MEDICA®

Prior Authorization (PA) Guidelines

Administered by

Medica Prior Authorization Guidelines have been reviewed and are current as of 05/01/2009. The guidelines are subject to change and are not a guarantee of coverage.

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Generic Name: Alefacept

Brand Name: Amevive

GUIDELINES FOR USE

Alefacept will be provided as a plan benefit within the following guidelines:

Initial Criteria:

1. Is the prescription written by a dermatologist or recommended by a dermatologist?

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

2. Does the patient have a diagnosis of chronic moderate to severe plaque psoriasis (a minimum body surface area involvement of 5%)?

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

3. If the body surface area affected is less than 5%, does the patient have chronic plaque psoriasis of the palms, soles of feet, face, or genitalia that interferes with daily activities?

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

4. Has the patient tried conventional systemic psoriasis therapies from at least 2 of the following 3 groups: Topicals (corticosteroids, calcipotriene, tazarotene, and coal tar), oral systemic agents (cyclosporine, methotrexate, and acitretin) and /or phototherapy/photochemotherapy..

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

5 Are the above therapies contraindicated for this patient?

   If yes, continue to #6. If no, do not approve.

6. Approve for up to 6 months per calendar year with a quantity limit of 4 vials per month. (MAX DAILY DOSE=0.14) POPULATE THE MAX DAILY DOSE FIELD WITH 0.14

Rationale:

Per Health Plan.

FDA Approved Indication:

Amevive is indicated for the treatment of adult patients (18 years or older) with chronic moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

References:

Amevive product information, Biogen, Inc. 2003.

Callen et al. AAD Consensus Statement on Psoriasis Therapies. J Am Acad Derm. 2003:49:897-899.

Created: 12/01/04 KS Updated: 12/2007 CBR

Generic Name: Anakinra

Brand Name: Kineret

GUIDELINES FOR USE

1. Has Kineret been prescribed by or recommended by a rheumatologist?

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

2. Does the patient have a diagnosis of chronic infantile neurological, cutaneous and articular syndrome (CINCA) or neonatal-onset multisystem inflammatory disease (NOMID), which is treatment-refractory?

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

3. Does the patient have a diagnosis of rheumatoid arthritis?

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

4. Has the patient tried and failed a 3-month trial of methotrexate or does the patient have a contraindication or intolerance to methotrexate?

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

5. Does the patient have an active infection or a history of recurring infections?

   If yes, do not approve. If no, continue to #6.

6. **Approve 1 syringe (100mg) per day for 12 months. (MAX DAILY DOSE=0.67) Populate the max daily dose field with 0.67**

Rationale:
Per Health Plan

FDA Approved Indication:
Kineret is indicated for the reduction in signs and symptoms and slowing the progression of structural damage in moderately to severely active rheumatoid arthritis, in patients 18 years of age or older who have failed 1 or more disease modifying antirheumatic drugs (DMARDs).

References:

1. Kineret Product Information, Amgen.
2. Olsen, Nancy J; Stein, Michael C. Drug Therapy: New Drugs for Rheumatoid Arthritis. NEJM. 2004;350(21):2167-2179.
3. American College of Rheumatology. Guidelines for the Management of Rheumatoid Arthritis. Arth & Rheum. 2002:46(2):328-346.

Created: 06/03/05KH Updated:12/2007 CBR

Generic Name: Apomorphine

Brand Name: Apokyn

GUIDELINES FOR USE

Apomorphine will be provided as a plan benefit within the following guidelines:

1. Has treatment been initiated and/or recommended by a Neurologist?

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

2. Is the patient currently taking a 5-HT3 antagonist, such as Zofran, Kytril, Anzemet, Aloxi, or Lotronex?

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

3. Is the patient receiving concurrent medication for the treatment of Parkinson's disease such as Sinemet (carbidopa/levodopa), Sinemet CR (carbidopa/levodopa SR), Stalevo (carbidopa/levodopa/entacapone), Lodosyn (carbidopa), Permax (pergolide), Mirapex (pramipexole), Requip (ropinirole), Comtan (entacapone), Tasmar (tolcapone), or Eldepryl (selegiline)?

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

4. **Approve for 12 months, maximum of 15 cartridges per month (one cartridge = 30mg).**

Rationale:
Ensure use consistent with FDA indication.

FDA Approved Indication:
Apokyn is indicated for the acute, intermittent treatment of hypomobility, *off* episodes (end-of-dose wearing off and unpredictable on/off episodes), associated with advanced Parkinson's disease. Apokyn has been studied as an adjunct to other medications.

References:
Apokyn Package Insert. Mylan Bertek Pharmaceuticals 2004.

Created: 12/01/04 SVK Updated:________

Generic Name: C1 Inhibitor

Brand Name: Cinryze

GUIDELINES FOR USE

C1 Inhibitor (Cinryze) will be provided as a plan benefit within the following guidelines:

1. Is the prescribing physician a specialist in allergy, immunology or hematology?
   a. If yes, continue to #2
   b. If no, do not approve
2. Is the member ≥ 9 y.o.?
   c. If yes, continue to #3
   d. If no, do not approve
3. Does the member have a diagnosis of hereditary angioedema (HAE) documented by C1 inhibitor enzyme deficiency (copy of lab results required)?
   e. If yes, continue to #4
   f. If no, do not approve
4. Has the member tried and not responded to treatment with oxandrolone, or danazol, or aminocaproic acid, or is therapy with these drugs not tolerated or contraindicated?
   g. If yes, continue to #5
   h. If no, do not approve
5. Is the medication being used for the prophylaxis of hereditary angioedema?
   i. If yes, continue to #7
   j. If no, continue #6
6. Is the medication being as treatment for an acute HAE attack?
   k. If yes, continue to #8
   l. If no, do not approve
7. Approve up to 20 vials per 30 days
8. Approve up to 4 vials per copay.

RATIONALE

Ensure use consistent with FDA indication and medical literature supported use.

FDA APPROVED INDICATION

Cinryze is indicated for routine prophylaxis against angioedema attacks in adolescents (≥ 9 y.o.) and adult patients with hereditary angioedema.

REFERENCES

Cinryze Package Insert. Viropharma 2008.

Status: Formulary Created: 03/10/09 CBR

Effective Date: 4/01/09 Client Approved: ________ P & T Approval: ________

Generic Name: Ciclopirox 8% topical solution

Brand Name: Penlac

GUIDELINES FOR USE:

1. Is the prescription for onychomycosis (also known as tinea ungium or dermatophytosis of the nail)?

    If yes, have Dr.'s office submit MRF along with a lab culture dated within the last 6 months.

    If no, have Dr.'s office submit MRF (no lab is necessary).

Initial Criteria:

1. Is the prescription for onychomycosis (also known as tinea ungium or dermatophytosis of the nail)?

    If yes, to continue to #2. If no, submit to Medica for review.

2. Has onychomycosis been confirmed by a positive PAS stain (copy of lab report must be submitted and dated within 6 months of the submitted request) or has a dermatophyte been identified as the causative agent by a recent culture (copy of lab report must be submitted and dated within 6 months of the submitted request)?

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

3. Is the patient suffering from diabetes mellitus or is the patient immunocompromised?

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

4. Does the provider consider the onychomycosis medically significant? Medically significant can be defined as causing the patient impaired mobility or significant discomfort.

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

5. **Approve for up to 12 months**.

Renewal Criteria:

1. Has a recent culture or PAS stain shown that the infecting organism is a fungus? A culture or PAS stain is considered recent if taken more than 6 months after discontinuation of initial course of therapy for fingernail infections, and more than 9 months after discontinuation of initial course of therapy for toenail infections.

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

2. **Approve for up to 12 months**.

CONTINUE NEXT PAGE

Generic Name: Ciclopirox 8% topical solution (continued)

Brand Name: Penlac

Rationale:

To encourage appropriate use of Penlac topical solution.

FDA Approved Indication:

Penlac (ciclopirox 8% topical solution) is indicated for the treatment of mild to moderate onychomycosis of the toenail or fingernail due to *Trichophyton rubrum*.

References:

1. Penlac Product Information. 2003.
2. Med**Impact** Onychomycosis Monograph. August, 2002.
3. Weinberg, JM et al. Comparison of Diagnostic Methods in the Evaluation of Onychomycosis. J Am Acad Dermatol. 2003, vol.49.

Created: 12/01/04 KS Updated: ___________

Generic Name: Darbepoetin Alfa

Brand Name: Aranesp

GUIDELINES FOR USE

1. Is the patient being treated for one of the following?
   a. Anemia associated with chronic renal failure?
   b. Anemia due to the effect of concomitantly administered chemotherapy?

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

2. Does the patient have documented hemoglobin less than 12gm/dL (lab result must be within the most recent 60 days)?

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

3. Does the patient have a diagnosis of myelodysplastic syndrome with a hematocrit of < 29% or hemoglobin level < 10 mg/dL (lab results must be within the most recent 60 days)?

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

4. **Approve for the following duration depending on diagnosis and continue to #5:**

   Renal failure – approve for defined treatment duration or 6 months, whichever is less.

   Cancer chemotherapy – approve for course of treatment based on chemotherapy cycle.

   Quantity limits: 4 vials per 30 days or per copay.

Rationale:

Ensure appropriate utilization.

FDA Approved Indications:

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 nonmyeloid malignancies.

References:

1. Amgen, Aranesp product information, Thousand Oaks, CA, March 2007.
2. National Kidney Foundation. K/DOQI Clinical Practice Guidelines for Anemia of Chronic Kidney Disease, 2000. Am J Kidney Dis 2001; 37:s182-s238 (suppl 1).

Created: 12/01/2007 CBR Updated:__________

Generic Name: Dronabinol
Brand Name: Marinol

GUIDELINES FOR USE

Dronabinol (Marinol) will be provided as a plan benefit within the following guidelines:

1. Is the member being treated for anorexia associated weight loss due to AIDS or HIV- Wasting Syndrome?
   If yes, continue to #4.
   If no, continue to #2.
2. Is the member being treated for Chemotherapy Induced Nausea & Vomiting (CINV)?
   If yes, continue to #3.
   If no, do not approve due to lack of indication (including diagnosis of cancer without concomitant treatment with chemotherapy or radiation).
3. Is the member experiencing breakthrough symptoms of nausea and/or vomiting despite receiving prior treatment with first-line antiemetic medications such as Emend (aprepitant), Zofran (ondansetron), Kytril (granisetron), Anzemet (dolasetron) Compazine (prochlorperazine), Reglan (metoclopramide), or Phenergan (promethazine)?

   If yes, continue to #5

   If no, deny and recommend formulary conventional antiemetics as primary therapy.
4. **Approve for up to 6 months (Populate Max Daily Dose = 2) Note: only approve up to 2 units daily – partial approval for quantities greater than 2 units daily.**
5. **Approve for length of chemotherapy course or up to 6 months (Populate Max Daily Dose = 2) Note: only approve up to 2 units daily – partial approval for quantities greater than 2 units daily.**

RATIONALE

Per Health Plan to require diagnosis prior to approval of coverage (Prior Authorization Required).

FDA APPROVED INDICATION

Chemotherapy Induced Nausea and Vomiting (CINV) secondary to conventional anti-emetic therapy. (Marinol & Cesamet).

Anorexia associated weight loss due to AIDS or HIV. (Marinol).

REFERENCES

Per Health Plan.

Status: FORMULARY-PA
Created: 04/09/2008 JW Updated: _08/28/08 SJS__________ Reviewed: ________

Generic Name: Efalizumab

Brand Name: Raptiva

GUIDELINES FOR USE

Efalizumab will be provided as a plan benefit within the following guidelines:

1. Is the prescription written by a dermatologist or recommended by a dermatologist?

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

2. Does the patient have a diagnosis of chronic moderate to severe plaque psoriasis (a minimum body surface area involvement of 5%)?

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

3. If the body surface area affected is less than 5%, does the patient have chronic plaque psoriasis of the palms, soles of feet, face, or genitalia that interferes with daily activities?

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

4. Has the patient tried conventional systemic psoriasis therapy, such as methotrexate, cyclosporine, acitretin/Soriatane, or phototherapy?

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

5. Is there a medical reason why the patient has not tried conventional systemic psoriasis therapy? Please list reason.

   If yes, continue to #6. If no, do not approve.

6. Does the patient weigh more than 275 lbs.?

   If yes, approve up to 8 vials per month for 12 months. **If no, approve up to 4 vials per month for 12 months.**

Rationale:
Per Health Plan.

FDA Approved Indication:
Raptiva is indicated for the treatment of adult patients (18 years or older) with chronic moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

References:

1. Raptiva product information, Genentech 2003.
2. Callen et al. AAD Consensus Statement on Psoriasis Therapies. J Am Acad Derm. 2003:49:897-899.

Created: 12/01/04 KS Updated: 06/03/05KH

Generic Name: **Eltrombopag**

Brand Name: **Promacta**

GUIDELINES FOR USE

Eltrombopag will be provided as a plan benefit within the following guidelines:

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. (Deny for lack of indication)
2. Did the patient have inadequate response to corticosteroids, immunoglobulins, or splenectomy?
   If yes, continue to #3.
   If no, do not approve. (Denial text: This medication is covered only after a trial or corticosteroids, immunoglobulin or splenectomy)
3. **Approve up to 75mg per day for one month.**
   - **Note: Approve one 50mg tablet MDD = 1 or three of the 25mg tablets (75mg) MDD = 3.**

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. (Deny for lack of indication)
2. Did the patient receive the maximum dose of 75mg for 4 consecutive weeks?
   If yes, continue to #3.
   If no, continue to #4.
3. Did the patient have a clinical response, as defined by an increase in platelet count to $\geq 50X10^9/L$?
   If yes, continue to #4.
   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 dosing)
4. **Approve up to 75mg per day per month X 12 months.**
   - **Note: Approve one 50mg tablet MDD = 1 or three of the 25mg tablets (75mg) MDD = 3.**

RATIONALE

To ensure appropriate utilization of Promacta.

FDA APPROVED INDICATION

Eltrombopag is indicated for the treatment of thrombocytopenia patients with chronic idiopathic thrombocytopenic purpura (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy.

REFERENCES

Promactal Product Information.

Status: Formulary
Created: 2/25/09 SJS   Updated: ___________   Reviewed: ________

Generic Name: Enfuvirtide

Brand Name: Fuzeon

GUIDELINES FOR USE

Enfuvirtide will be provided as a plan benefit within the following guidelines:

1. Is the member at least 6 years old?
   If yes, continue to # 2 If no, do not approve
2. Is the request from an infectious disease physician?
   If yes, continue to #4. If no, continue to #3.
3. Does the patient have a diagnosis of HIV/AIDS and has the patient tried/failed at least one HAART regimen?
   If yes, continue to #4. If no, do not approve.
4. **Approve for 1 kit/month for 12 months**. **(MAX DAILY DOSE=0.03) Populate the max daily dose field with 0.03**

Rationale:
Per Health Plan

FDA Approved Indication:
Treatment of HIV-1 infection in treatment-experienced patients.

References:
Per Health Plan

Created: 06/17/03 KH Updated: 12/2007 CBR

Generic Name: Epoetin Alfa

Brand Name: Epogen/ Procrit

GUIDELINES FOR USE

Epoeitin Alfa will be provided as a plan benefit within the following guidelines:

1. Does the patient have chronic kidney disease?

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

2. Does the patient have documented hemoglobin less than 11gm/dL (lab result must be within the most recent 60 days)?

   If yes, continue to #11. If no, do not approve.

3. Does the patient have anemia related to AZT therapy?

   If yes, continue to #10. If no, continue to #4.

4. Is the patient being treated for anemia due to the effect of concomitantly Administered chemotherapy?

   If yes, continue to #10. If no, continue to #5.

5. Is the patient scheduled for elective, noncardiac, nonvascular surgery and is the patient's hemoglobin level greater than 10mg/dL and less than or equal to 12gm/dL (lab results must be within the most recent 60 days)?

   If yes, continue to #11. If no, continue to #6.

6. Does the patient have a diagnosis of myelodysplastic syndrome with a hematocrit of < 29% or hemoglobin level < 10 mg/dL (lab results must be within the most recent 60 days)?

   If yes, continue to #11. If no, continue to #7.

7. Does the patient have anemia of chronic disease characterized by hematocrit ≤ 24% or Hgb < 10 g/dL, and transferrin saturation < 20% and ferritin is < 100 ng/mL (lab results must be within the most recent 60 days)?

   If yes, continue to #11. If no, continue to #8

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Generic Name: Epoetin Alfa (con't)

Brand Name: Epogen/ Procrit (con't)

8. Is patient an infant and have anemia as a result of low birth weight (< 1500 grams) and hematocrit < 32% or hemoglobin < 10 mg/dL(lab results from the most recent 60 days)?

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

9. Does the patient have Hepatitis C with a Hgb < 12 g/dL and being treated with interferon and ribavirin (lab results must be within the most recent 60 days)?

   If yes, continue to #11. If no, do not approve.

10. Does the patient have documented hemoglobin less than 12gm/dL (lab result must be within the most recent 60 days)?

   If yes, continue to #11. If no, do not approve.

11. **Approve for the defined treatment period or 6 months, whichever is less, with the following quantity limits:**
    - 2,000U, 3,000U, 4,000U and 10,000U vials: 12 vials per 30 days or per copay.
    - 20,000U and 40,000U vials: 4 vials per 30 days or per copay.

Rationale:
Ensure appropriate utilization.

FDA Approved Indications:
Epoetin alfa is indicated for the treatment of anemia of chronic renal failure patients; treatment of anemia in zidovudine-treated HIV infected patients; treatment of anemia in cancer patients receiving chemotherapy; and reduction of allogenic blood transfusions in patients undergoing elective surgery.

References:

1. Ortho Biotech, Procrit product information, Raritan, New Jersey, March 2007.
2. Amgen, Epogen product information, Thousand Oaks, CA, March 2007.
3. National Kidney Foundation. K/DOQI Clinical Practice Guidelines for Anemia of Chronic Kidney Disease, 2000. Am J Kidney Dis 2001; 37: s182-s238 (suppl 1).
4. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology Cancer and Treatment-related anemia. Available at: http://www.ncc.org.professionals/physician-gls/PDF/anemia.pdf
5. Eagel K, et al. ACC/AHA guideline update on perioperative cardiovascular evaluation of noncardiac surgery. A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. American College of Cardiology and the American Hearth Association, Inc 2002; 1-58.
6. Weiss G, Goodnough L. Anemia of Chronic Disease. NEJM 2005; 352: 1001-23.
7. Rizzo JD, et al. Use of epoetin in patients with cancer: evidence-based clinical practice guidelines of the American Society of Clinical Oncology and the American Society of Hematology. J Clin Oncol 2002; 20 (19): 4083-107.
8. Voldering P, et al. Anemia in HIV Infection: Clinical Impact and Evidence Based Management Strategies. CID 2004; 38: 1454-63.

Created: 12/01/2007 CBR Updated:

Generic Name: Everolimus

Brand Name: Afinitor

GUIDELINES FOR USE

Everolimus (Afuinitor) will be provided as a plan benefit within the following guidelines:

1. Is the prescribing physician a specialist in oncology or hematology?
    - m. If yes, continue to #2
    - n. If no, do not approve
2. Does the member have a diagnosis of renal cell carcinoma?
    - o. If yes, continue to #3
    - p. If no, do not approve
3. Has the member tried and not responded to treatment with sunitinib (Sutent) or sorafenib (Nexavar), or is therapy with these drugs not tolerated or contraindicated?
    - q. If yes, continue to #4
    - r. If no, do not approve
4. Approve 1 tablet daily 30 for 6 months – Max 30 day supply per fill

RATIONALE

Ensure use consistent with FDA indication and medical literature supported use.

FDA APPROVED INDICATION

Afinitor is indicated for the treatment of adults with advanced renal cell carcinoma after failure with sunitinib or sorafenib.

REFERENCES

Afinitor Package Insert. Novartis 2009.

Status: Formulary
Created: 041409 CBR Effective Date: 4/14/09

Generic Name: Fentanyl, Transmucosal

Fentanyl citrate lollipops
Fentanyl buccal tablets

Brand Name: Actiq
Fentora

GUIDELINES FOR USE:

Initial Criteria (No Previous Use within past 12 months):

1. Does the member have a diagnosis of cancer?

   If yes, continue to #2.

   If no do not approve; forward to Medica for review.

2. Is the member currently taking a long-acting opioid analgesic agent and this long-acting agent is going to be continued for maintenance pain control (is the member currently Opioid Tolerant)?

Long Acting Opioids Examples Include:

Brand name	Generic Name
Duragesic Patches	fentanyl transdermal
Oxycontin	oxycodone CR
MS Contin	morphine SR
Avinza	morphine LA
Kadian	morphine LA
Opana ER	oxymorphone ER
Oramorph ER/SR	morphine SR
Opioid Tolerance is considered present when morphine 60mg per day or fentanyl 50mcg per hour (or equianalgesic dose) for at least 7 consecutive days)	

If yes, continue to #3.

If no, do not approve; transmucosal & buccal fentanyl is for opioid-tolerant patients and indicated to be used as needed for breakthrough pain only.

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Generic Name: Fentanyl, Transmucosal (continued)

Fentanyl citrate lollipops
Fentanyl buccal tablets

Brand Name: Actiq (continued
Fentora

GUIDELINES FOR USE (continued):

3. Does the member have uncontrolled nausea/vomiting, esophagitis, or dysphasia (or similar condition resulting in NPO [nothing-by-mouth] status), AND is unable to swallow oral medications for breakthrough pain medications due to one of these conditions?

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

4. Has the member tried and failed at least two other non-oral route of administration products for breakthrough pain control?

Non-Oral Short Acting Examples Include:

Brand	Generic	Route of Administration
Dilaudid	hydromorphone	Rectal Suppositories
Roxanol, MS-IR liquid	morphine	Oral concentrate (SL or buccal administration), or oral suspension
RMS	morphine	Rectal suppositories
OxyFast, OxyIR, Roxicodone Intensol, Eth-Oxydose	oxycodone	Oral concentrate (SL or buccal administration)
Morphine Soluble Tab	morphine	Soluble/oral disintegrating tablets
Self-administered injections of opioid products (SQ, IM, PCA, etc.) can count towards one non-oral route of administration attempt, but do not recommend this route as an alternative route of administration.		

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

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Generic Name: Fentanyl, Transmucosal (continued)
Fentanyl citrate lollipops
Fentanyl buccal tablets

Brand Name: Actiq (continued)
Fentora

GUIDELINES FOR USE (continued):

5. Has the member tried and failed at least two short-acting high potency opioid agents for breakthrough pain relief?

Examples of Higher Potency Oral Opioids:

Brand	Generic	Route of Administration
Dilaudid	hydromorphone	Any
Roxanol, MS-IR, RMS,	morphine	Any
Demerol	meperidine	Any
OxyFast, OxyIR, Roxicodone Intensol, Eth-Oxydose	oxycodone	Any
Dolophine	methadone	Any
Percocet, Roxicet, Tylox, Percodan, Lynox, Perlox	oxycodone/acetaminophen	Any
Vicodin, Xodol, Lortab, Lorcet, Norco	hydrocodone/acetaminophen	Any
Opana IR	oxymorphone	Any
Codeine/acetaminophen and propoxyphene/acetaminophen products should not count towards the trial/failure formulary alternatives for qualification for Actiq.		

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

6. Does the member have a documented medication allergy to morphine, oxycodone, hydrocodone, codeine, AND hydromorphone or is the physician concerned about cross-sensitivity that may result in anaphylaxis or severe allergy to one of these other medications?

If yes, continue to #8. If no, do not approve and recommend trial/failure of at least two other oral formulary high-potency opioid alternatives.

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Generic Name: Fentanyl, Transmucosal (continued)
Fentanyl citrate lollipops
Fentanyl buccal tablets

Brand Name: Actiq (continued)
Fentora

GUIDELINES FOR USE (continued):

7. Does the member have a documented medication allergy to morphine and oxycodone or is the physician concerned about cross-sensitivity that may result in anaphylaxis or severe allergy to one of these other medications?

   If yes, continue to #8.

   If no, do not approve and recommend trial/failure of at least two other non-oral routes of administration formulary higher potency opioid alternatives. (Medication allergy required, not side effects).

8. Is the request for fentanyl lollipops?

   If yes, continue to #10.

   If no, continue to #9.

9. Is the request for Fentora and has the member tried and failed generic fentanyl lollipops?

   If yes, continue to #10.

   If no do not approve and recommend trial/failure of generic fentanyl lollipops. (Note: generic also requires PA, so you may enter PA for what would be approved).

10. **Approve for up to 6 months (MAX DAILY DOSE = 4) at the HICL Level**.

**** Actiq, fentanyl lollipops, and Fentora are approved for only 4 units per day of any strength at any given time.**

Renewal Criteria (Previous PA History within past 12 months):

1. Is the diagnosis cancer AND Is there are previous PA approved within the past 12 months for any strength of Actiq, fentanyl lollipops, or Fentora ?

   If yes, continue to #2.

   If no, return to initial guidelines.

2. Is the member still taking a long acting opioid product for maintenance pain control?

   If yes, continue to #3

   If no, deny due to no long acting medication.

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Generic Name: Fentanyl, Transmucosal (continued)
Fentanyl citrate lollipops
Fentanyl buccal tablets

Brand Name: Actiq (continued)
Fentora

GUIDELINES FOR USE (continued):

3. I Is this request for a dose increase or dose decrease causing a refill too soon rejection issue?

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

4. Approve early refill x 1 fill, and continue to #5.
5. **Approve for up to 6 months (MAX DAILY DOSE = 4) at the HICL Level for the new dose. Please note to approve early refill if needed due to QL in place at the HICL level**.

   ****Actiq, fentanyl lollipops, and Fentora are approved for only 4 units per day of any strength at any given time.**

Rationale:
Per health plan, to ensure appropriate use of Actiq for breakthrough pain relief, in combination with a long-acting opioid medication regimen in patients with chronic pain secondary to cancer. Actiq is not to be used as a first-line opioid pain relieving agent and should be reserved for use when other agents are ineffective, contraindicated, or not tolerated per guidelines. Actiq should never be used without a concomitant long acting opioid medication.

FDA Approved Indication:
Actiq is indicated only for the management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.

References:

1. Actiq Product Information, Cephalon, Inc. 2004.
2. Fentanyl citrate Product Information, Barr Labs, 2006.
3. Fentora Product Information, Cephalon, Inc 2006.
4. Healthcare Guidelines: Assessment and Management of Acute Pain. ICSI March 2006. www.ICSI.org accessed 8/21/2006.
5. Healthcare Guidelines: Assessment and Management of Chronic Pain. ICSI May 2006. www.ICSI.org accessed 8/21/2006.
6. Healthcare Guidelines: Headache Diagnosis and Treatment. ICSI Jan 2006. www.ICSI.org accessed 8/21/2006.

Status: Formulary/Non-formulary - PA Required
Created: 01/01/06ML Updated: 7/11/07 JW

Generic Name: Itraconazole (Capsules)

Brand Name: Sporanox (Capsules)

GUIDELINES FOR USE

Initial Criteria:

1. Is the prescription for onychomycosis (also known as tinea ungium or dermatophytosis of the nail)?

   If yes, continue to #2. If no, continue to #7.

2. Has the member tried and failed terbinafine (Lamisil) tablets?

   If yes, continue to #3 If no, deny recommend terbinafine (Lamisil) tablets.

3. Has onychomycosis been confirmed by a positive PAS stain (copy of lab report must be submitted and dated within 6 months of the submitted request) **or** has a dermatophyte been identified as the causative agent by a recent culture (copy of lab report must be submitted and dated within 6 months of the submitted request) AND has it been 9 months since the last oral antifungal treatment for onychomycosis

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

4. Is the patient suffering from diabetes mellitus or is the patient immunocompromised?

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

5. Does the provider consider the onychomycosis medically significant? Medically significant can be defined as causing the patient impaired mobility or significant discomfort.

   If yes, continue to #6. If no, do not approve.

6. **Approve 200mg (#2 capsules) daily for up to 3 months for traditional therapy, or 400mg (#4 capsules) daily for 1 week per month for up to 4 months (#28 capsules per month) for pulse therapy.**

CONTINUED ON NEXT PAGE

Generic Name: Itraconazole (Capsules) (continued)

Brand Name: Sporanox (Capsules) (continued)

GUIDELINES FOR USE: **(continued)**

7. Is the prescription for *tinea corporis, tinea cruris,* or *tinea pedis*?

   If yes, do not approve, recommend member try & fail topicals or terbinafine (Lamisil),ketoconazole (Nizoral), .fluconazole (Diflucan), or griseofulvin (Fulvicin, GrisPeg).

   If no, continue to # 8.

8. Is the prescription for pulmonary (Lung) or extrapulmonary (systemic or blood) fungal infections due to aspergillosis, histoplasmosis, sporotrichosis, paracoccidioidomycosis, chromomycosis, or blastomycosis?

   If yes, continue to #10. If no, continue to #9

9. Is the prescription from or recommended by an infectious disease specialist or pulmonologist?

   If yes, continue to #10. If no, do not approve.

10. **Approve for up to 12 months or for the requested dose.**

Renewal Criteria for Onychomycosis:

1. Has the member tried and failed terbinafine (Lamisil) tablets and has it been at least 9 months since discontinuation of therapy?

   If yes, continue to #2 If no, deny and recommend trial of terbinafine (Lamisil) tablets.

2. Has a recent culture or PAS stain shown that the infecting organism is a fungus? A culture is considered recent if taken more than 6 months after discontinuation of initial course of therapy for fingernail infections AND more than 9 months after discontinuation of initial course of therapy for toenail infections.

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

3. **Approve 200mg (#2 capsules) daily for up to 3 months for traditional therapy, or 400mg (#4 capsules) daily for 1 week per month for up to 4 months (#28 capsules per month) for pulse therapy.**

CONTINUED ON NEXT PAGE

Generic Name: Itraconazole capsules (continued)

Brand Name: Sporanox capsules (continued)

Rationale:
Encourage appropriate use of Sporanox capsules.

FDA Approved Indication:
Sporanox (itraconazole) capsules are indicated for the treatment of the following fungal infections in immunocompromised and non-immunocompromised patients:

1. Blastomycosis, pulmonary and extrapulmonary.
2. Histoplasmosis, including chronic cavitary pulmonary disease and disseminated, non-meningeal histoplasmosis, and
3. Aspergillosis, pulmonary and extrapulmonary, in patients who are intolerant of or who are refractory to amphotericin B therapy.

Sporanox capsules are also indicated for the treatment of the following fungal infections in non-immunocompromised patients:
1. Onychomycosis of the toenail, with or without fingernail involvement, due to dermatophytes (tinea unguium), and
2. Onychomycosis of the fingernail due to dermatophytes (tinea unguium).

References:

1. Onychomycosis. Med**Impact** P&T Monograph, August 2002.
2. Sporanox Capsules product information. Janssen. February 2002.
3. Onychomycosis New Treatments are Effective. Accessed from www.medscape.com November 11, 2002.
4. Weimberg, JM et al. Comparison of Diagnostic Methods in the Evaluation of Onychomycosis. J Am Acad Dermatol. 2003, vol 49.

Status: FormularyPA
Created: 04/01/01 ZN Updated: 08/13/07JW

Generic Name: Itraconazole (Oral Solution)

Brand Name: Sporanox (Oral Solution)

GUIDELINES FOR USE

1. Does the patient have either oropharyngeal or esophageal candidiasis?
   If yes, continue to #2.
   If no, do not approve.
2. Does the patient have HIV?
   If yes, continue to #3.
   If no, continue to #5.
3. Is the CD4 count less than 50?
   If yes, continue to #4.
   If no, continue to #5.
4. Has the patient tried and failed fluconazole?
   If yes, continue to #6.
   If no, do not approve.
5. Has the patient tried and failed two formulary antifungals (examples include fluconazole, clotrimazole troches and nystatin suspension)?
   If yes, continue to #6.
   If no, do not approve.
6. **Approve for 12 months.**

Rationale:
Per Health Plan.

FDA Approved Indication:

References:
Per Health Plan.

Created: 04/01/01 ZN Updated: 12/2007 CBR

Generic Name: Linezolid

Brand Name: Zyvox

GUIDELINES FOR USE

Linezolid will be provided as a plan benefit within the following guidelines:

1. Was the patient started in the hospital on IV Zyvox, and is this prescription for oral Zyvox to enable continuation of therapy in an outpatient setting?

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

2. Does the patient have an infection and a documented blood, tissue or sputum culture, which is positive for *Vancomycin-resistant enterococcus* (VRE)?

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

3. Does the patient have an infection and a documented blood, tissue or sputum culture, which is positive for *Methicillin-resistant staphylococcus* (MRSA)?

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

4. **Approve for one time only.**

Rationale:
Per Health Plan.

FDA Approved Indication:

References:
Per Health Plan.

Created: 04/01/01 ZN Updated: 03/03/05 KH

Generic Name: Mecasermin

Brand Name: Increlex

GUIDELINES FOR USE:

1. Does the patient have Primary IGF-1 deficiency (Primary IGFD) defined by:
   - height standard deviation score ≤ -3.0 AND
   - basal IGF-1 standard deviation score < -2.0 AND
   - normal or elevated growth hormone (GH)?

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

2. Does the patient have growth hormone deletion and developed neutralizing antibodies to growth hormone?

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

3. **Approve for 12 months**.

Recommended Dosing:

The recommended starting dose of Increlex is 0.04 – 0.08mg/kg (40-80mcg/kg) twice daily SQ administered within 20 minutes of a meal or snack. If well tolerated for at least one week, the dose may be increased by 0.04mg/kg per dose to the maximum dose of 0.12mg/kg given twice daily. Doses greater than this have not been evaluated.

Rationale:

Ensure appropriate use of mecasermin (insulin-like growth factor-1).

FDA Approved Indication:

Increlex and IPLEX are indicated for the long-term treatment of growth failure in children with severe primary IGF-1 deficiency or with growth hormone (GH) gene deletion who have developed neutralizing antibodies to GH.

References:

1. Product Package Insert, Increlex, Tercica, Inc. Aug 2005.
2. Product Package Insert, IPLEX, Insmed, 2006.

Created: 11/21/05 ML Updated: 07/01/06 CBR

Generic Name: Nabilone

Brand Name: Cesamet

GUIDELINES FOR USE

Cesamet will be provided as a plan benefit within the following guidelines:

1. Is the member being treated for Chemotherapy Induced Nausea & Vomiting (CINV)?
   If yes, continue to #2.
   If no, do not approve due to lack of indication (including diagnosis of cancer without concomitant treatment with chemotherapy or radiation).
2. Is the member experiencing breakthrough symptoms of nausea and/or vomiting despite receiving prior treatment with first-line antiemetic medications such as Emend (aprepitant), ondansetron (Zofran), granisetron (Kytril), prochlorperazine (Compazine), metoclopramide (Reglan), or promethazine (Phenergan)?

   If yes, continue to #3

   If no, deny and recommend formulary antiemetics as primary therapy.
3. Does the member have an open formulary benefit?

   If yes, continue to #5

   If no, continue to #4
4. Has the member previously tried dronabinol (Marinol)?

   If yes, continue to #6

   If no, deny and recommend trial of dronabinol (Marinol) (Note: Remember to have the PAC's enter an approved PA for dronabinol
5. **Approve Prior Authorization for length of chemotherapy course or up to 6 months (Populate Max Daily Dose = 4) at the non-formulary copay level. Note: only approve up to 4 units daily – partial approval for quantities greater than 4 units daily.**
6. **Approve Prior Authorization and override formulary status for length of chemotherapy course or up to 6 months (Populate Max Daily Dose = 4). Note: only approve up to 4 units daily – partial approval for quantities greater than 4 units daily.**

RATIONALE
Per Health Plan to require diagnosis prior to approval of coverage (Prior Authorization Required).

FDA APPROVED INDICATION
Chemotherapy Induced Nausea and Vomiting (CINV) secondary to conventional anti-emetic therapy. (Marinol & Cesamet).

Anorexia associated weight loss due to AIDS or HIV. (Marinol).

REFERENCES
Per Health Plan.Status: FORMULARY-PA
Created: 04/09/2008 JW Updated: ___________ Reviewed: ___________

Generic Name: Omalizumab

Brand Name: Xolair

GUIDELINES FOR USE

Omalizumab will be provided as a plan benefit within the following guidelines:

1. Is the prescription written by a Pulmonologist, Allergist, or Immunologist?

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

2. Is the patient 12 years of age or older?

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

3. Does the patient have a diagnosis of moderate to severe persistent allergic asthma?

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

4. Is the patient's FEV1 <80% of predicted? *(Documentation must be provided).*

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

5. Does the patient have a documented positive skin test or RAST test to a perennial aeroallergen? *(Documentation must be provided).*

   If yes, continue to #6. If no, do not approve.

6. Has the patient <u>*demonstrated therapeutic failure*</u> to an inhaled or oral corticosteroid product (such as inhaled Azmacort, Flovent, Qvar, Aerobid Aerobid-M, Beclovent, Vanceril or oral prednisone, prednisolone, methylprednisolone) ***combined*** with a second asthma controller agent such as a long-acting inhaled beta2-agonist (i.e., Serevent, Foradil), leukotriene modifier (i.e., Singulair or Accolate), theophylline or combination products (i.e., Advair-fluticasone/salmeterol)? (*Documentation of drug(s) and dosage must be provided).*

   If yes, continue to #7. If no, do not approve.

7. Is the patient's IgE level > 30 IU/mL? *(Documentation must be provided).*

   If yes, continue to #8. If no, do not approve.

8. Is the patient's body weight < 150 kg?

   If yes, continue to #9. If no, do not approve.

9. **Approve for up to 12 months with a quantity limit of #6 vials/30 days.**

CONTINUED ON NEXT PAGE

Generic Name: Omalizumab (continued)

Brand Name: Xolair (continued)

GUIDELINES FOR USE (continued)

Rationale:
Per Health Plan.

FDA Approved Indication:
Xolair is indicated for 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. Xolair has been shown to decrease the incidence of asthma exacerbations in these patients. Safety and efficacy have not been established in other allergic conditions.

References:
Per Health Plan.

Created: 09/24/03 MM Updated: ___________

Generic Name: **Plerixafor**

Brand Name: **Mozobil**

<u>GUIDELINES FOR USE:</u>

Plerixafor will be provided as a plan benefit within the following guidelines:

1. Does the patient have a diagnosis of Non-Hodgkins Lymphoma or Multiple Myeloma?
    a. If yes, continue to #2.
    b. If no, do not approve
2. Is the patient receiving Mozobil (plerixafor) in combination with G-CSF prior to apheresis in preparation for stem cell harvest and bone marrow transplant?
    a. If yes, continue to #3.
    b. If no, do not approve
3. **Approve up to 4 units per treatment if pt is ≤ 100 kg. If member weighs > 100kg, approve up to 8 units per treatment.**

RATIONALE

Ensure use consistent with FDA Indication

FDA APPROVED INDICATION

Mozobil, a hematopoietic stem cell mobilizer, is indicated in combination with granulocyte-colony stimulating factor (G-CSF) to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with non-Hodgkin's lymphoma and multiple myeloma.

REFERENCES

1. Genzyme Corporation, Mozobil product information, Cambridge, MA, December 2008.

Status: <u>Non-Formulary-PA</u>
Created: <u>01/05/09 CBR</u> Updated:________________ Reviewed:_________________

Generic Name: Sildenafil Citrate

Brand Name: Revatio

GUIDELINES FOR USE:

1. Is the patient currently receiving nitrate therapy?

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

2. Does patient (male or female) have pulmonary hypertension?

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

3. **Approve for 12 months**.

Rationale:
Encourage appropriate use based on available medical evidence.

FDA Approved Indications:
Revatio: Treatment of pulmonary hypertension to improve exercise tolerability.

References:
1. Revatio Product Information.

Created: 04/01/01HK Updated: 07/20/06 HK

Generic Name: Somatropin

Brand Name: Humatrope
Nutropin, Nutropin AQ, Nutropin Depot
Genotropin
Norditropin, Norditropin Nordiflex
Saizen
Serostim
TevTropin
Zorbtive **(Note: See separate guidelines below for Zorbtive.)**

GUIDELINES FOR USE:

1. Does the member's benefit include coverage of growth hormones?

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

2. Does the patient have a diagnosis of Idiopathic Short Stature (not growth hormone-deficient short stature)?

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

3. Does the member have AIDS related cachexia/wasting syndrome and meeting at least 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/m^2
   - In women: BCM<23% of total body weight and BMI<27kg/m^2

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

4. Is this an initial PA request?

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

5. Has the member tried and failed any of the following medications?
   a. Dronabinol, or
   b. Oxandrolone, or
   c. Megestrol, or

   If yes, continue to # 21. If no, do not approve and recommend one of the above agents.

6. Has the member experienced a significant weight gain while on growth hormone (significant weight gain defined as + 0.5kg/month)?

   If yes, continue to # 21. If no, do not approve.

7. Is the member less than 18 years old?

    If yes, continue to #8. If no, continue to #17.

8. Is this an initial prior authorization request?

    If yes, continue to #9. If no, continue to #13.

9. Is the prescriber an endocrinologist <u>or</u> a nephrologist?

    If yes, continue to #10. If no, do not approve and respond with the following: “Guidelines require initiation of therapy and monitoring by pediatric endocrinologists or by nephrologists. If this request is a continuation of recommendations from a specialist, please contact Med**Impact** or provide documentation”.

10. Does the member have **<u>ONE</u>** of the following diagnoses?
    a. Growth hormone deficiency, <u>or</u>
    b. Small for Gestational age (birth weight of less than 2.5kg at a gestational age of 37 weeks, or birth length or weight below the 3rd percentile for gestational age), <u>or</u>
    c. Pre-transplant chronic renal insufficiency, <u>or</u>
    d. Neonatal hypoglycemia associated with growth hormone deficiency.

    If yes, continue to #11. If no, continue to #15.

11. If male, is bone age less than 16 years old **<u>OR</u>** if female, is bone age less than 14 years old and is there evidence of non-closure of the epiphyseal plate as confirmed by radiograph of the wrist and hand?

    If yes, continue to #12. If no, do not approve.

12. Does the member meet at least **<u>ONE</u>** of the following criteria?
    a. Lack of response to growth hormone stimulation tests. [serum growth hormone level of < 10ngm/ml to at least two stimuli (insulin, levodopa, arginine, clonidine, sinemet or glucagons)], <u>or</u>
    b. IGF-1 is -2 standard deviations (SD) below the normal range for age and sex, <u>or</u>
    c. IGFBG-3 level is -2 SD below the normal range for age and sex.

    If yes, continue to # 21. If no, do not approve.

13. Has the patient shown a positive response to the first 12 months of growth hormone therapy (i.e increase in height, increase in growth velocity, IGF-1 level normalization)? and under supervision of endocrinologist?

    If yes, continue to #14. If no, do not approve.

14. If male, is bone age less than 16 years old **<u>OR</u>** if female, is bone age less than 14 years old and is there evidence of non-closure of the epiphyseal plate as confirmed by radiograph of the wrist and hand?

If yes, continue to # 21. If no, do not approve.

15. Does the member have a diagnosis of Turner's syndrome that is confirmed by appropriate genetic testing or does the member have the SHOX mutation?

If yes, continue to # 21. If no, go to #16.

16. Does the patient have Prader-Willi syndrome as confirmed by DNA methylation analysis, FISH, or qualitative PCR?

If yes, go to # 21 If no, do not approve.

17. Does the member have growth hormone deficiency that is from an organic cause (i.e., pituitary hormone deficiency) and the prescriber is an endocrinologist?

If yes, and induction go to #20. If no, continue to #18.

If yes, and renewal go to #19

18. Does the member have growth hormone deficiency that is idiopathic in nature and the prescriber is an endocrinologist?

If yes, and induction go to #20. If no, do not approve.

If yes, and renewal go to #19

19. Has the patient shown clinical benefits from the growth hormone as assessed by any of the following:

- Normalization of IGF-1
- Improvement in body composition (i.e body density increase, lipolysis changes)
- Clinical assessment of patient focusing on improvement in quality of life issues

If yes, continue to # 21 If no, do not approve.

20. Does the member meet at least **ONE** of the following criteria?

a. Lack of response to growth hormone stimulation tests. [serum growth hormone level of < 5ngm/ml to at least two stimuli (insulin, levodopa, arginine, or glucagons)], or
b. IGF-1 is -2 SD below the normal range for age and sex, or
c. IGFBG-3 level is -2 SD below the normal range for age and sex.

If yes, continue to # 21. If no, do not approve.

21. Approve for 12 months. ***Please enter the PA for the growth hormone medication by NDC.*** See table below for dosage recommendations.

Dosage Recommendations for GH	
Clinical condition	**Dose (mcg/kg/day)**
GHD children	25-50
GHD adolescents	25-100
GHD adults	6-25
Chronic renal insufficiency	50
Turner Syndrome	50
Small for gestational age	50-70
Prader-Willi Syndrome	35-50
AIDS related cachexia	100

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GUIDELINES FOR ZORBTIVE (SOMATROPIN)

1. Does the member have short bowel syndrome (SBS) and is currently receiving specialized nutritional support?

If yes, go to #2	If no, do not approve

2. Is this initial therapy for the patient or renewal?

If initial therapy, approve for 4 weeks	If renewal, do not approve. Administration for more than 4 weeks has not been adequately studied.

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

FDA Approved Indications:
Growth hormone deficiency in children and in adults, chronic renal insufficiency, Turner Syndrome, small for gestational age, Prader-Willi Syndrome, AIDS-related cachexia, and idiopathic short stature. Zorbtive is approved for treatment of short bowel syndrome in patients receiving specialized nutritional support.

References:

1. Consensus guidelines for the diagnosis and treatment of adults with growth hormone deficiency: summary statement of the Growth Hormone Research Society Workshop on Adult Growth Hormone Deficiency. *J Clin Endocrinol Metab.* 1998;83(2):379-381.
2. Wilson TA, Rose SR, Cohen P, Rogol AD, Backeljauw P, Brown R, 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(4):415-421.
3. The American Association of Clinical Endocrinologists and The American College of Endocrinology. AACE clinical practice guidelines for growth hormone use in adults and children. *Endocr Pract.* 1998;4(3):165-173.
4. Product Package Insert, Zorbtive, Serono, Jan. 2004.

Created: 12/13/04 KH Updated: 12/2007 CBR

Generic Name: Teriparatide

Brand Name: Forteo

GUIDELINES FOR USE

Teriparatide will be provided as a plan benefit within the following guidelines:

1. Does the patient have a diagnosis of Paget's disease, a history of radiation therapy, bone malignancy, a history of hypercalcemia or hyperparathyroidism?

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

2. Does the patient have a diagnosis of severe osteoporosis at a high risk for fracture (T < -2.5 with a history of fragility fractures), or does the patient have multiple risk factors for fracture (e.g., history of multiple recent low trauma fractures, history of corticosteroid use, use of GnRH analogues such as nafarelin, etc.)?

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

3. Has the patient failed an adequate trial (at least 6 months) of bisphosphonate (Fosamax,Fosamax D) or selective estrogen-receptor modulator (Evista) or is the patient intolerant or does the patient have a contraindication to these medications for the treatment of osteoporosis?

   If yes, continue to #4. If no, do not approve and recommend a trial of Fosamax, Fosamax D, or Evista.

4. **Approve for 12 months with a quantity limit of 1 pen per month.**

Rationale:

To ensure the cost-effective and safe use of teriparatide for the treatment of severe osteoporosis in patients who have failed or are intolerant to anti-resorptive agents.

FDA Approved Indications:

1. 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.

CONTINUED ON NEXT PAGE

Generic Name: Teriparatide (continued)

Brand Name: Forteo (continued)

FDA Approved Indications (continued):

2. 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:

Forteo Product Information, Eli Lilly.

Created: 06/02/03 SVK Updated: 12/2007 CBR

Generic Name: Tetrabenazine

Brand Name: Xenazine

GUIDELINES FOR USE

Tetrabenazine will be provided as a plan benefit within the following guidelines:

1. Is the prescriber a neurologist or was the therapy initiated on the recommendation of a neurologist?
   If yes, continue to #2.
   If no, do not approve.
2. Is the patient being treated for chorea associated with Huntington's disease?
   If yes, continue to #3
   If no, deny for lack of indication
3. **Approve up to 100mg per day x 12 months**

RATIONALE
Per Health Plan.

FDA APPROVED INDICATION
Treatment of chorea associated with Huntington's disease

REFERENCES
Package Insert.
Micromedex accessed 3/25/09

Status: Non-Formulary
Created: 03/25/09 DB Updated__________________

Generic Name: Tretinoin

Brand Name: Avita, Retin-A, Retin-A Micro

GUIDELINES FOR USE

Tretinoin will be provided as a plan benefit within the following guidelines:

1. Is the patient under 35 years of age?

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

2. Is the prescription written for cosmetic use, such as premature aging, photo-damaged skin, hyperpigmentation, stretch marks, acne scarring, androgenic alopecia, alopecia areata, melasma or chloasma?

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

3. Is the prescription written for acne, precancerous lesions, skin cancers, pseudofolliculitis barbae, molluscum contagiosum, flat warts, psoriasis, Darier's disease (keratosis follicularis), keloids, lichen planus, ichthyosis vulgaris, ichthyosis congenita, dermatitis, folliculitis or geographic tongue?

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

4. **Approve for up to 12 months.**

Rationale:
Per Health Plan.

FDA Approved Indication:

References:
Per Health Plan.

Created: 04/01/01 ZN Updated: 10/25/04 KH

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