.
    If no, continue to #17.

17. Is the request for Pegasys?

    If yes, continue to #18.
    If no, continue to #19.

18. Is the request for continuing treatment of chronic hepatitis B?

    If yes, continue to #25.
    If no, continue to #19.

CONTINUED ON NEXT PAGE

INTERFERON AGENTS

GUIDELINES FOR USE (CONTINUED)

19. Is the request for combination therapy with ribavirin and an interferon, or does the patient have a contraindication to combination therapy with ribavirin?

    If yes, continue to #20.
    If no, do not approve.
    DENIAL TEXT: Renewal requires combination therapy with ribavirin.

20. Is the patient infected with genotype 1, 4, 5, or 6 hepatitis C?

    If yes, continue to #21.
    If no, do not approve.
    DENIAL TEXT: Renewal requires a diagnosis of hepatitis C with genotype 1, 4, 5, or 6.

21. Has the patient already received 24 weeks of treatment for hepatitis C?

    If yes, continue to #24.
    If no, continue to #22.

22. Did the patient achieve at least a 2 log reduction (100 fold decrease) in quantitative HCV RNA by week 12?

    If yes, continue to #23.
    If no, do not approve.
    DENIAL TEXT: Renewal requires at least a 2 log reduction (100 fold decrease) in quantitative HCV RNA by week 12.

23. Is the patient HCV RNA detectable (> 50 IU/mL) at 12 weeks?

    If yes, **APPROVE FOR 8 WEEKS.** Recommend re-testing at 24 weeks to determine if the patient will become HCV RNA negative by week 24 and if therapy will be continued.
    If no, **APPROVE 32 WEEKS FOR A TOTAL OF 48 WEEKS TREATMENT.**

24. Is the patient HCV RNA undetectable (< 50 IU/mL) at 24 weeks?

    If yes, **APPROVE 48 WEEKS FOR A TOTAL OF 72 WEEKS TREATMENT.**
    If no, do not approve.
    DENIAL TEXT: Renewal criteria require HCV RNA to be undetectable (less than 50 IU/mL) after 24 weeks of treatment.

25. **APPROVE FOR 24 WEEKS (6 MONTHS).**

CONTINUED ON NEXT PAGE

INTERFERON AGENTS

RATIONALE

Ensure that ribavirin and interferon are used for combination treatment of chronic hepatitis C. U.S. Clinical guidelines recommend a combination of the current standard of care therapy with a peginterferon alfa-2 agent and ribavirin. The 16 week initial approval for hepatitis C allow a sufficient length of time for the 12-week HCV RNA result (EVR) to be reported and evaluated by the physician. If the patient did not achieve undetectable viral load at 12 weeks then a total of 72 weeks may be considered if the 24-week HCV RNA is undetectable. Total therapy time for HCV genotypes 1, 4, 5 and 6 is 48 weeks, and for HCV genotypes 2 and 3 is 16 to 24 weeks.

FDA APPROVED INDICATIONS

INTRON A (Interferon alfa-2b) is indicated for treatment of hairy cell leukemia, condylomata acuminata, AIDS-related Kaposi's sarcoma, hepatitis C (in combination), malignant melanoma, follicular lymphoma, and chronic hepatitis B.

PEGASYS (peginterferon alfa-2a) alone or in combination with COPEGUS (ribavirin) is indicated for the treatment of adults with chronic hepatitis C virus infection who have compensated liver disease and have not been previously treated with interferon or peginterferon alfa.

PEGASYS is also indicated for treatment of adults with chronic hepatitis C virus infection in patients with HIV/HCV co-infection.

PEGASYS is also indicated for treatment of adults with HBeAg positive and negative chronic hepatitis B who have compensated liver disease and evidence of viral replication and inflammation.

PEGINTRON (peginterferon alfa-2b) is indicated for use alone for the treatment of chronic hepatitis C in adults at least 18 years of age with compensated liver disease who have and those who have not been previously treated with interferon alfa.

PEGINTRON (peginterferon alfa-2b) in combination with REBETOL (ribavirin) is indicated for use in the treatment of chronic hepatitis C in adults and children at least 3 years of age with compensated liver disease.

INFERGEN is indicated for the treatment of chronic HCV infection in patients 18 years of age or older with compensated liver disease (retreatment).

REFERENCES

- Anon. National Institutes of Health Consensus Development Conference Statement. Management of Hepatitis C: 2002 [online]. Available at: <http://consensus.nih.gov/2002/2002HepatitisC2002116html.htm> [Accessed June 30, 2010].
- Bacon B, Shiffman M, Mendes F, et al. Retreating Chronic Hepatitis C with Daily Interferon alfacon-1/ribavirin after non-response to pegylated interferon/ribavirin: DIRECT Results. Hepatology 2009; 49:1838-1846.
- Ghany et al. AASLD Practice Guidelines. Diagnosis, Management, and Treatment of Hepatitis C. Hepatology 2009, 49(4) 1335-74.
- Fried MW et al. Peginterferon alfa-2a plus ribavirin for chronic hepatitis C virus infection. NEJM 2002, 347(13):975-82.

CONTINUED ON NEXT PAGE

REFERENCES (CONTINUED)

- Management and Treatment of Hepatitis C Virus Infection in HIV-Infected Adults: Recommendations from the Veterans Affairs Hepatitis C Resource Center Program and National Hepatitis C Program Office [online]. September 1, 2005. Available at: <http://hepatitis.va.gov/vahep?page=prtop04-00-rr> [Accessed June 30, 2010] and Am J Gastroenterol 2006; 101:2360-78.
- Merck/Schering Corporation. Intron A Product Information. Whitehouse Station, NJ. January 2011.
- Merck/Schering Corporation. PegIntron Product Information. Whitehouse Station, NJ. Available at, <http://www.spfiles.com/pipeg-intron.pdf> [Accessed January 2011].
- Roche Pharmaceuticals. Pegasys Product Information. Nutley, NJ. January 2011.
- Shiffman ML. Management of Patients with Chronic Hepatitis C Virus Infection and Previous Nonresponse. Rev Gastroenterol Disord 2004; 4(suppl1):S22-30.
- Shiffman M et al. 2006. Peginterferon alfa-2a (PEGASYS) plus ribavirin (COPEGUS) for 16 or 24 weeks in patients with HCV genotype 2 or 3 [abstract]. In: 41st Annual Meeting of The European Association for the Study of the Liver; 2006 April 26-30; Vienna, Austria.
- Three Rivers Pharmaceuticals. Infergen [Package Insert]. Warrendale, Pennsylvania. Available at <http://infergen.com/hc_prescribing.php > [Accessed January 2011].
- HCV Treatment Algorithm [online]. Available at <http://clinicaloptions.com/Hepatitis> [Accessed June 30, 2010].
- M H Nguyen and E B Keefe. Prevalence and Treatment of Hepatitis C virus Genotype 4, 5, and 6. Clinical Gastroenterology and Hepatology 3: Suppl 2:97-101. October 2005.
- Micromedex® Healthcare Series [database online]. Greenwood Village, Colo: Thomson Healthcare. Available at: https://www.thomsonhc.com/hcs/librarian/PFDefaultActionId/pf.LoginAction. [Accessed: January 12, 2011].
- D'heygere F, George C, Nevens F, et al. Patients infected with HCV-5 present the same response rate as patients infected with HCV-1: results from the Belgian Randomized Trial for Naïve and Relapsers (BERNAR-1). Program and Abstracts of the 40th Annual Meeting of the European Association for the Study of the Liver. Abstract 558.

Created: 02/03
Effective: 10/26/11 Client Approval: 08/05/11 P&T Approval: 08/11

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

AVONEX- REBIF- BETASERON

Generic	Brand	HICL	GCN	Exception/Other
INTERFERON BETA-1A INTERFERON BETA-1B	AVONEX REBIF BETASERON	11253 23353 08537		

GUIDELINES FOR USE

1. Has the patient had a single demyelinating episode with consistent MRI findings, and is considered at high risk for clinically definite multiple sclerosis (MS)?

   If yes, continue to #4.
   If no, continue to #2.

2. Does the patient have a diagnosis of relapsing-remitting MS?

   If yes, continue to #4.
   If no, continue to #3.

3. Does the patient have a diagnosis of secondary progressive MS with a history of superimposed relapses?

   If yes, continue to #4.
   If no, continue to #5.

4. **APPROVE FOR ONE YEAR.**

5. **DO NOT APPROVE.**

CONTINUED ON NEXT PAGE

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

AVONEX- REBIF- BETASERON

RATIONALE
To assure safe and appropriate use of Interferon beta-1a and beta-1b.

FDA APPROVED INDICATIONS
AVONEX® (Interferon beta-1a) is indicated for the treatment of patients with relapsing forms of multiple sclerosis to slow the accumulation of physical disability and decrease the frequency of clinical exacerbations. Patients with multiple sclerosis in whom efficacy has been demonstrated include patients who have experienced a first clinical episode and have MRI features consistent with multiple sclerosis.

BETASERON® (Interferon beta-1b) is indicated for the treatment of relapsing forms of multiple sclerosis to reduce the frequency of clinical exacerbations. Patients with multiple sclerosis in whom efficacy has been demonstrated include patients who have experienced a first clinical episode and have MRI features consistent with multiple sclerosis.

REBIF® (Interferon beta-1a) is indicated for the treatment of patients with relapsing forms of multiple sclerosis to decrease the frequency of clinical exacerbations and delay the accumulation of physical disability. Efficacy of Rebif® in chronic progressive multiple sclerosis has not been established.

REFERENCES

- Avonex Prescribing Information available at www.avonex.com.
- Betaseron Prescribing Information available at www.betaseron.com.
- Rebif Prescribing Information available at http://media.pfizer.com/files/products/uspi_rebif.pdf.

Created: 11/17/08
Effective: 01/01/09 Client Approval 12/10/08

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

INTERFERON GAMMA-1B

Generic	Brand	HICL	GCN	Exception/Other
INTERFERON GAMMA-1B,RECOMB.	ACTIMMUNE	06068		

GUIDELINES FOR USE

Interferon gamma-1b will be provided as a plan benefit within the following guidelines:

1. Is the prescribing physician a Hematologist, Oncologist, Pediatrician, or Infectious Disease specialist?

   If yes, continue to #3.
   If no, continue to #2.

2. Does the patient have chronic granulomatous disease or osteopetrosis?

   If yes, continue to #3.
   If no, do not approve.

3. **APPROVE FOR 6 MONTHS BY HICL WITH A QUANTITY LIMIT OF A MAXIMUM OF #24 VIALS/MONTH.**

RATIONALE

Ensure appropriate diagnostic usage criteria.

FDA APPROVED INDICATIONS

1. Chronic granulomatous disease.
2. Osteopetrosis – congenital.

REFERENCES

- Micromedex Healthcare Series [database online]. Greenwood Village, CO: Thomson Healthcare. Available at: http://www.thomsonhc.com/hcs/librarian. [Accessed: July 10, 2008]
- Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2008. Available at: http://www.clinicalpharmacology.com. [Accessed: July 10, 2008].

Created: 09/05
Effective: 10/15/09 Client Approval: 10/01/09

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

IVACAFTOR

Generic	Brand	HICL	GCN	Exception/Other
IVACAFTOR	KALYDECO	38461		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of cystic fibrosis?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of cystic fibrosis, patient age of at least 6 years, and the presence of a *G551D* mutation.

2. Is the patient at least 6 years old?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of cystic fibrosis, patient age of at least 6 years, and the presence of a *G551D* mutation.

3. Does the patient have a G551D mutation?

   If yes, **APPROVE FOR 12 MONTHS WITH A QUANTITY LIMIT OF 2 TABLETS PER DAY.**
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of cystic fibrosis, patient age of at least 6 years, and the presence of a *G551D* mutation.

CONTINUED ON NEXT PAGE

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

IVACAFTOR

RATIONALE
Promote appropriate utilization of Kalydeco based on FDA approved indication.

CF is an inherited chronic disease that affects about 30,000 patients in the US. A defective cystic fibrosis transmembrane conductance regulator (*CFTR*) protein leads to production of unusually thick, sticky mucus that clogs the lungs and prevents the body from breaking down and absorbing food. Ivacaftor increases chloride transport by potentiating the channel open probability of *G551D-CFTR* protein resulting in more fluid mucus. About 4-5% of CF patients have a *G551*D mutation. There is no cure for this disease however current treatments that offer symptomatic relief include the single source brands: Cayston, Pulmozyme, and Tobi.

Two double-blind trials randomized clinically stable patients with CF who have a *G551D* mutation to ivacaftor 150mg twice daily (n=109) or placebo (n=104) for 48 weeks. Patients could receive other CF treatments. Trial 1 involved patients 12 years of age and older while trial 2 involved patients who were 6 to 11 years of age. In both trials change from baseline in percent predicted pre-dose FEV1 through 24 weeks of treatment significantly increased: 10.6% in trial 1 and 12.5% in trial 2.

Common adverse reactions include headache, oropharyngeal pain, upper respiratory tract infection, nasal congestion, abdominal pain, nasopharyngitis, diarrhea, rash, nausea, and dizziness. Transaminases (ALT and AST) should be assessed prior to initiation of therapy, every 3 month during first year of treatment and annually thereafter.

Dosage: One 150mg tablet every 12 hours with fat-containing food. Reduce dose to 150mg twice weekly when co-administered with strong CYP3A inhibitors ad reduce dose to 150mg once daily when co-administered with moderate CYP3A inhibitors. Avoid food containing grapefruit or Seville oranges.

FDA APPROVED INDICATION
Kalydeco is indicated for the treatment of cystic fibrosis (CF) in patients age 6 years and older who have a *G551D* mutation in the *CFTR* gene. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the *G551D* mutation.

Limitations of Use:
Not effective in patients with CF who are homozygous for the F508del mutation in the CFTR gene. Kalydeco has not been studied in other populations of patients with CF.

REFERENCES

- Vertex Pharmaceuticals Incorporated. Kalydeco package insert. Cambridge, MA. January 2012.

Created: 09/12
Effective: 10/01/12 Client Approval: 08/30/12

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

LOW MOLECULAR WEIGHT HEPARIN

Generic	Brand	HICL	GCN	Exception/Other
DALTEPARIN	FRAGMIN	07429		
ENOXAPARIN	LOVENOX	07878		
TINZAPARIN	INNOHEP	08989		

GUIDELINES FOR USE

1. Is this request for enoxaparin or tinzaparin for treatment of DVT or PE in pregnant females?

   If yes, continue to #3.
   If no, continue to #2.

2. Is this request for a patient who is pregnant and diagnosed with antiphospholipid syndrome (phospholipid antibody syndrome) or other hypercoagulable state (e.g. Protein C/S deficiency)?

   If yes, continue to #3.
   If no, continue to #4.

3. **APPROVE FOR A MAXIMUM OF 1 YEAR.**

4. Does the patient have a diagnosis of multiple myeloma and taking thalidomide or lenalidomide and chemotherapy or dexamethasone?

   If yes, continue to #6.
   If no, continue to #5.

5. Does the patient have cancer and requires a LMWH to reduce the recurrence of VTE (venous thromboembolism: DVT and/or PE)?

   If yes, continue to #6.
   If no, continue to #7.

6. **APPROVE FOR LIFETIME.**

7. Does the patient require DVT prophylaxis following major surgery or for prevention of ischemic complications of unstable angina and non-Q-wave MI?

   If yes, continue to #8.
   If no, do not approve.

8. **APPROVE FOR 14 DAYS PLUS ONE REFILL.**

CONTINUED ON NEXT PAGE

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

LOW MOLECULAR WEIGHT HEPARIN

RATIONALE
Appropriate use for extended courses of treatment

FDA APPROVED INDICATIONS
***Dalteparin*:**
- Prophylaxis of deep vein thrombosis (DVT).
- Prophylaxis of ischemic complications in unstable angina and non-Q-wave myocardial infarction.
- Extended treatment of symptomatic venous thromboembolism to reduce the recurrence of VTE in patients with cancer.

Enoxaparin:
- Prophylaxis of deep vein thrombosis (DVT).
- For DVT/Pulmonary embolism (PE) treatment in conjunction with warfarin for inpatient treatment of acute DVT with and without PE or outpatient treatment of acute DVT without PE.
- For the prevention of ischemic complications of unstable angina and non-Q-wave MI when co-administered with aspirin and Q-wave MI (ST-segment elevation MI).

Tinzaparin:
- Treatment of acute symptomatic deep vein thrombosis with or without pulmonary embolism when administered in conjunction with warfarin sodium
- Treatment of DVT or PE in pregnant females.

REFERENCES

- American Society of Clinical Oncology Guideline: Recommendations for Venous Thromboembolism Prophylaxis and Treatment in Patients With Cancer. *J Clin Oncol 25. © 2007 by American Society of Clinical Oncology*
- Venous Thromboembolism, Thrombophilia, Antithrombotic Therapy, and Pregnancy*. American College of Chest Physicians Evidence-Based Clinical Practice Guidelines (8th Edition). CHEST 2008; 133:844S–886S.
- Pfizer Inc. Fragmin product information. New York, NY. April 2007.
- LEO Pharmaceuticals. Innohep product information. April 2008.
- Sanofi-Aventis. Lovenox product information. October 2007.
- MICROMEDEX® Healthcare Series [database online]. Greenwood Village, CO: Thomson Healthcare. Available at: https://www.thomsonhc.com/hcs/librarian/PFDefaultActionId/pf.LoginAction. [Accessed: June 23, 2008].
- Dranitsaris, G, Vincent, M Cronther, M, *Dalteparin versus warfarin for the prevention of recurrent venous thromboembolism events in cancer patients: a pharmacoeconomic analysis*. Pharmacoeconics: 2006; 24 (6):593-607.

Created: 02/04/09 Revised 05/01/09
Effective: 05/15/09 Client Approval: 04/15/09

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

MECASERMIN

Generic	Brand	HICL	GCN	Exception/Other
MECASERMIN	INCRELEX	33207		
MECASERMIN RINFABATE	IPLEX	33621		

GUIDELINES FOR USE

1. Is this an initial prior authorization request?

   If yes, continue to #2.
   If no, continue to #10.

2. Is the member less than 18 years old?

   If yes, continue to #3.
   If no, do not approve.

3. Is the prescriber a pediatric endocrinologist or a pediatric nephrologist?

   If yes, continue to #4.
   If no, do not approve and respond with the following: "Guidelines require initiation of therapy and monitoring by pediatric endocrinologists or nephrologists. If this request is a continuation of recommendations from a specialist, please contact Med**Impact** or provide documentation."

4. Does the member have one of the following diagnoses:

   a. Severe primary IGF-1 deficiency, **or**
   b. Growth hormone (GH) gene deletion (not growth hormone-deficient short stature) **AND** have neutralizing antibodies to GH?

   If yes, continue to #5.
   If no, do not approve.

5. Does the member meet **all** of the following criteria?

   a. Height standard deviation score ≤ -3.0, **and**
   b. Basal IGF-1 standard deviation score ≤ -3.0 , **and**
   c. Normal or elevated growth hormone (GH), [serum growth hormone level of ≥ 10ngm/mL to at least two stimuli (insulin, levodopa, arginine, clonidine, or glucagon)].

   If yes, continue to #6.
   If no, do not approve.

CONTINUED ON NEXT PAGE

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

MECASERMIN

GUIDELINES FOR USE (CONTINUED)

6. If male, is bone age less than 16 years old OR if female, is bone age less than 14 years old and is there evidence of non-closure of the epiphyseal plate?

   If yes, continue to #7.
   If no, do not approve.

7. Does the member have normal thyroid function (TSH in the range of 0.5 – 6 uU/ml)?

   If yes, continue to #8.
   If no, do not approve.

8. Is the member malnourished (BMI < 18, where BMI=Weight (kg)/Height^2(m))?

   If yes, do not approve.
   If no, continue to #9.

9. Does the member have active or suspected neoplasia (i.e., cancer)?

   If yes, do not approve.
   If no, continue to #11.

10. Has the patient shown a response in the first 6 months of IGF-1 therapy (i.e. increase in height, increase in height velocity)?

    If yes, continue to #11.
    If no, do not approve.

11. **INDUCTION THERAPY: APPROVE FOR 6 MONTHS**. **LIMIT TO 8MG PER 1 DAY SUPPLY. RENEWAL: APPROVE FOR 12 MONTHS.**

RATIONALE
Ensure appropriate use of mecasermin with respect to evidence based guidelines.

FDA APPROVED INDICATIONS
Long-term treatment of growth failure in children with severe primary IGF-1 deficiency (Primary IGFD) or with growth hormone (GH) gene deletion who have developed neutralizing antibodies to GH.

REFERENCES

- Tercica Incorporated. Increlex package insert. Brisbane, CA. August 2007.
- Insmed Incorporated. Iplex package insert. Glen Allen, VA. December 2005.

Created: 02/06 Revised 5.1.09
Effective: 05/15/09 Client Approval: 04/15/09

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

MONTELUKAST

Generic	Brand	HICL	GCN	Exception/Other
MONTELUKAST	SINGULAIR	16911		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of asthma?

   If yes, continue to #2.
   If no, continue to #3.

2. Has the patient tried or have contraindications to oral inhaled corticosteroids (e.g. Flovent, QVAR, Pulmicort, Asmanex, Azmacort) and beta agonist (e.g., albuterol, Serevent, Foradil) inhalers?

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: Approval requires a trial or contraindication to an oral inhaled corticosteroid (e.g. Flovent, QVAR, Pulmicort, Asmanex, Azmacort) and a beta agonist inhaler (e.g. albuterol, Serevent, Foradil).

3. Does the patient have a diagnosis of allergic rhinitis (hay fever) or asthma aggravated by allergic rhinitis?

   If yes, continue to #4.
   If no, continue to #6.

4. Is the patient less than 2 years of age?

   If yes, continue to #7.
   If no, continue to #5.

5. Has the patient tried or have contraindications to nasal corticosteroid inhalers (e.g. Nasonex, Rhinocort, Nasacort, Flonase) and non-sedating antihistamines (e.g. Allegra, Zyrtec, Claritin)?

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: Approval requires a trial or contraindication to a non sedating antihistamine (e.g. OTC loratadine) and a nasal corticosteroid inhaler (e.g. Nasonex, Rhinocort, Nasacort, Flonase).

6. Is the patient at least 15 years of age and have exercise-induced bronchoconstriction?

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of asthma, allergic rhinitis, or exercise-induced bronchoconstriction.

7. **APPROVE FOR 12 MONTHS WITH A QUANTITY LIMIT OF #30 PER MONTH SUPPLY BY HICL.**

CONTINUED ON NEXT PAGE

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

MONTELUKAST

RATIONALE
To promote OTC loratadine (Claritin, Alavert) as a lower cost alternative therapy for allergic rhinitis.

FDA APPROVED INDICATIONS
Indicated for the relief of symptoms of seasonal allergic rhinitis in adults and pediatric patients 2 years of age and older and perennial allergic rhinitis in adults and children 6 months of age and older, prevention of exercise-induced bronchoconstriction in patients 15 years of age and older.

Indicated for the prophylaxis and chronic treatment of asthma in adults and pediatric patients 12 months of age and older.

REFERENCES

- Merck and Company, Inc. Singulair package insert. Whitehouse Station, NJ. July 2008.

Created: 06/11
Effective: 07/01/11 Client Approval: 06/13/11

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

OMALIZUMAB

Generic	Brand	HICL	GCN	Exception/Other
OMALIZUMAB	XOLAIR	25399		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is a physician specializing in Allergy or Pulmonary Medicine currently prescribing or supervising treatment?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: Approval requires that therapy should be prescribed by a qualified specialist.

2. Is the patient 12 years of age or older?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: Approval requires that the patient is 12 years of age and older.

3. Does the patient currently smoke cigarettes?

   If yes, do not approve.
   DENIAL TEXT: Approval requires that the patient is not a current smoker. Xolair has not been studied in patients who smoke cigarettes.
   If no, continue to #4.

4. Does the patient have at least 1 of the following criteria to meet the diagnosis of moderate to severe persistent asthma?
   a. Daily asthma symptoms,
   b. Daily use of inhaled short-acting $beta_2$ agonist (e.g., albuterol),
   c. Exacerbations ≥ 2 times a week,
   d. Nighttime symptoms > 1 time a week,
   e. FEV_1 or PEF < 80% predicted,
   f. PEF variability > 30%.

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: Approval requires that the patient meet the diagnosis of moderate to severe persistent asthma.

5. Does the patient have a positive skin prick or RAST test to a perennial aeroallergen?

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: Approval requires that the patient has a positive skin prick or RAST test to a perennial aeroallergen.

CONTINUED ON NEXT PAGE

OMALIZUMAB

INITIAL CRITERIA (CONTINUED)

6. Does the patient have a measured FEV_1 of < 80%?

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: Approval requires that the patient has a measured FEV1 of < 80%.

7. Has the patient demonstrated therapeutic failure to an inhaled or oral corticosteroid product combined with a second asthma controller agent such as long-acting inhaled $beta_2$ agonist (Serevent, Foradil, or Advair), leukotriene modifier (Singulair or Accolate), or theophylline?

   If yes, continue to #8.
   If no, do not approve.
   DENIAL TEXT: Approval requires that the patient's symptoms are inadequately controlled by an inhaled or oral corticosteroid product combined with a second asthma controller agent.

8. Does the patient have a history of intubation secondary to an asthma exacerbation?

   If yes, continue to #10.
   If no, continue to #9.

9. In the past year, has the patient had an emergency room visit or required hospitalization directly related to and/or for an asthma exacerbation, or required one or more pulses of oral corticosteroid use for the treatment of an asthma exacerbation?

   If yes, continue to #10.
   If no, do not approve.
   DENIAL TEXT: Approval for Xolair requires that the patient's asthma is inadequately controlled and has experienced an asthma exacerbation in the past year.

10. Is the patient's baseline IgE serum level ≥ 30IU/ml?

    If yes, continue to #11.
    If no, do not approve.
    DENIAL TEXT: Approval requires that the patient's baseline IgE serum level be ≥ 30IU/ml.

11. **APPROVE FOR 12 MONTHS WITH A QUANTITY LIMIT OF 30 ML (#6 VIALS) PER 30 DAYS OR COPAY.**

CONTINUED ON NEXT PAGE

OMALIZUMAB

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. In the previous year, has the patient experienced at least a 25% reduction in asthma exacerbations (e.g., hospitalizations, urgent or emergent care visits, use of rescue medications, etc.) from their pre-Xolair baseline?

   If yes, continue to #5.
   If no, continue to #2.

2. Was the patient receiving maintenance therapy with an oral corticosteroid prior to initiation of Xolair?

   If yes, continue to #3.
   If no, continue to #4.

3. Has the patient been able to reduce their oral corticosteroid dose by 75% from their pre-Xolair baseline or to ≤ 5mg daily?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: Renewal requires that patient has had clinical improvement from baseline as measured by reduced oral corticosteroid use.

4. Has the patient been able to reduce their inhaled corticosteroid dose by at least 25% from their pre-Xolair dose?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: Renewal requires that patient has had clinical improvement from baseline as measured by reduced inhaled corticosteroid use.

5. **APPROVE FOR 12 MONTHS WITH A QUANTITY LIMIT OF 30 ML (6 VIALS) PER 30 DAYS OR COPAY.**

CONTINUED ON NEXT PAGE

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

OMALIZUMAB

RATIONALE
Ensure appropriate diagnostic and utilization criteria.

FDA APPROVED INDICATIONS
Adults and adolescents (12 years of age and above) with moderate to severe persistent asthma who have a positive skin test or *in vitro* reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids.

REFERENCES

- Busse W, Corren J, Lanier BQ, McAlary MA, Fowler-Tayler A, et al. Omalizumab, anti-IgE recombinant humanized monoclonal antibody, for the treatment of severe allergic asthma. J Allergy Clin Immunol 2001;108:184-90.
- Global Initiative for Asthma: Global Strategy for Asthma Management and Prevention. Bethesda, MD: National Institutes of Health;2002:Publication No. 02-3659.
- Holgate S, Bousquet J, Wenzel S, Fox H, Liu J, et al. Efficacy of omalizumab, an anti-immunoglobulin E antibody in patients with allergic asthma at high risk of serious asthma-related morbidity and mortality. Curr Med Res Opin 2001;17(4):233-240.
- NAEPP Expert Panel Report: Guidelines for the diagnosis and management of asthma-update on selected topics 2002. Bethesda, MD: National Institutes of Health;2002:Publication No. 02-5075.
- Soler M, Matz J, Townley R, Buhl R, O'Brien J, et al. The anti-IgE antibody omalizumab reduces exacerbations and steroid requirement in allergic asthmatics. Eur Respir J 2001;18(2):254-61.
- Genentech, INC. Xolair package insert. South San Francisco, CA. July 2007.
- National Heart, Lung, and Blood Institute National Asthma Education and Prevent Program. Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma. Full Report 2007. August 28, 2007.

Created: 08/03
Effective: 10/15/09 Client Approval: 10/01/09

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

OPIOID DEPENDENCY AGENTS

Generic	Brand	HICL	GCN	Exception/Other
BUPRENORPHINE	SUBUTEX	01762		ROUTE = SUBLINGUAL
BUPRENORPHINE / NALOXONE	SUBOXONE	24846		ROUTE = SUBLINGUAL

GUIDELINES FOR USE

1. Does the patient have a diagnosis of opioid addiction/dependence?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of opioid addiction/dependence; the prescriber must be a buprenorphine certified prescriber in accordance with the Drug Addiction Treatment Act; the medication must be used in conjunction with psychosocial counseling; and that the patient is not currently taking opioid analgesics.

2. Is the prescribing physician certified to prescribe buprenorphine for opioid dependence as noted by special DEA wavier and prefix code (X DEA number), in accordance with the Drug Addiction Treatment Act?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of opioid addiction/dependence; the prescriber must be a buprenorphine certified prescriber in accordance with the Drug Addiction Treatment Act; the medication must be used in conjunction with psychosocial counseling; and that the patient is not currently taking opioid analgesics.

3. Will the patient undergo psychosocial counseling?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of opioid addiction/dependence; the prescriber must be a buprenorphine certified prescriber in accordance with the Drug Addiction Treatment Act; the medication must be used in conjunction with psychosocial counseling; and that the patient is not currently taking opioid analgesics.

4. Is the patient currently taking opioid analgesics?

   If yes, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of opioid addiction/dependence; the prescriber must be a buprenorphine certified prescriber in accordance with the Drug Addiction Treatment Act; the medication must be used in conjunction with psychosocial counseling; and that the patient is not currently taking opioid analgesics.

   If no, continue to #5.

CONTINUED ON NEXT PAGE

OPIOID DEPENDENCY AGENTS

GUIDELINES FOR USE (CONTINUED)

5. Is the request for Suboxone?

   If yes, **APPROVE FOR 6 MONTHS BY GPID WITH THE FOLLOWING QUANTITY LIMITS:**
   2mg/0.5mg SL film (GPID = 28958) **#90 films per 30 days.**
   2mg/0.5mg SL tablet (GPID = 18973) **#90 tablets per 30 days.**
   4mg/1mg SL film (GPID = 33741) **#90 films per 30 days.**
   8mg/2mg SL film (GPID = 28959) **#90 films per 30 days.**
   8mg/2mg SL tablet (GPID = 18974) **#90 tablets per 30 days.**
   12mg/3mg SL film (GPID = 33744) **#60 films per 30 days.**
   NOTE: Recommended target dose is 16mg/day but therapeutic dose may range from 4mg/day - 24mg/day.

   If no, continue to #6.

6. Is the request for induction therapy with Subutex?

   If yes, **APPROVE MAXIMUM ONE WEEK SUPPLY BY GPID WITH THE FOLLOWING QUANTITY LIMITS:**
   2mg SL tablets (GPID = 64672) **#21 tablets for 7 days.**
   8mg SL tablets (GPID = 64673) **#21 tablets for 7 days.**
   NOTE: Recommended induction dosing regimen - Day 1: 8mg; Day 2 and after: 16mg until maintenance dose achieved.

   If no, continue to #7.

7. Does the patient have a contraindication to or is the patient unable to tolerate naloxone in combination with buprenorphine?

   If yes, **APPROVE FOR 6 MONTHS BY GPID WITH THE FOLLOWING QUANTITY LIMITS:**
   2mg SL tablets (GPID = 64672) **#90 tablets for 30 days.**
   8mg SL tablets (GPID = 64673) **#90 tablets for 30 days.**
   NOTE: Recommended target dose is 16mg/day but therapeutic dose may range from 4mg/day-24mg/day.

   If no, do not approve
   DENIAL TEXT: Approval requires a contraindication or intolerance to naloxone.

CONTINUED ON NEXT PAGE

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

OPIOID DEPENDENCY AGENTS

RATIONALE
Avoid use for unapproved indications. Ensure counseling is part of a comprehensive addiction treatment program. Avoid use of Subutex for maintenance therapy unless indicated. Provide appropriate quantity limits for induction and maintenance therapy. Encourage dose consolidation since buprenorphine has a high risk potential for abuse.

FDA APPROVED INDICATIONS
Treatment of opioid dependence - induction and maintenance.

Please note: The physician must obtain a unique ID# from the DEA prior to prescribing Suboxone and Subutex.

Buprenorphine maintenance doses can range from 4mg -24mg/day as recommended by the manufacturer. US Health and Human Services references a potential max dose of 32mg/day but manufacturer noted no scientific evidence to support doses higher than 24mg.

REFERENCES

- Reckitt Benckiser Pharmaceuticals, Inc. Suboxone product information. Richmond, VA. August 2012.
- Reckitt Benckiser Pharmaceuticals, Inc. Subutex product information. Richmond, VA. December 2011.
- Substance Abuse and Mental Health Services Administration. http://buprenorphine.samhsa.gov/. [Accessed on October 10, 2012].

Created: 02/21/13
Effective: 03/25/13 Client Approval: 02/14/13

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

OPRELVEKIN

Generic	Brand	HICL	GCN	Exception/Other
OPRELVEKIN	NEUMEGA	16916		

GUIDELINES FOR USE

1. Is the prescribing physician an oncologist?

   If yes, continue to #2.
   If no, do not approve.

2. Is the patient receiving myeloablative chemotherapy for bone marrow transplantation?

   If yes, do not approve.
   If no, continue to #3.

3. Is the patient receiving myelosuppressive chemotherapy? (e.g. cyclophosphamide, vinblastine, carboplatin, doxorubicin, etc.)

   If yes, continue to #4.
   If no, do not approve.

4. **APPROVE AS REQUESTED (10-21 DOSES) PER CYCLE OF CHEMOTHERAPY, UP TO 6 CYCLES.**

RATIONALE

Ensure appropriate use of Neumega for chemotherapy induced thrombocytopenia.

FDA APPROVED INDICATIONS

Neumega is indicated for the prevention of severe thrombocytopenia and the reduction of the need for platelet transfusions following myelosuppressive chemotherapy in adult patients with nonmyeloid malignancies who are at high risk of severe thrombocytopenia. Neumega is not indicated following myeloablative chemotherapy. The safety and effectiveness of Neumega have not been established in pediatric patients.

REFERENCES

Wyeth Pharmaceuticals, Inc. Neumega Product Insert. Philadelphia, PA. September 2006.

Created: 09/05
Effective: 10/15/09 Client Approval: 10/01/09

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

ORLISTAT

Generic	Brand	HICL	GCN	Exception/Other
ORLISTAT	XENICAL	18751		GCN ≠ 98573

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a body mass index (BMI) greater than or equal to 30 kg/m^2, or 27 kg/m^2 in the presence of other risk factors (e.g., diabetes, dyslipidemia, controlled hypertension, heart disease)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: Approval requires a body mass index (BMI) greater than or equal to 30 kg/m^2, or 27 kg/m^2 in the presence of other risk factors such as diabetes, dyslipidemia, controlled hypertension, or heart disease.

2. **APPROVE FOR ONE YEAR WITH A QUANTITY LIMIT OF 90 PER 30 DAYS.**

RENEWAL CRITERIA

1. Has the patient maintained their initial weight loss or continued to lose weight with Xenical?

   If yes, **APPROVE FOR ONE YEAR WITH A QUANTITY LIMIT OF 90 PER 30 DAYS.**
   If no, do not approve.
   DENIAL TEXT: Approval for continued use of orlistat requires weight reduction to occur while taking orlistat.

RATIONALE
Ensure appropriate use of Xenical.

FDA APPROVED INDICATION
For obesity management, including weight loss and weight maintenance, when used in conjunction with a reduced-calorie diet; to reduce the risk for weight regain after prior weight loss.

Orlistat is indicated for obese patients with an initial body mass index (BMI) of 30 kg/m^2 or more or 27 kg/m^2 or more in the presence of other risk factors (e.g., hypertension, diabetes, dyslipidemia).

REFERENCES

- Xenical Package Insert. Genentech. http://www.gene.com/gene/products/information/xenical/pdf/pi.pdf. Accessed online 3.9.2012.

Created: 03/09/12
Effective: 03/20/12 Client Approval: 03/09/12

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

PDE5 INHIBITORS FOR PULMONARY ARTERIAL HYPERTENSION

Generic	Brand	HICL	GCN	Exception/Other
SILDENAFIL	REVATIO		24758, 28273	
TADALAFIL	ADCIRCA		26587	

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Is the prescribing physician a cardiologist or pulmonologist?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: Approval requires supervision by a cardiologist or a pulmonologist.

2. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH)?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of pulmonary arterial hypertension.

3. **FOR REVATIO: APPROVE FOR 12 MONTHS WITH A QUANTITY LIMIT OF UP TO 3 TABLETS OR 37.5ML (3 VIALS) PER DAY.**
   FOR ADCIRCA: APPROVE FOR 12 MONTHS WITH A QUANTITY LIMIT OF UP TO 2 TABLETS PER DAY.

RATIONALE
Ensure appropriate utilization of PDE5 inhibitors, Revatio and Adcirca. FDA indicated dosage for Revatio tablets in the treatment of PAH is 20mg three times daily. For Revatio injection, the dosage is 10mg (12.5mL) three times daily administered as an IV bolus injection. The 10mg dose of Revatio injection is predicted to provide an equivalent pharmacological effect of 20mg Revatio tablet. For Adcirca, the dosage is 40mg once daily.

FDA APPROVED INDICATIONS
Revatio and Adcirca are indicated for treatment of pulmonary artery hypertension (WHO Group 1) to improve exercise capacity and delay clinical worsening.

World Health Organization Classification of Pulmonary Hypertension Group 1:
- Idiopathic (familial)
- Congenital systemic-to-pulmonary shunts
- HIV infection
- Collagen vascular disease
- Portal Hypertension
- Drugs and toxins

REFERENCES

- Pfizer, Inc. Revatio® (Sildenafil) package insert. New York, NY. November 2009.
- Eli Lilly and Company. Adcirca™ (Tadalafil) package insert. Indianapolis, IN. May 2009.

Created: 01/08
Effective: 01/23/13 Client Approval: 11/29/12

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

PHENTERMINE/TOPIRAMATE ER

Generic	Brand	HICL	GCN	Exception/Other
PHENTERMINE/TOPIRAMATE	QSYMIA	39347		

GUIDELINES FOR USE

1. Is this an initial request for Qsymia (per MRF and claims history)?

   If yes, continue to #2.
   If no, continue to #4.

2. Does the patient have a body mass index (BMI) of 30kg/m^2 or higher?

   If yes, **APPROVE. ENTER TWO AUTHORIZATIONS BY GPID AS FOLLOWS:**
   - **Qsymia 3.75/23mg: #1 capsule per day for 2 weeks.**
   - **Qsymia 7.5/46mg: #1 capsule per day for 12 weeks with a start date one day after the end date of the first authorization.**

   If no, continue to #3.

3. Does the patient have a BMI of 27kg/m^2 or greater **AND** at least one weight-related co-morbidity (e.g. hypertension, type 2 diabetes mellitus, hyperlipidemia)?

   If yes, **APPROVE. ENTER TWO AUTHORIZATIONS BY GPID AS FOLLOWS:**
   - **Qsymia 3.75/23mg: #1 capsule per day for 2 weeks.**
   - **Qsymia 7.5/46mg: #1 capsule per day for 12 weeks with a start date one day after the end date of the first authorization.**

   If no, do not approve.
   DENIAL TEXT: Approval requires a body mass index (BMI) of either; 1) 30kg/m^2 or higher, or 2) a BMI of 27kg/m^2 or greater AND at least one weight-related co-morbidity.

4. Is this request for continuation of therapy with Qsymia 7.5/46mg?

   If yes, continue to #5.
   If no, continue to #6.

5. Has the patient lost at least 3% of baseline body weight on Qsymia 7.5/46mg after at least 12 weeks of treatment?

   If yes, **APPROVE QSYMIA 7.5/46MG BY GPID FOR #1 CAPSULE PER DAY FOR 12 MONTHS.**
   If no, do not approve.
   DENIAL TEXT: The Qsymia 7.5/46mg dose should be escalated or discontinued if patient has not lost at least 3% of baseline body weight after 12 weeks of treatment. Approval for Qsymia 7.5/46mg requires weight loss of at least 3% of baseline body weight after 12 weeks of treatment.

CONTINUED ON NEXT PAGE

PHENTERMINE/TOPIRAMATE ER

GUIDELINES FOR USE (CONTINUED)

6. Is this request for dose escalation to Qsymia 11.25/69mg for 2 weeks then Qsymia 15/92mg?

   If yes, **APPROVE. ENTER TWO AUTHORIZATIONS BY GPID AS FOLLOWS:**
   - **Qsymia 11.25/69mg: #1 capsule per day for 2 weeks.**
   - **Qsymia 15/92mg: #1 capsule per day for 12 weeks with a start date one day after the end date of the first authorization.**

   If no, continue to #7.

7. Is this request for continuation of therapy after at least 12 weeks of Qsymia 15/92mg?

   If yes, continue to #8.
   If no, continue to #9.

8. Has the patient lost at least 5% of baseline body weight on Qsymia 15/92mg after 12 or more weeks of treatment?

   If yes, **APPROVE QSYMIA 15/92MG BY GPID FOR #1 CAPSULE PER DAY FOR 12 MONTHS.**
   If no, **PARTIAL APPROVE BY HICL FOR ONE FILL OF UP TO #4 CAPSULES TOTAL TO TAPER DOSE IN ORDER TO DISCONTINUE THERAPY.**
   PARTIAL APPROVAL TEXT: Qsymia dose should be discontinued if patient has not lost at least 5% of baseline body weight after 12 weeks of treatment. Approval requires weight loss of at least 5% of baseline body weight after 12 weeks of treatment. A partial fill has been approved to allow dose tapering as recommended by the manufacturer.
   NOTE: The package insert recommends that Qsymia is discontinued if patient has not lost at least 5% of baseline body weight on Qsymia 15/92mg after 12 weeks.

9. Is this request for continuation of Qsymia 11.25/69mg?

   If yes, continue to #10.
   If no, do not approve.
   DENIAL TEXT: Approval requires weight loss of at least 3% after 12 weeks of Qsymia 7.5/46mg or weight loss of at least 5% after 12 weeks of Qsymia 15/92mg.

10. Has the patient lost at least 5% of baseline body weight on Qsymia 11.25/69mg after 12 or more weeks of treatment?

    If yes, **APPROVE QSYMIA 11.25/69MG BY GPID FOR #1 CAPSULE PER DAY FOR 12 MONTHS.**
    If no, **PARTIAL APPROVE BY HICL FOR ONE FILL OF UP TO #4 CAPSULES TOTAL TO TAPER DOSE IN ORDER TO DISCONTINUE THERAPY.**
    PARTIAL APPROVAL TEXT: Approval requires weight loss of at least 5% of baseline body weight after 12 weeks of treatment. A partial fill has been approved to allow dose tapering as recommended by the manufacturer.

CONTINUED ON NEXT PAGE

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

PHENTERMINE/TOPIRAMATE ER

RATIONALE
Limit use to FDA approved indications and based on efficacy (weight loss) at time points in therapy per manufacturer's recommendations in the prescribing insert.

FDA APPROVED INDICATIONS
As an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of 30kg/m^2 or above (obese), or those with a BMI of 27kg/m^2 (overweight) or above with at least one weight-related co-morbidity (e.g. hypertension, type 2 diabetes mellitus, or dyslipidemia).

- Maximum dose is Qsymia 15/92mg once daily. The maximum dose for patients with moderate to severe renal impairment or moderate hepatic impairment is Qsymia 7.5/46mg once daily.

- The manufacturer recommends discontinuation of therapy or dose escalation if 3% of baseline body weight is not lost after 12 weeks of therapy with Qsymia 7.5/46mg once daily and discontinuation of therapy if 5% of baseline body weight is not lost after 12 weeks of therapy with Qsymia 15/92mg once daily.

QSYMIA REMS PROGRAM
Qsymia is pregnancy category X. Females taking Qsymia should utilize effective contraception during Qsymia treatment. A negative pregnancy test should be obtained prior to initiation of Qsymia therapy and each month thereafter. Administration of topiramate, a component of Qsymia, during the first trimester of pregnancy has been associated with an increased risk of oral cleft lip and cleft palate. If a patient becomes pregnant during Qsymia therapy, treatment should be immediately discontinued. Because of the fetal risk associated with Qsymia use during pregnancy, a Qsymia risk evaluation and mitigation strategy (REMS) program is available, and Qsymia can be obtained through certified pharmacies only.

REFERENCES

- Qsymia [Prescribing Information]. Mountain View, CA: Vivus, Inc.; July 2012.

Created: 11/12
Effective: 03/25/13 Client Approval: 02/14/13

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

PROTON PUMP INHIBITORS

Generic	Brand	HICL	GCN	Exception/Other
ESOMEPRAZOLE MAG TRIHYDRATE	NEXIUM	21607		
DEXLANSOPRAZOLE	DEXILANT		16305 16306	
LANSOPRAZOLE	PREVACID	08993		
OMEPRAZOLE	PRILOSEC	11115 04673		
PANTOPRAZOLE SODIUM	PROTONIX	11590		
RABEPRAZOLE SODIUM	ACIPHEX	18847		
OMEPRAZOLE/SODIUM BICARBONATE	ZEGERID	33512		

GUIDELINES FOR USE

1. Has the member been diagnosed with one of the following diagnoses:

    a. Zollinger-Ellison syndrome
    b. Esophagitis with underlying Barrett's
    c. Barrett's Esophagus
    d. Erosive and/or Ulcerated Esophagitis (Grades III and IV Esophagitis)
    e. Esophageal Stricture
    f. History of or current diagnosis of gastric or stomach cancer
    g. Current diagnosis of cancer
    h. Patient is post-bariatric surgery within the last 4 months **OR**
    i. Patient is less than 18 years of age

    If yes, continue to #2.
    If no, do not approve.
    DENIAL TEXT: Approval requires a diagnosis of either Zollinger-Ellison syndrome, esophagitis with underlying Barrett's, Barrett's Esophagus, erosive and/or ulcerated esophagitis (Grades III and IV Esophagitis), esophageal stricture, history of or current diagnosis of gastric or stomach cancer, current diagnosis of cancer, post-bariatric surgery within the last 4 months, or patient is less than 18 years of age. Please note that the first line agent is omeprazole. The second line agents include pantoprazole or lansoprazole.

2. Is the request for Prevacid SoluTabs for a patient 2 years old or less?

    If yes, **APPROVE FOR 1 YEAR FOR ONCE DAILY DOSING.**
    If no, continue to #3.

CONTINUED ON NEXT PAGE

PROTON PUMP INHIBITORS

GUIDELINES FOR USE (CONTINUED)

3. Is the request for Prevacid SoluTabs and has the provider documented on the request that the patient cannot swallow pills/capsules?

   If yes, **APPROVE FOR 1 YEAR FOR ONCE DAILY DOSING.**
   If no, continue to #4.

4. Is the request for omeprazole?

   If yes, continue to #9.
   If no, continue to #5.

5. Has the patient been on the requested agent prior to this request?

   If yes, continue to #7.
   If no, continue to #6.

6. Has the patient had a 12 week trial of omeprazole?

   If yes, continue to #7.
   If no, do not approve.
   (ENTER PROACTIVE AUTHORIZATION FOR OMEPRAZOLE BY HICL 1 PER DAY FOR 1 YEAR.)
   DENIAL TEXT: Approval requires a 12 week trial of omeprazole.

7. Is the request for pantoprazole or Prevacid?

   If yes, continue to #9.
   If no, continue to #8.

8. Has the patient had a trial of pantoprazole or Prevacid?

   If yes, continue to #9.
   If no, do not approve.
   DENIAL TEXT: Approval requires a trial of pantoprazole or Prevacid which also requires a prior authorization.

9. Is the diagnosis Zollinger-Ellison syndrome?

   If yes, **APPROVE FOR 1 YEAR UP TO TWICE DAILY DOSING.**
   If no, **APPROVE FOR 1 YEAR FOR ONCE DAILY DOSING.**
   TEXT: Approval criteria requires once daily dosing for all approved indications except for Zollinger-Ellison syndrome which allows twice daily dosing which is consistent with FDA approved labeling.

CONTINUED ON NEXT PAGE

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

PROTON PUMP INHIBITORS

RATIONALE
To ensure appropriate and cost effective utilization.

FDA APPROVED INDICATIONS
- DUODENAL ULCER: For short-term treatment of active duodenal ulcer.
- DUODENAL ULCER ASSOCIATED WITH H. PYLORI: In combination with antibiotics to eradicate *H. pylori*.
- GASTRIC ULCER: For short-term treatment (4 to 8 weeks) of active benign gastric ulcer; for prophylaxis therapy for NSAID-induced ulcer.
- EROSIVE ESOPHAGITIS: For short-term treatment (4 to 8 weeks) of erosive esophagitis diagnosed by endoscopy; to maintain healing of erosive esophagitis.
- GASTROESOPHAGEAL REFLUX DISEASE (GERD): For the treatment of heartburn and other symptoms associated with GERD.
- HYPERSECRETORY CONDITIONS: For long-term treatment of hypersecretory conditions (e.g., Zollinger-Ellison syndrome).

REFERENCES

- American Society for Gastrointestinal Endoscopy. The Role of Endoscopy in the Management of GERD. Gastrointest Endosc 1999 June;49(6):834-5.
- Katz PO. Gastroesophageal Reflux Disease. J Am Geriat Soc 1998 Dec;46(12):1558-65.
- Richter JE. Long-Term Management of Gastroesophageal Reflux Disease and its Complications. Am J Gastroenterol 1997 Apr;92 (4 Suppl):30S-34S.
- Richardson P, Hawkey CJ, Stack WA. Proton Pump Inhibitors. Pharmacology and Rationale for Use in Gastrointestinal Disorders. Drugs 1998 Sep;56 (3):307-35.
- Schwartz H, et al. Triple Versus Dual Therapy for Eradicating Helicobacter pylori and Preventing Ulcer Recurrence: A Randomized Double-blind Multicenter Study of Lansoprazole, Clarithromycin, and/or Amoxicillin in Different Dosing Regiments. Am J Gastroenterol 1998;93(4):584-590.
- Wolters Kluwer Company. Gastrointestinal Agents. Facts and Comparisons. 2001 January.
- American Society for Gastrointestinal Endoscopy. The Role of Endoscopy in the Management of GERD. Gastrointest Endosc 1999 June;49(6):834-5.
- Katz PO. Gastroesophageal Reflux Disease. J Am Geriat Soc 1998 Dec;46(12):1558-65.
- Richter JE. Long-Term Management of Gastroesophageal Reflux Disease and its Complications. Am J Gastroenterol 1997 Apr;92 (4 Suppl):30S-34S.
- Richardson P, Hawkey CJ, Stack WA. Proton Pump Inhibitors. Pharmacology and Rationale for Use in Gastrointestinal Disorders. Drugs 1998 Sep;56 (3):307-35.
- Schwartz H, et al. Triple Versus Dual Therapy for Eradicating Helicobacter pylori and Preventing Ulcer Recurrence: A Randomized Double-blind Multicenter Study of Lansoprazole, Clarithromycin, and/or Amoxicillin in Different Dosing Regiments. Am J Gastroenterol 1998;93(4):584-590.
- Wolters Kluwer Company. Gastrointestinal Agents. Facts and Comparisons. 2001.
- Fendrick AM, Garabedian-Ruffalo, SM. A clinician's guide to the selection of NSAID therapy. P&T 2002;27(11):579-82.
- Micromedex Healthcare Series, Drugdex Evaluations: Nexium, Prevacid, Prilosec, Protonix, Aciphex.

Created: 11/08
Effective: 06/01/10 Client Approval: 05/03/10

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

ROFLUMILAST

Generic	Brand	HICL	GCN	Exception/Other
ROFLUMILAST	DALIRESP	37123		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of severe chronic obstructive pulmonary disease (COPD)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of severe chronic obstructive pulmonary disease (COPD) and a trial of Spiriva and a long acting beta agonist (LABA) or LABA inhaled corticosteroid combination such as Dulera, Foradil, Perforomist, or Serevent.

2. Has the patient previously tried, or does the patient have a contraindication to Spiriva and a long acting beta agonist (LABA) or LABA inhaled corticosteroid combination such as Dulera, Advair Diskus, Advair HFA, Brovana, Foradil, Perforomist, Serevent, or Symbicort?

   If yes, **APPROVE FOR 1 YEAR WITH A QUANTITY LIMIT OF #1 PER DAY.**
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of severe chronic obstructive pulmonary disease (COPD), and a trial of Spiriva and a long acting beta agonist (LABA) or LABA inhaled corticosteroid combination such as Dulera, Foradil, Perforomist, or Serevent.

RATIONALE
Ensure appropriate utilization of roflumilast based on FDA approved indication and COPD clinical practice guidelines.

FDA APPROVED INDICATIONS
Roflumilast is indicated as a treatment to reduce the risk of COPD exacerbations in patients with severe COPD associated with chronic bronchitis and a history of exacerbations.

REFERENCES

- Forest Pharmaceuticals, Inc. Daliresp package insert. St Louis, MO. February 2011.
- Global Initiative for Chronic Obstructive Lung Disease. Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease (Updated 2010). Available at: http://www.goldcopd.com/GuidelinesResources.asp?l1=2&l2=0 [Accessed March 4, 2011].
- National Clinical Guideline Centre. (2010) Chronic obstructive pulmonary disease: management of chronic obstructive pulmonary disease in adults in primary and secondary care. London: National Clinical Guideline Centre. Available at: http://guidance.nice.org.uk/CG101/Guidance/pdf/English [Accessed March 4, 2011].

Created: 05/11
Effective: 12/14/11 Client Approval: 08/05/11 P&T Approval: 05/11

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

ROMIDEPSIN

Generic	Brand	HICL	GCN	Exception/Other
ROMIDEPSIN	ISTODAX		28397	

GUIDELINES FOR USE

1. Does the patient have cutaneous T-cell lymphoma (CTCL)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: Approval requires diagnosis of cutaneous T-cell lymphoma.

2. Has the patient received at least one prior systemic therapy (see table below) **and** Zolinza?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: Approval requires prior treatment with at least one systemic therapy and Zolinza.

3. **APPROVE 3 VIALS EVERY 28 DAYS FOR 12 MONTHS.**

RATIONALE
Ensure appropriate utilization criteria are met for the management of requests for romidepsin.

FDA APPROVED INDICATION
For the treatment of cutaneous T-cell lymphoma in patients who have received at least one prior systemic therapy.

SYSTEMIC TREATMENT OPTIONS	
Retinoids (bexarotene, retinoic acid, isotretinoin, acitretin)	Chlorambucil (Leukeran)
Interferons (Intron A)	Pentostatin
Extracorporeal photopheresis	Etoposide (VePesid)
Denileukin diftitox (Ontak)	Cyclophosphamide (Cytoxan)
Methotrexate	Temozolomide (Temodar)
Liposomal doxorubicin (Doxil)	Bortezomib (Velcade)
Gemcitabine (Gemzar)	

REFERENCES

- Istodax package insert. Cambridge, MA. Gloucester Pharmaceuticals. November 2009.

Created: 05/10
Effective: 09/22/10 Client Approval: 05/03/10

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

ROMIPLOSTIM

Generic	Brand	HICL	GCN	Exception/Other
ROMIPLOSTIM	NPLATE	35798		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Has the drug been prescribed by or is currently being supervised by a prescriber enrolled in the NPlate Nexus program?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: This medication can only be prescribed by physicians enrolled in the NPlate Nexus program.

2. Is the patient being treated for chronic immune (idiopathic) thrombocytopenia purpura (ITP)?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: This medication is not covered for the diagnosis provided.

3. Has the patient tried and failed corticosteroids or immunoglobulins, or has had an insufficient response to a splenectomy?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: This medication is covered only after a trial of corticosteroids, immunoglobulin or if the patient has undergone a splenectomy.

4. **APPROVE UP TO #8 (250MCG OR 500MCG SINGLE-USE WEEKLY) VIALS PER MONTH X 2 MONTHS.**

RENEWAL CRITERIA

1. Is the patient being treated for chronic immune (idiopathic) thrombocytopenia purpura (ITP)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: This medication is not covered for the diagnosis provided.

2. Did the patient have a clinical response, as defined by an increase in platelet count to ≥ 50 X 10^9/L (≥ 50,000 per μl)?

   If yes, continue to #4.
   If no, continue to #3.

CONTINUED ON NEXT PAGE

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

ROMIPLOSTIM

RENEWAL CRITERIA (CONTINUED)

3. Did the patient receive the maximum dose of 10mcg/kg weekly for 4 consecutive weeks?

   If yes, do not approve.
   DENIAL TEXT: This medication is only covered in patients who have had a clinical response after 4 weeks at maximum dosing.
   If no, continue to #5. Recommend titrating dose up. Maximum dose is 10mcg/kg weekly.

4. **APPROVE UP TO #8 (250MCG OR 500MCG SINGLE-USE WEEKLY) VIALS PER MONTH X 12 MONTHS.**

5. **APPROVE UP TO #8 (250MCG OR 500MCG SINGLE-USE WEEKLY) VIALS PER MONTH X 1 MONTH.**

RATIONALE
To ensure safe and appropriate utilization of NPlate.

FDA APPROVED INDICATIONS
NPlate is indicated for the treatment of thrombocytopenia in patients with chronic immune thrombocytopenic purpura (ITP) who have an insufficient response to corticosteroids, immunoglobulins, or splenectomy.

Note: NPlate is available only through a restricted distribution program called NPlate NEXUS (Network of Experts Understanding and Supporting NPlate and Patients) Program. Only prescribers and patients registered in the NEXUS program can receive, prescribe, or administer NPlate.

REFERENCES

- Amgen Inc. NPlate Product Information, Thousand Oaks, CA. Aug 2008.
- Thomson Healthcare. Romiplostim. DRUGDEX® System [database online]. Greenwood Village, CO. Available at: https://www.thomsonhc.com/hcs/librarian/PFDefaultActionId/pf.LoginAction. [Accessed: November 12th, 2008].

Created: 10/08
Effective: 05/15/09 Client Approval: 04/15/09

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

SAPROPTERIN

Generic	Brand	HICL	GCN	Exception/Other
SAPROPTERIN	KUVAN	35266		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the patient being treated by an endocrinologist?

   If yes, continue to #2.
   If no, do not approve.

2. Is the patient aged 4 years or older?

   If yes, continue to #3.
   If no, do not approve.

3. Has the patient failed to achieve adequate reduction of phenylalanine (Phe) levels with dietary modifications?

   If yes, continue to #4.
   If no, do not approve.

4. **APPROVE UP TO 10MG/KG/DAY FOR 4 WEEKS.**

   Determination of number of tablets required:
   (10mg/kg x 60 Kg (avg) = 600mg = 6 tablets (100mg each) per day times 28 days.

RENEWAL CRITERIA

1. Did the patient achieve at least 20% reduction in blood Phe with initial treatment?

   If yes, approve up to maximum of 20mg/kg/day for 6 months.
   If no, do not approve.

2. **APPROVE UP TO 20MG/KG/DAY FOR 28 DAYS TIMES 6 MONTHS.**

   Determination of number of tablets required:
   (20mg/kg x 60 Kg (avg) = 1200mg = 12 tablets (100mg each) per day times 28 days.

CONTINUED ON NEXT PAGE

SAPROPTERIN

RATIONALE
Ensure appropriate use of Kuvan.

FDA APPROVED INDICATIONS
Kuvan™ is indicated to reduce blood phenylalanine (Phe) levels in patients with hyperphenylalanine (HPA) due to tetrahydrobiopterin- (BH4-) responsive Phenylketonuria (PKU). Kuvan is to be used in conjunction with a Phe-restricted diet.

REFERENCES
BioMarin Pharmaceutical Inc. Kuvan™ Prescribing Information, Novato, CA. Dec. 2007

Created: 01/08
Effective: 10/15/09 Client Approval: 10/01/09

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

SARGRAMOSTIM

Generic	Brand	HICL	GCN	Exception/Other
SARGRAMOSTIM	LEUKINE	06074		

GUIDELINES FOR USE

1. Is the prescription written or currently being supervised by a hematologist or oncologist?

   If yes, continue to #4.
   If no, continue to #2.

2. Is the patient being treated for febrile neutropenia associated with the administration of cancer chemotherapy?

   If yes, continue to #4.
   If no, continue to #3.

3. Is the patient receiving cancer chemotherapy and being treated prophylactically due to a history of febrile neutropenia associated with prior cancer chemotherapy?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: The medication is not approved for the requested indication.

4. **APPROVE FOR 3 MONTHS OR COURSE OF TREATMENT BASED UPON CHEMOTHERAPY CYCLE.**

RATIONALE

Ensure appropriate diagnostic usage criteria for sargramostim.

FDA APPROVED INDICATIONS

Acute myelogenous leukemia following induction chemotherapy in older adult patients, bone marrow transplant engraftment delay or failure, mobilization of peripheral blood progenitor cells, myeloid reconstitution following bone marrow transplant, and neutropenia associated with either chemotherapy, acute myelogenous leukemia, PBPC transplant, or peripheral blood stem cell transplantation.

REFERENCES

Bayer Healthcare Pharmaceuticals, LLC. Leukine package insert. Seattle, WA. April 2008.

Created: 02/03
Effective: 10/15/09 Client Approval: 10/01/09

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

SIMVASTATIN 80MG

Generic	Brand	HICL	GCN	Exception/Other
EZETIMIBE/SIMVASTATIN	VYTORIN		23126	
SIMVASTATIN	ZOCOR		26535	

GUIDELINES FOR USE

1. Has the patient been taking the requested medication for at least 12 months?

   If yes, **APPROVE BY GPID FOR 1 YEAR WITH A QUANTITY LIMIT OF #1 PER DAY.**
   APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.
   If no, do not approve.
   DENIAL TEXT: The requested medication is restricted to patients who have been on this strength for at least 12 months. Please consider the use of the formulary alternatives Crestor or Lipitor.

RATIONALE

To ensure appropriate use of Vytorin 10/80 and Zocor 80mg by limiting their use to patients who have been stable on that strength for at least one year.

Approximate reduction in LDL is as follows:

- Crestor (rosuvastatin): 5mg 46%, 10mg 54%, 20mg 56%, 40mg 64%
- Lescol, Lescol XL (fluvastatin): 20mg 17%, 40mg 23%, 80mg 34%
- Lipitor (atorvastatin): 10mg 41%, 20mg 43%, 40mg 51%, 80mg 60%
- Livalo (pitavastatin): 1mg 31%, 2mg 39%, 4mg 44%
- Mevacor, Altoprev (lovastatin): 10mg 22%, 20mg 28%, 40mg 31%
- Pravachol (pravastatin): 10mg 23%, 20mg 29%, 40mg 31%
- Vytorin (ezetimibe/simvastatin): 10/10mg 45%,10/20mg 52%, 10/40mg 55%, 10/80mg 60%
- Zocor (simvastatin): 10mg 31%, 20mg 39%, 40mg 42%, 80mg 46%

FDA APPROVED INDICATIONS

Vytorin is indicated as adjunctive therapy to diet to:

- Reduce elevated total-C, LDL-C, Apo B, TG, and non-HDL-C, and to increase HDL-C in patients with primary (heterozygous familial and non-familial) hyperlipidemia or mixed hyperlipidemia
- Reduce elevated total-C and LDL-C in patients with homozygous familial hypercholesterolemia (HOFH), as an adjunct to other lipid-lowering treatments.

Limitations of Use:

- No incremental benefit of Vytorin on cardiovascular morbidity and mortality over and above that demonstrated for simvastatin has been established.
- Vytorin has not been studied in Fredrickson Type I, III, IV, and V dyslipidemias.

CONTINUED ON NEXT PAGE

SIMVASTATIN 80MG

FDA APPROVED INDICATIONS (CONTINUED)

Zocor is indicated as an adjunctive therapy to diet to:

- Reduce the risk of total mortality by reducing CHD deaths and reduce the risk of non-fatal myocardial infarction, stroke, and the need for revascularization procedures in patients at high risk of coronary events.
- Reduce elevated total-C, LDL0C, Apo B, TG and increase HDL-C in patient with primary hyperlipidemia (heterozygous familial and nonfamilial) and mixed dyslipidemia.
- Reduce elevated TG in patient with hypertriglyceridemia and reduce TG and VLDL-C in patients with primary dysbetalipoproteinemia.
- Reduce total-C and LDL-C in adult patients with homozygous familial hypercholesterolemia.
- Reduce elevated total-C, LDL-C, and Apo B in boys and postmenarchal girls, 10 to 17 years of age with heterozygous familial hypercholesterolemia after failing an adequate trial of diet therapy.

Limitations of Use:

- Zocor has not been studied in Fredrickson Types I and V dyslipidemias.

REFERENCES

- Merck/Schering-Plough Pharmaceuticals. Vytorin package insert. North Wales, PA. June 2011.
- Merck & Co., Inc. Zocor package insert. Whitehouse Station, NJ. June 2011.
- Rosenson RS. Statins, side effects, and administration. UpToDate, 2011.

Created: 10/11
Effective: 10/26/11 Client Approval: 08/05/11 P&T Approval: 08/11

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

SMOKING CESSATION AGENTS

Generic	Brand	HICL	GCN	Exception/Other
BUPROPION	ZYBAN		27901	
NICOTINE NASAL NICOTINE INHALER NICOTINE PATCH	NICODERM CQ NICOTROL NS NICOTROL INHALER NICOTINE PATCH	06249		
NICOTINE POLACRILEX	NICOTINE GUM NICOTINE LOZENGE	02049		
VARENICLINE	CHANTIX	33766		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: SEE BELOW FOR RENEWAL CRITERIA FOR VARENICLINE ONLY)

1. Is this request is for a member with Seton Family, Austin TX (ASC02)?

   If yes, continue to #2.
   If no, continue to #5.

2. Is the member enrolled in the Seton Smoking Cessation Program?

   If yes, continue to #4.
   If no, continue to #3.

3. Please refer the provider to Seton Health Plan at 512-324-3135 or email SHP-Authorization@seton.org to obtain information regarding the Seton Smoking Cessation Program.

4. **REQUESTS FOR ZYBAN, NICOTROL INHALER AND NASAL SPRAY, NICOTINE GUM, LOZENGES, AND PATCHES: APPROVE FOR 3 MONTHS ONLY PER LIFETIME.**

   REQUESTS FOR VARENICLINE:
   APPROVE FOR 3 MONTHS ONLY PER LIFETIME AS FOLLOWS: APPROVE #53 TABLET STARTER KIT FOR 4 WEEKS; THEN APPROVE BY HICL FOR #56 TABLETS PER 28 DAYS OR PER COPAY.

5. Is this request is for a member with St. Vincent, Indianapolis IN (ASC26)?

   If yes, continue to #6.
   If no, continue to #8.

6. Has the physician submitted the MRF for smoking cessation?

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: Requests for smoking cessation medications must be accompanied by a completed Medication Request Form AND the Cigna Lifestyle Management enrollment letter for the smoking cessation program.

CONTINUED ON NEXT PAGE

SMOKING CESSATION AGENTS

GUIDELINES FOR USE (CONTINUED)

INITIAL CRITERIA

7. Has the physician also submitted the Cigna Lifestyle Management enrollment letter for the smoking cessation program?

   If yes, continue to #9.
   If no, do not approve.
   DENIAL TEXT: Requests for smoking cessation medications must be accompanied by a completed Medication Request Form AND the Cigna Lifestyle Management enrollment letter for the smoking cessation program.
   NOTE TO PAC: Members who are tobacco users can enroll in the Cigna Lifestyle Management program on an annual basis in order to receive preferred medical plan rates. One approval per calendar year. No lifetime limit.

8. Is the patient enrolled in a smoking cessation program (e.g., "Get Quit" at https://www.get-quit.com/content/R_Intro_Page.jsp)?

   If yes, continue to #10.
   If no, do not approve.
   DENIAL TEXT: Requests for smoking cessation medications must be accompanied by participation in a smoking cessation program.

9. **REQUESTS FOR VARENICLINE:**
   APPROVE FOR 12 WEEKS AS FOLLOWS: APPROVE #53 TABLET STARTER KIT FOR 4 WEEKS; THEN APPROVE BY HICL FOR #56 TABLETS PER 28 DAYS OR PER COPAY.

   REQUESTS FOR ZYBAN: APPROVE FOR 6 MONTHS.

10. **REQUESTS FOR ZYBAN, NICOTROL INHALER AND NASAL SPRAY, NICOTINE GUM, LOZENGES, AND PATCHES: APPROVE FOR 6 MONTHS.**

    REQUESTS FOR VARENICLINE:
    APPROVE FOR 12 WEEKS AS FOLLOWS: APPROVE #53 TABLET STARTER KIT FOR 4 WEEKS; THEN APPROVE BY HICL FOR #56 TABLETS PER 28 DAYS OR PER COPAY.

CONTINUED ON NEXT PAGE

SMOKING CESSATION AGENTS

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA – FOR VARENICLINE ONLY

NOTE: RENEWAL CRITERIA DOES NOT APPLY TO ASC02 MEMBERS

1. Has the patient been able to abstain from cigarette use during the initial 12 weeks of treatment?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: Continued use of Chantix requires abstinence from cigarette use during the initial 12 weeks of treatment.

2. **APPROVE VARENICLINE FOR AN ADDITIONAL 12 WEEKS FOR #56 TABLETS PER 28 DAYS OR PER COPAY (OR FOR A TOTAL OF #168 TABLETS).**

RATIONALE
Promote effective utilization of Chantix.

FDA APPROVED INDICATIONS
As an aid to smoking cessation treatment.

NOTE: It is highly recommended that the member set a QUIT DATE. Chantix dosing should start one week before this date.

REFERENCES
- Pfizer Labs. Chantix package insert. New York, NY May 2006.

Created: 04/01/00
Effective: 11/01/12 Client Approval: 10/10/12

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

SODIUM OXYBATE

Generic	Brand	HICL	GCN	Exception/Other
SODIUM OXYBATE	XYREM	12346	18104	

GUIDELINES FOR USE

1. Is the patient 16 years of age or older?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: Approval requires that the patient is 16 years or older.

2. Does the patient have a diagnosis of narcolepsy with cataplexy?

   If yes, continue to #6.
   If no, continue to #3.

3. Does the patient have a diagnosis of narcolepsy with excessive daytime sleepiness?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: Approval requires that the patient has a diagnosis of narcolepsy with cataplexy or narcolepsy with excessive daytime sleepiness.

4. Is the patient currently receiving or has the patient previously tried and failed therapy with a standard stimulant agent (modafinil, armodafinil, methylphenidate, dextroamphetamine, or amphetamine/dextroamphetamine)?

   If yes, continue to #6.
   If no, continue to #5.

5. Does the patient have an allergy, contraindication, or intolerance to standard stimulant treatment?

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: Approval requires that the patient has tried and failed or has an allergy, contraindication, or intolerance to standard stimulant treatment (modafinil, armodafinil, methylphenidate, dextroamphetamine, or amphetamine/dextroamphetamine).

CONTINUED ON NEXT PAGE

SODIUM OXYBATE

GUIDELINES FOR USE (CONTINUED)

6. Has the prescriber documented that the patient is enrolled in the Xyrem Success Program?

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: Approval requires that the patient be enrolled in the Xyrem Success Program.

7. Does the patient have succinic semialdehyde dehydrogenase deficiency?

   If yes, do not approve.
   DENIAL TEXT: Succinic semialdehyde dehydrogenase deficiency is a contraindication to the use of Xyrem.
   If no, continue to #8.

8. Is the patient being treated with any sedative hypnotic agents?

   If yes, do not approve.
   DENIAL TEXT: Use of sedative hypnotic agents is a contraindication to the use of Xyrem.
   If no, continue to #9.

9. Does the patient have a history of substance abuse?

   If yes, do not approve.
   DENIAL TEXT: A history of substance abuse is a contraindication to the use of Xyrem.
   If no, **APPROVE FOR 12 MONTHS FOR A MAXIMUM OF #540MLS PER 30 DAYS**.

RATIONALE

The intent of prior authorization is to ensure appropriate selection of patients according to product labeling and/or clinical studies and/or guidelines.

FDA APPROVED INDICATIONS

Treatment of excessive daytime sleepiness and cataplexy in patients with narcolepsy.

REFERENCES

- Xyrem [package insert]. Palo Alto, CA: Jazz Pharmaceuticals Inc. 2005
- Micromedex Healthcare Series Web site. Available at: Micromedex Healthcare Series Web site. Available at: http://www.thomsonhc.com/hcs/librarian. Accessed May 09, 2011.
- Morgenthaler TI, Kapur VK, Brown TM, et al. Practice parameters for the treatment of narcolepsy and other Hypersomnia of central origin. An American Academy of Sleep Medicine Report. *SLEEP* 2007;30(12):1705-1711.

Created: 05/11
Effective: 05/26/11 Client Approval: 05/12/11

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

TELAPREVIR

Generic	Brand	HICL	GCN	Exception/Other
TELAPREVIR	INCIVEK	37629		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Is the requested medication being used with ribavirin and peginterferon alfa?
   Note: The patient must have an active prior authorization for peginterferon alfa before proceeding.

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of chronic hepatitis C, genotype 1, a minimum age of 18 years old, current supervision by a gastroenterologist, infectious disease specialist, or a physician specializing in the treatment of hepatitis (e.g. hepatologist), and concurrent use of ribavirin and peginterferon alfa. Approval requires that the patient is not currently taking rifampin.

2. Is the patient currently taking the requested medication as indicated on the MRF, claims history, or prior authorization history?

   If yes, continue to #9.
   If no, continue to #3.

3. Does the patient have a diagnosis of chronic hepatitis C, genotype 1?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of chronic hepatitis C, genotype 1, a minimum age of 18 years old, current supervision by a gastroenterologist, infectious disease specialist, or a physician specializing in the treatment of hepatitis (e.g. hepatologist), and concurrent use of ribavirin and peginterferon alfa. Approval requires that the patient is not currently taking rifampin.

4. Is the patient at least 18 years old?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of chronic hepatitis C, genotype 1, a minimum age of 18 years old, current supervision by a gastroenterologist, infectious disease specialist, or a physician specializing in the treatment of hepatitis (e.g. hepatologist), and concurrent use of ribavirin and peginterferon alfa. Approval requires that the patient is not currently taking rifampin.

CONTINUED ON NEXT PAGE

TELAPREVIR

GUIDELINES FOR USE (CONTINUED)

5. Is the patient currently supervised by a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (e.g. hepatologist), or specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model?

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of chronic hepatitis C, genotype 1, a minimum age of 18 years old, current supervision by a gastroenterologist, infectious disease specialist, or a physician specializing in the treatment of hepatitis (e.g. hepatologist), and concurrent use of ribavirin and peginterferon alfa. Approval requires that the patient is not currently taking rifampin.

6. Has the patient completed a prior course of therapy with telaprevir (Incivek) or boceprevir (Victrelis) and not achieved a sustained virologic response (SVR)?

   If yes, do not approve.
   DENIAL TEXT: Approval requires that the patient has not failed therapy with telaprevir (Incivek) or boceprevir (Victrelis). Approval requires a diagnosis of chronic hepatitis C, genotype 1, a minimum age of 18 years old, current supervision by a gastroenterologist, infectious disease specialist, or a physician specializing in the treatment of hepatitis (e.g. hepatologist), and concurrent use of ribavirin and peginterferon alfa. Approval requires that the patient is not currently taking rifampin.
   If no, continue to #7.

7. Is the patient currently taking rifampin?

   If yes, do not approve.
   DENIAL TEXT: Approval requires that the patient is not currently taking rifampin. Approval requires a diagnosis of chronic hepatitis C, genotype 1, a minimum age of 18 years old, current supervision by a gastroenterologist, infectious disease specialist, or a physician specializing in the treatment of hepatitis (e.g. hepatologist), and concurrent use of ribavirin and peginterferon alfa.
   If no, continue to #8.

CONTINUED ON NEXT PAGE

GUIDELINES FOR USE (CONTINUED)

8. Does the patient have coinfection with HIV or hepatitis B, or have a history of a previous solid organ transplant?

   If yes, do not approve.
   DENIAL TEXT: Approval requires that the patient does not have coinfection with HIV or hepatitis B, or have a history of a previous solid organ transplant.

   If no, **APPROVE FOR #6 TABLETS PER DAY FOR 8 WEEKS.**
   PAC: The days supply is based on the benefit structure. Enter the Maximum Daily Dose (MDD) = 6 tablets and a duration of 56 days.
   APPROVAL TEXT: Renewal requires HCV RNA level at baseline and at 4 weeks of telaprevir therapy (level 1,000 IU/mL or less). Drugs that are contraindicated with Incivek include alfuzosin, rifampin, ergot derivatives, cisapride, St. John's wort, atorvastatin, lovastatin, simvastatin, pimozide, sildenafil or tadalafil (when used for pulmonary arterial hypertension [PAH]), orally administered midazolam and triazolam.

9. Renewal criteria for treatment week 9, the patient has an approved PA for telaprevir: Did the patient have a HCV RNA level/viral load of 1,000 IU/mL or less at 4 weeks of telaprevir therapy?

   If yes, **APPROVE FOR #6 TABLETS PER DAY FOR 4 WEEKS. MAXIMUM OF TELAPREVIR THERAPY IS NOT TO EXCEED 12 WEEKS.**
   PAC: The days supply is based on the benefit structure. Enter the Maximum Daily Dose (MDD) = 6 tablets and a duration of 28 days; total telaprevir therapy duration not to exceed 84 days (12 weeks).
   APPROVAL TEXT: Drugs that are contraindicated with Incivek include alfuzosin, rifampin, ergot derivatives, cisapride, St. John's wort, atorvastatin, lovastatin, simvastatin, pimozide, sildenafil or tadalafil (when used for pulmonary arterial hypertension [PAH]), orally administered midazolam and triazolam.

   If no, do not approve.
   DENIAL TEXT: Renewal requires HCV RNA level/viral load of less than 1,000 IU/mL at 4 weeks of telaprevir therapy.

   CLINICAL SPECIALISTS: If HCV RNA level greater than 1,000 IU/mL at week 4, triple therapy will be discontinued at this time. Review the prior authorization history and close peginterferon PA (and ribavirin PA, if applicable).
   CLINICAL SPECIALISTS: Please review peginterferon/ribavirin dosing regimens:
   - For treatment-naïve and prior relapse patients with undetectable HCV-RNA at weeks 4 and 12, dual therapy is for a total treatment duration of 24 weeks.
   - For treatment-naïve and prior relapse patients with detectable (1,000 IU/mL or less) HCV-RNA at weeks 4 and/or 12, dual therapy is for a total duration of 48 weeks.
   - For prior partial and null responder patients dual therapy is for a total duration of 48 weeks.
   - For treatment-naïve patients with cirrhosis who have undetectable HCV-RNA levels at week 4 and 12, dual therapy for a total duration of 48 weeks would be beneficial.

CONTINUED ON NEXT PAGE

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

TELAPREVIR

RATIONALE
Ensure appropriate utilization of telaprevir based on FDA approved indication.

FDA APPROVED INDICATIONS
Incivek, in combination with peginterferon alfa and ribavirin, is indicated for the treatment of genotype 1 chronic hepatitis C in adult patients with compensated liver disease, including cirrhosis, who are treatment-naïve (patients who have not received interferon-based drug therapy for their infection), or who have previously been treated with interferon-based treatment and not responded adequately, including prior null responders, partial responders, and relapsers.

FDA APPROVED DOSAGE
Incivek 750mg (two 375mg tablets) orally three times daily is added to peginterferon alfa and ribavirin for the first twelve weeks of therapy.

REFERENCES

- Vertex Pharmaceuticals. Incivek package insert. Cambridge, MA. May 2011.

Created: 06/11
Effective: 12/14/11 Client Approval: 11/07/11 P&T Approval: 08/11

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

TERIFLUNOMIDE

Generic	Brand	HICL	GCN	Exception/Other
TERIFLUNOMIDE	AUBAGIO	39624		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsing-remitting, secondary-progressive or progressive-relapsing multiple sclerosis?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of relapsing-remitting, secondary-progressive or progressive-relapsing multiple sclerosis and a trial of Copaxone and an interferon such as Rebif (the interferons Avonex, Betaseron, and Extavia require prior use of Rebif and Copaxone).

2. Has the patient tried or does the patient have a contraindication to interferon therapy (Avonex, Betaseron, Extavia, or Rebif) **AND** Copaxone?

   If yes, **APPROVE FOR 12 MONTHS BY HICL WITH A QUANTITY LIMIT OF #28 TABLETS PER 28 DAYS.**
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of relapsing-remitting, secondary-progressive or progressive-relapsing multiple sclerosis and a trial of Copaxone and an interferon such as Rebif (the interferons Avonex, Betaseron, and Extavia require prior use of Rebif and Copaxone).

RATIONALE
To ensure appropriate use of Aubagio consistent with FDA approved indication.

The recommended dose of Aubagio is 7 mg or 14 mg orally once daily, with or without food.

Aubagio is the second oral medication to treat relapsing forms of multiple sclerosis. It is an immunomodulatory agent that inhibits dihydroorotate dehydrogenase, an enzyme involved in pyrimidine synthesis. The drug reduces T- and B- cell activation, proliferation and function in response to auto antigens. Aubagio is the active metabolite of leflunomide, an agent used for rheumatoid arthritis, which has been on the market since 1998.

The relapsing remitting form of multiple sclerosis accounts for roughly 85% of the total multiple sclerosis population. Guidelines and consensus statements from the American Academy of Neurology and National Clinical Advisory Board of the National Multiple Sclerosis Society do not indicate preference of first line agents. Current first line treatments available for relapsing forms of multiple sclerosis include: interferon beta-1a (Avonex, Rebif), interferon beta-1b (Betaseron, Extavia), glatiramer acetate (Copaxone), and fingolimod (Gilenya). Other agents reserved as second line agents include mitoxantrone (Novantrone) and natalizumab (Tysabri).

The U.S. Food and Drug Administration approval of Aubagio stems from one large phase III study and another smaller phase III imaging study.

CONTINUED ON NEXT PAGE

TERIFLUNOMIDE

RATIONALE (CONTINUED)

Study 1 (TEMSO) was a double-blind, placebo-controlled study that evaluated teriflunomide 7mg and 14mg versus placebo in 1088 patients with relapsing forms of multiple sclerosis over 108 weeks. Inclusion criteria included a definite diagnosis of MS and at least 1 relapse over the year preceding the trial or 2 relapses over the 2 years preceding the trial. MRI was performed at screening and at various time points thereafter. Upon entry to the trial, the patient's Expanded Disability Status Scale (EDSS) score was ≤ 5.5. The primary endpoint of the study was the annualized relapse rate (ARR).

The ARR was reduced in both the 7mg (ARR= 0.370) and 14mg (ARR=0.369) treatment arms compared with placebo (ARR= 0.539), which was statistically significant (p=0.0005 and p=0.0002, respectively). The disability progression measurement assessed by EDSS at week 108 was only statistically significant in the 14mg arm (20.2%) versus placebo (27.3%). MRI endpoints included median change from baseline in total lesion volume and mean number of Gd-enhancing T1-lesions per scan. Teriflunomide 7mg and 14 mg demonstrated statistically significant decreases in both lesion volume and fewer Gd-enhancing lesions versus placebo.

Study 2 was a randomized, double blind, placebo-controlled study in 179 patients treated for 36 weeks that further demonstrated the effects of teriflunomide on MRI activity. The primary endpoint of average number of unique active lesions per MRI scan was lower in the teriflunomide 7mg and 14mg arms (0.98, 1.06) compared to placebo (2.69; p=0.0052 and p=0.0234, respectively).

Aubagio has a black box warning for hepatotoxicity and risk of teratogenicity, and is contraindicated in patients with severe hepatic impairment and in pregnant women. Aubagio is classified as pregnancy category X. Women of childbearing potential must not be started on Aubagio until pregnancy is excluded and it has been confirmed that they are using reliable contraception.

Warnings and precautions include hepatotoxicity, bone marrow and immunosuppression, risk of infections, malignancy, peripheral neuropathy, acute renal failure, hyperkalemia, dermatological toxicity, increases in blood pressure, and respiratory disease. The most common side effects seen with Aubagio are ALT elevations, alopecia, diarrhea, influenza, nausea and paresthesia. Co-administration with leflunomide is contraindicated. Aubagio may increase levels of CYP2C8 substrates and oral contraceptives, and decrease levels of warfarin and CYP1A2 substrates.

FDA APPROVED INDICATIONS

Aubagio is indicated for the treatment of patients with the relapsing forms of multiple sclerosis.

CONTINUED ON NEXT PAGE

TERIFLUNOMIDE

REFERENCES

- Aubagio [Prescribing Information]. Cambridge, MA: Genzyme Corporation; September 2012.
- Goodin DS et al. Disease modifying therapies in multiple sclerosis: Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology and the MS Council for Clinical Practice Guidelines. *Neurology*. 2002;58(2):169-178.
- National Clinical Advisory Board of the National Multiple Sclerosis Society. MS Disease Management Consensus Statement. 2007. Available at: http://www.nationalmssociety.org/for-professionals/healthcare-professionals/publications/expert-opinion-papers/index.aspx [Accessed October 1, 2012].

Created: 10/12
Effective: 03/25/13 Client Approval: 02/14/13

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

TERIPARATIDE

Generic	Brand	HICL	GCN	Exception/Other
TERIPARATIDE	FORTEO	24700		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Paget's disease, a history of radiation therapy, bone malignancy, unexplained elevations of alkaline phosphatase, open epiphyses, a history of hypercalcemia or hyperparathyroidism?

   If yes, do not approve.
   If no, continue to #2.

2. Does the patient:
   a. have a diagnosis of severe osteoporosis (T-score <-2.5 with fragility fracture(s)), or
   b. a T-score ≤ -2.5 and multiple risk factors for fracture (e.g., history of multiple recent low trauma fractures, corticosteroid use, or use of GnRH analogs such as nafarelin, etc.), or
   c. has the patient failed an adequate trial of bisphosphonates (Fosamax, Actonel, Boniva), is intolerant, or has a contraindication to these medications?

   If yes, continue to #3.
   If no, do not approve.

3. **APPROVE FOR 12 MONTHS WITH A QUANTITY LIMIT OF 1 PEN PER 30 DAYS/COPAY.**

RATIONALE
To ensure safe use of teriparatide for the treatment of osteoporosis in patients who have failed or are intolerant to anti-resorptive agents.

FDA APPROVED INDICATIONS
For the treatment of postmenopausal women with osteoporosis who are at high risk for fracture, such as women with a history of osteoporotic fracture, or who have multiple risk factors for fracture, or who have failed or are intolerant to previous osteoporosis therapy. In postmenopausal women with osteoporosis, teriparatide can increase bone mineral density and reduce the risk of vertebral and non-vertebral fractures.

Teriparatide is also indicated to increase bone mass in men with primary or hypogonadal osteoporosis who are at high risk of fracture such as men with a history of osteoporotic fracture, or who have multiple risk factors for fracture, or who have failed or are intolerant to previous osteoporosis therapy. In men with osteoporosis, teriparatide increases bone mineral density but the effects of this drug on the risk for fracture in men has not been studied.

REFERENCES

- Eli Lilly and Company. Forteo package insert. Indianapolis, IN. February 2008.
- Osteoporosis. Med**Impact** P&T Monograph, August 2005.

Created: 05/03
Effective: 10/15/09 Client Approval: 10/01/09

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

TESTOSTERONE

Generic	Brand	HICL	GCN	Exception/Other
TESTOSTERONE	ANDRODERM ANDROGEL AXIRON FORTESTA TESTOPEL TESTIM STRIANT	01403		
TESTOSTERONE CYPIONATE	DEPO-TESTOSTERONE	01400		
TESTOSTERONE ENANTHATE	DELATESTRYL	01401		

GUIDELINES FOR USE

1. Is there a previous approved PA in the system or did the physician state patient is currently on testosterone replacement?

   If yes, continue to #7.
   If no, continue to #2.

2. Is the patient a male 12 years of age or older diagnosed with hypogonadism (primary or secondary)?

   If yes, continue to #3.
   If no, continue to #5.

3. Does the patient have a laboratory confirmed total serum testosterone level of less than 250ng/dL (8.7nmol/L) obtained within 90 days?

   If yes, continue to #7.
   If no, continue to #4.

4. Does the patient have a laboratory confirmed total serum testosterone level between 250ng/dL and 350ng/dL (12nmol/L) and a free serum testosterone level of less than 50ng/L (174 pmol/L)?

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: The diagnosis provided does not meet plan criteria. Approval criteria requires appropriate lab values with the indication of hypogonadism.

5. Is the patient a male and have a diagnosis of delayed puberty not secondary to a pathological disorder?

   If yes, continue to #7.
   If no, continue to #6.

CONTINUED ON NEXT PAGE

TESTOSTERONE

GUIDELINES FOR USE (CONTINUED)

6. Is the patient female and have a diagnosis of metastatic breast cancer?

   If yes, continue to #7.
   If no, do not approve.

7. **APPROVE FOR 12 MONTHS WITH APPROPRIATE QUANTITY LIMITS:**
   - **AndroGel (testosterone): 5g/day/month (2.5 g/packet) and up to 10 g/day/month (5 g/packet), or up to 4 x 75g pump**
   - **Androderm (testosterone):**
     - **2.5 mg patches: #60 systems per month**
     - **5 mg patches: #30 systems per month**
   - **Axiron (testosterone): 30mg/pump, 60 pumps/container: up to #2 metered-dose pumps/month**
   - **Depo-Testosterone (testosterone cypionate): up to 10 mL (1 vial) per month**
   - **Delatestryl (testosterone enanthate) 200mg/ml, 5ml vial: One 5 mL vial per month**
   - **Delatestryl (testosterone enanthate) 200mg/ml, 1ml syringe: Two 1ml syringes per month**
   - **Fortesta (testosterone): up to 120grams (2 x 60gram pumps) per month**
   - **Striant (testosterone): #60 systems (tablets) per month**
   - **Testim (testosterone): up to 10 g/day/month (5 g/tube)**
   - **Testopel (testosterone): up to #6 pellets per 3 months**

RATIONALE
Ensure appropriate diagnostic, utilization, and safety criteria. Normal testosterone level is defined as for males as between 300 -1,200 ng/dL per the National Institute on Aging. Low free serum testosterone level is defined as less than 50ng/L per Adult Men with Androgen Deficiency Syndrome: An Endocrine Society Clinical Practice Guideline.

FDA APPROVED INDICATIONS
ANDRODERM (testosterone transdermal system) is indicated for testosterone replacement therapy in men for conditions associated with a deficiency or absence of endogenous testosterone. Primary hypogonadism (congenital or acquired) - Testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, or orchidectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations accompanied by gonadotropins (FSH, LH) above the normal range. Secondary, i.e., hypogonadotropic hypogonadism (congenital or acquired) - idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low serum testosterone concentrations without associated elevation in gonadotropins. Appropriate adrenal cortical and thyroid hormone replacement therapy may be necessary in patients with multiple pituitary or hypothalamic abnormalities.

CONTINUED ON NEXT PAGE

TESTOSTERONE

FDA APPROVED INDICATIONS (CONTINUED)

ANDROGEL, an androgen, is indicated for replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone: Primary Hypogonadism (Congenital or Acquired) - testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone levels and gonadotropins (FSH, LH) above the normal range. Hypogonadotropic Hypogonadism (Congenital or Acquired) - idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum levels but have gonadotropins in the normal or low range.

AXIRON, an androgen is indicated for replacement therapy in males for conditions associated with a deficiency of absence of endogenous testosterone: Primary hypogonadism (congenital or acquired); Hypogonadotropic hypogonadism (congenital or acquired). Not indicated in males <18 years of age.

TESTIM® is indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone: Primary hypogonadism (congenital or acquired): testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone levels and gonadotropins (FSH, LH) above the normal range. Hypogonadotropic hypogonadism (congenital or acquired): idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum levels but have gonadotropins in the normal or low range. Testim® has not been clinically evaluated in males under 18 years of age.

STRIANT® is indicated for replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone: Primary hypogonadism (congenital or acquired) - testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchidectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone levels and gonadotropins (FSH, LH) above the normal range. Hypogonadotropic hypogonadism (congenital or acquired) - idiopathic gonadotropin or LHRH deficiency, or pituitary hypothalamic injury from tumors, trauma, or radiation. These patients have low serum testosterone levels but have gonadotropins in the normal or low range.

DEPO-TESTOSTERONE INJECTION is indicated for replacement therapy in the male in conditions associated with symptoms of deficiency or absence of endogenous testosterone. Primary hypogonadism (congenital or acquired) - testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome; or orchidectomy. Hypogonadotropic hypogonadism (congenital or acquired) - idiopathic gonadotropin or LHRH deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation.

DELATESTRYL® (Testosterone Enanthate Injection, USP) is indicated for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone.

CONTINUED ON NEXT PAGE

TESTOSTERONE

REFERENCES

- Lilly USA, LLC. Axiron Package Insert. Indianapolis, IN. November, 2010.
- Auxilium Pharmaceuticals, Inc. Testim package insert. Malvern, PA. September 2009.
- Bartor Pharmacal Co.; Inc. Testopel package insert. Rye, NY. January 2009.
- Columbia Laboratories, Inc. Striant package insert. Livingston, NJ. February 2007.
- Conway AJ, Handelsman DJ, Lording DW, Stuckey B, Zajac JD. Use, misuse and abuse of androgens. MJA. 2000; 172:220-224.
- Endo Pharmaceuticals. Fortesta package insert. February 2011.
- Francis S. Greenspan and David G. Gardner eds. Lange Basic and Clinical Endocrinology. 7th ed. McGraw-Hill Companies, Inc.; 2004
- Gould DC, Petty R, Jacobs HS. The male menopause: does it exist? BMJ. 2000; 320:858-861.
- Indevus Pharmaceuticals, Inc. Delatestryl package insert. Lexington, MA. July 2007.
- Lui PY, Swerdloff RS, Wang C. Relative testosterone deficiency in older men: Clinical definition and presentation. Endocrinol Metab Clin N Am. 2005; 34:957-72.
- Miller KK. Special Articles: Hormones and Reproductive Health. J Clin Endocrinol Metab 2001; 86(6):2395-2401.
- National Institute on Aging. Scientific task force to examine usefulness of testosterone replacement therapy in older men [online]. NIH News Release. November 6, 2002. Available at: http://www.nia.nih.gov/NewsAndEvents/PressReleases/PR20021106ScientificTask.htm [Accessed July 21, 2009].
- Petak SM. American Association of Clinical Endocrinologists Medical Guidelines for Clinical Practice for the Evaluation and Treatment of Hypogonadism in Adult Male Patients-2002 Update. Endocrine Practice. 2002; 8 (6): 439-456.
- Pharmacia & Upjohn Company. Depo-Testosterone package insert. New York, NY. September 2006.
- Shalender B, Glenn,Cunningham, FJ, et al. Adult Men with Androgen Deficiency Syndrome: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab, June 2010, 95(6):2536–2559. Available at http://www.endo-society.org/guidelines/final/upload/final-androgens-in-men-standalone.pdf [Accessed July 25, 2011].
- The Formulary Monograph Service, Facts and Comparisons, St Louis, Missouri, 2003.
- Unimed Pharmaceuticals, LLC. Androgel package insert. Marietta, GA. December 2007.
- Watson Pharma, Inc. Androderm package insert. Corona, CA. September 2006.

Created: 02/01
Effective: 12/14/11 Client Approval: 11/07/11 P&T Approval: 02/11

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

THALIDOMIDE

Generic	Brand	HICL	GCN	Exception/Other
THALIDOMIDE	THALOMID	11465		

GUIDELINES FOR USE

1. Is the patient pregnant?

   If yes, continue to #10.
   If no, continue to #2.

2. Does the patient have a diagnosis of Erythema Nodosum Leprosum (ENL) treatment?

   If yes, continue to #9.
   If no, continue to #3.

3. Does the patient have a diagnosis of Erythema Nodosum Leprosum (ENL) suppression?

   If yes, continue to #9.
   If no, continue to #4.

4. Does the patient have a diagnosis of Multiple Myeloma and is being treated in combination with dexamethasone?

   If yes, continue to #9.
   If no, continue to #5.

5. Does the patient have a diagnosis of Behcet's syndrome?

   If yes, continue to #9.
   If no, continue to #6.

6. Does the patient have a diagnosis of HIV-associated wasting syndrome?

   If yes, continue to #9.
   If no, continue to #7.

7. Does the patient have a diagnosis of Aphthous Stomatitis?

   If yes, continue to #9.
   If no, continue to #8.

8. Is the patient infected with HIV and have a diagnosis of Esophageal Aphthous Ulcers?

   If yes, continue to #9.
   If no, continue to #10.

CONTINUED ON NEXT PAGE

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

THALIDOMIDE

GUIDELINES FOR USE (CONTINUED)

9. **APPROVE WITH DOSAGES LIMITED TO 400 MG PER DAY. MAX DOSE PER PACKAGE INSERT IS 400MG/DAY. APPROVE FOR ONE YEAR.**

10. **DO NOT APPROVE.**

Thalomid (thalidomide) must only be administered in compliance with all of the terms outlined in the *S.T.E.P.S.*® program. Thalomid may only be prescribed by prescribers and dispensed by pharmacists registered with the *S.T.E.P.S.*® program.

RATIONALE
To assure safe and appropriate use of thalidomide

FDA APPROVED INDICATIONS
Thalomid in combination with dexamethasone is indicated for the treatment of patients with newly diagnosed multiple myeloma.

Thalomid is indicated for the acute treatment of the cutaneous manifestations of moderate to severe erythema nodosum leprosum (ENL). Thalomid is not indicated as monotherapy for such ENL in the presence of moderate to severe neuritis.

Thalomid is indicated as maintenance therapy for the prevention and suppression of the cutaneous manifestations of ENL recurrence.

Thalomid has the following indications recognized in a major compendium: Behcet's Syndrome, HIV-associated wasting syndrome, Aphthous Stomatitis treatment and Esophageal Aphthous ulcers in HIV patients.

REFERENCES
Thalomid prescribing information available at: www.thalomid.com

Created: 11/17/08
Effective: 01/01/09 Client Approval 12/10/08

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

TICAGRELOR

Generic	Brand	HICL	GCN	Exception/Other
TICAGRELOR	BRILINTA	37328		

GUIDELINES FOR USE

1. Is the requested agent being used to reduce the rate of thrombotic cardiovascular events in a patient with a diagnosis of acute coronary syndrome (ACS-includes unstable angina, non-ST elevation MI or ST elevation MI)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of acute coronary syndrome (ACS) and a previous trial of clopidogrel or a genotype test result that demonstrates poor response to clopidogrel.

2. Has the patient had a previous trial of clopidogrel (Plavix)?

   If yes, **APPROVE FOR 1 YEAR BY HICL WITH A QUANTITY LIMIT OF #2 TABLETS PER DAY.**
   APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.
   If no, continue to #3.

3. Has the patient had a CYP2C19 genotype test with genotype result that predicts low clopidogrel exposure (CYP2C19* variant CYP2C19*2 through CYP2C19*8)?

   If yes, **APPROVE FOR 1 YEAR BY HICL WITH A QUANTITY LIMIT OF #2 TABLETS PER DAY.**
   APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of acute coronary syndrome (ACS) and a previous trial of clopidogrel or a genotype test result that demonstrates poor response to clopidogrel.

RATIONALE

To promote clopidogrel, an antiplatelet agent with a proven safety and efficacy record as well as once-daily dosing, with exceptions when clinically indicated (patients who have not benefited from clopidogrel).

Some individuals with CYP2C19 allele variants are associated with poor response to clopidogrel (CYP2C19*2, CYP2C19*3, CYP2C19*4, CYP2C19*5, CYP2C19*6, CYP2C19*7, CYP2C19*8 alleles are known to have lower response to clopidogrel). CYP2C19*1 is associated with normal response.

CONTINUED ON NEXT PAGE

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

TICAGRELOR

FDA APPROVED INDICATIONS

To reduce the rate of thrombotic cardiovascular events in patients with acute coronary syndrome (ACS – including unstable angina, non-ST elevation MI, or ST elevation MI). Brilinta should be co-administered with aspirin (usually doses 75-100mg).

REFERENCES

- Astra Zeneca. Brilinta package insert. Revised July 2007. Accessed online at http://www1.astrazeneca-us.com/pi/brilinta.pdf

Created: 02/12
Effective: 03/20/12 Client Approval: 02/16/12

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

TOFACITINIB

Generic	Brand	HICL	GCN	Exception/Other
TOFACITINIB CITRATE	XELJANZ	39768		

GUIDELINES FOR USE

1. Is this for initial therapy?

   If yes, continue to #2.
   If no, continue to #4.

2. Does the patient have a diagnosis of rheumatoid arthritis?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of rheumatoid arthritis and a trial of methotrexate.

3. Has the patient had a trial of or does the patient have a contraindication to methotrexate?

   If yes, **APPROVE FOR 3 MONTHS BY HICL WITH A QUANTITY LIMIT OF #2 TABLETS PER DAY.**
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of rheumatoid arthritis and a trial of methotrexate.

4. Has the patient experienced or maintained a 20% improvement in tender or swollen joint count while on therapy?

   If yes, **APPROVE FOR 12 MONTHS BY HICL WITH A QUANTITY LIMIT OF #2 TABLETS PER DAY.**
   If no, do not approve.
   DENIAL TEXT: Renewal requires that the patient has experienced or maintained a 20% improvement in tender or swollen joint count while on therapy.

RATIONALE
To ensure appropriate use of Xeljanz consistent with FDA approved indication.

The recommended dose of Xeljanz is 5 mg orally twice daily with or without food. Dosage modifications are needed for patients with moderate hepatic impairment, moderate to severe renal impairment, concomitant use of potent inhibitors of CYP2C19, concomitant use of moderate/potent inhibitors/inducers of CYP3A4, lymphopenia, neutropenia and anemia.

CONTINUED ON NEXT PAGE

TOFACITINIB

RATIONALE (CONTINUED)

Xeljanz, an oral agent, is the first selective inhibitor of Janus kinase (JAK) 1 and JAK3 available for the treatment of RA. JAKs are intracellular kinases which transmit signals arising from cytokine or growth factor-receptor interactions on the cellular membrane to influence intracellular immune processes. Xeljanz inhibits the signaling of several cytokine members simultaneously and is therefore being studied for use in the treatment of other autoimmune disorders including ulcerative colitis. While Xeljanz is FDA approved as first line therapy following failure of a DMARD, initially its utilization is expected to be limited to those patients who have failed or are not candidates for injectable biologic therapy (i.e., TNF inhibitors).

The American College of Rheumatology RA treatment guidelines recommend DMARDs (i.e. MTX, hydroxychloroquine, leflunomide, minocycline and sulfasalazine) as first line pharmacological treatment. Failure with a DMARD is followed by a trial of one or more TNF inhibitors (Humira, Cimzia, Enbrel, Simponi, and Remicade) followed by a non-TNF biologic such as abatacept (T-cell costimulation modulator), Rituximab (B-cell CD20 antagonist) and tocilizumab (IL-6 receptor antagonist). The TNF and non-TNF inhibitor biologics currently on the market today are administered via subcutaneous (SC) injection or intravenous (IV) infusion.

The safety and efficacy of Xeljanz was studied in five phase 3, double-blind, controlled, multicenter trials, in adult patients with moderate to severe active RA who had an inadequate response (IR) to previous DMARD treatment. Studies included IR to MTX, IR to TNF inhibitors and IR to any DMARD (biologic and nonbiologic). The trials ranged from 6 months to an ongoing 2-year trial and totaled 3,315 patients. The primary endpoints for all of the studies were proportion of patients who achieved an ACR 20 response, change in Health Assessment Questionnaire-Disability Index (HAQ-DI), and rates of Disease Activity Score DAS28-4 (ESR) less than 2.6. One study also included mean change from baseline in van der Heijde-modified total Sharp Score (mTSS) as another co-primary endpoint. All of the studies had different time points for primary endpoints ranging from 3 months to 6 months.

In all trials, patients treated with 5 mg twice daily Xeljanz had higher ACR20, ACR50, and ACR70 response rates versus placebo, with or without background non-biologic DMARD treatment, at Month 3 and Month 6. Higher ACR20 response rates were observed within 2 weeks compared to placebo. In the 12-month trials, ACR response rates in Xeljanz -treated patients were consistent at 6 and 12 months.

Study III, known in the literature as the Oral Standard trial, was the only trial to have an active comparator arm (Humira). Study duration was 12 months. Patients (N=792) were on stable doses of MTX and were randomly assigned to receive Xeljanz 5 mg or 10 mg twice daily, Humira 40 mg once every two weeks, or placebo. The ACR20 response rates for Xeljanz 5 mg, Humira and placebo were 51.5%, 47.2% and 28.3% respectively ($p<0.001$ for all comparison groups vs. placebo). The mean change from baseline in the HAQ-DI score at month 3 and percentage of patients with a DAS28-4 (ESR) below 2.6 at month 6 were also significantly greater with the active treatment versus placebo. The study was not designed or powered to directly compare the efficacy of Xeljanz versus Humira.

CONTINUED ON NEXT PAGE

TOFACITINIB

RATIONALE (CONTINUED)

Xeljanz has black box warnings of serious infections and malignancies. Prior to starting Xeljanz patients should be tested for latent tuberculosis (TB) and all patients should be monitored for active TB during treatment even if the initial TB test was negative. Other warnings and precautions include gastrointestinal perforations, hepatic impairment, concurrent use of live vaccines, and the necessity to monitor specific laboratory parameters including lymphocytes, neutrophils, hemoglobin, liver enzymes, and lipids. The most common adverse reactions reported in >2% of patients treated with Xeljanz monotherapy or in combination with DMARDs were upper respiratory tract infections, headache, diarrhea and nasopharyngitis.

As Xeljanz undergoes hepatic metabolism via the Cytochrome P450 enzymes CYP3A4 and CYP2C19, drug-drug interactions with inhibitors/inducers of those enzymes can occur. Xeljanz is pregnancy category C.

FDA APPROVED INDICATIONS

Xeljanz is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to methotrexate. It may be used as monotherapy or in combination with methotrexate or other nonbiologic disease-modifying antirheumatic drugs (DMARDs)

Xeljanz should not be used in combination with biologic DMARDs or potent immunosuppressants such as azathioprine and cyclosporine.

REFERENCES

- Xeljanz [Prescribing Information]. New York, NY: Pfizer; August 2012.
- FDA News Release. US Food and Drug Administration. Available at http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm327152.htm [Accessed 11/12/12].
- American College of Rheumatology Committee to Reevaluate Improvement Criteria. A proposed revision to the ACR20: the hybrid measure of American College of Rheumatology response. Arthritis Rheum 2007;57:193-202.
- Sokka T. Radiographic scoring in rheumatoid arthritis. Bulletin of the NYU Hospital for Joint Diseases 2008;66:166-168.
- Kyttaris, VC. Kinase inhibitors: a new class of antirheumatic drugs. Drug Design, Development and Therapy 2012:6 245–250.
- McInnes IB, Schett G. The pathogenesis of rheumatoid arthritis. N Engl J Med. 2011; 365:2205–19.
- van Vollenhoven RF, Fleischmann R, Cohen S, et al. Tofacitinib or adalimumab versus placebo in rheumatoid arthritis. N Engl J Med 2012; 367:508-19.

Created: 11/12
Effective: 03/25/13 Client Approval: 02/14/13

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

USTEKINUMAB

Generic	Brand	HICL	GCN	Exception/Other
USTEKINUMAB	STELARA	36187		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Has this drug been prescribed by or is it currently being supervised by a dermatologist or rheumatologist?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: Approval requires supervision by a dermatologist or rheumatologist.

2. Does the patient have moderate to severe plaque psoriasis of greater than or equal to 10% Body Surface Area (BSA) or PASI score ≥ 12?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of moderate to severe plaque psoriasis covering 10% or more of Body Surface Area or PASI score ≥ 12.

3. Has the patient failed or does the patient have a contraindication to one or more forms of preferred therapy (PUVA, UVB, acitretin, methotrexate, or cyclosporine)?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: Approval requires a trial of one or more forms of preferred therapy (e.g. PUVA, UVB, methotrexate, or cyclosporine).

4. Does the patient weigh 100kg (220 lbs) or less?

   If yes, continue to #5.
   If no, continue to #6.

5. **TOTAL INITIAL APPROVAL EQUAL TO 4 MONTHS: ENTER A MAX DAYS SUPPLY OF 90. APPROVE 2 X 45MG/0.5ML PREFILLED SYRINGES OR VIALS PER 90 DAY SUPPLY FOR ONE FILL. PLEASE APPROVE FOR A TIME FRAME OF 4 MONTHS.**

   PAC NOTE – OVERRIDE RESTR WITH "F" TO ALLOW PHARMACY TO PROCESS CLAIM FOR TWO PREFILLED SYRINGES OF VIALS FOR THE INITIAL FILL ONLY.

   APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information please ask your doctor or pharmacist.

CONTINUED ON NEXT PAGE

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

USTEKINUMAB

INITIAL CRITERIA (CONTINUED)

6. **TOTAL INITIAL APPROVAL EQUAL TO 4 MONTHS: ENTER A MAX DAYS SUPPLY OF 90. APPROVE 2 X 90MG/ML PREFILLED SYRINGES OR VIALS PER 90 DAYS SUPPLY FOR ONE FILL. PLEASE APPROVE FOR A TIME FRAME OF 4 MONTHS.**

   PAC NOTE – OVERRIDE RESTR WITH "F" TO ALLOW PHARMACY TO PROCESS CLAIM FOR TWO PREFILLED SYRINGES OF VIALS FOR THE INITIAL FILL ONLY.

   APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information please ask your doctor or pharmacist.

RENEWAL CRITERIA

1. Does the patient have moderate to severe plaque psoriasis?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: Renewal requires a diagnosis of moderate to severe plaque psoriasis.

2. Has the patient achieved clear or minimal disease (Physician's Global Assessment = 0 or 1) or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: Renewal requires patient has achieved clear or minimal disease (Physician's Global Assessment = 0 or 1) or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more.

3. Does the patient weigh 100kg (220 lbs) or less?

   If yes, continue to #4.
   If no, continue to #5.

4. **TOTAL RENEWAL APPROVAL:**
   APPROVE UP TO 2 X 45MG/0.5ML PREFILLED SYRINGES OR VIALS EVERY 12 WEEKS FOR ONE YEAR. ENTER A MAX DAY SUPPLY OF 90 PER FILL.
   APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information please ask your doctor or pharmacist.

5. **TOTAL RENEWAL APPROVAL:**
   APPROVE UP TO 1 X 90MG/ML PREFILLED SYRINGE OR VIAL EVERY 12 WEEKS FOR ONE YEAR. ENTER A MAX DAY SUPPLY OF 90 PER FILL
   APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information please ask your doctor or pharmacist.

CONTINUED ON NEXT PAGE

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

USTEKINUMAB

RATIONALE

Ensure that appropriate diagnostic, utilization, and safety criteria are utilized for the management of ustekinumab.

The Psoriasis Area Severity Index (PASI) is a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. The PASI produces a numeric score that can range from 0 to 72.

The Physician's Global Assessment (PGA) is used to determine the subject's psoriasis lesions overall at a given time point. Overall lesions are graded for induration, erythema, and scaling based on a scale from 0 to 5, with higher scores indicating greater severity.

Total PGA Scores

0 = Cleared
1 = Minimal
2 = Mild
3 = Moderate
4 = Marked
5 = Severe

FDA APPROVED INDICATIONS

Treatment of adult patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.
Stelara is indicated for the treatment of adult patients (18 yr or older) with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.

REFERENCES

- Centocor Ortho Biotech. Stelara product information. Horsham, PA. September 2009.
- Centocor Ortho Biotech. Stelara Dossier. Horsham, PA. September 2009.
- Micromedex® Healthcare Series [database online]. Greenwood Village, Colo: Thomson Healthcare. Available at: https://www.thomsonhc.com/hcs/librarian/PFDefaultActionId/pf.LoginAction. [Accessed: October 8, 2009].
- Menter A, Gottlieb A, et al. Guidelines of care for the management of Psoriasis and Psoriatic Arthritis: section 1. Overview of Psoriasis and guidelines of care for the treatment of Psoriasis with biologics. *J Am Acad Dermatol* 2008;58: 826-850.
- Feldman SF, Koo JY, et al. The Psoriasis and Psoriatic pocket guide: treatment algorithms and management options. National Psoriasis Foundation. Available from: www.psoriasis.org. [Accessed: October 8, 2009].

Created: 10/09
Effective: 02/15/11 Client Approval: 02/01/11

ASCENSION HEALTH
MEDICATION REQUEST GUIDELINES

INDEX

F

G

H

I

J

K

L

M

N

O

P

Q

R

S

T

U

V

X

Z