STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR MEDICAL SERVICES

Office of Pharmacy Service
Prior Authorization Criteria

HUMIRA® (adalimumab) and ENBREL® (etanercept)

Effective 10/01/2016

Prior Authorization Request Form

Prior authorization requests for Humira and Enbrel may be approved for their FDA approved indications provided the following criteria are met. Diagnoses must accompany all requests.

- Patient is eighteen (18) years of age or older (see below if diagnosed with juvenile idiopathic arthritis or pediatric Crohn's Disease); **AND**
- Initial treatment plan is done in consultation with an appropriate specialist (such as a dermatologist, gastroenterologist or rheumatologist); **AND**
- Negative tuberculin skin test before initiation of therapy; **AND**

THE FOLLOWING INDICATION-SPECIFIC CRITERIA MUST ALSO BE SATISFIED:

- **Ankylosing spondylitis:** must include documentation indicating ninety (90) day treatment history with NSAIDs (unless contraindicated).

- **Psoriasis** must have:
  1. Diagnosis of moderate to severe psoriasis; **AND**
  2. Prior treatment with a potent topical corticosteroid plus calcipotriol; **AND**
  3. Prior treatment with a Vitamin D analogue; **AND**
  4. Prior treatment with phototherapy; **AND**
  5. Prior ninety (90) day treatment history with a disease-modifying agent (DMARD) such as methotrexate, cyclosporine, acitretin, etc.

- **Psoriatic arthritis:** must have a documented ninety (90) day history of NSAID therapy as well as ninety (90) day trials of at least two DMARDs.

- **Rheumatoid arthritis:** must have documented ninety (90) day trials of at least two DMARDs.

- **Juvenile idiopathic arthritis**: Prior authorization for Humira and Enbrel may be granted if the patient is two (2) years of age or older and has failed a ninety (90) day course of therapy with methotrexate.

- **Crohn's Disease:** Humira is approvable for moderate to severe Crohn's disease. *Enbrel is not indicated for treatment of Crohn's disease and will not be approved.*

- ***Pediatric Crohn's disease*** **(moderate to severe):** For patients 6 years of age and older, prior authorization requests for Humira are approvable with documentation of an inadequate response to a 14-day trial of corticosteroids or an immunomodulator such as azathioprine, 6-mercaptopurine, or methotrexate.

- **Ulcerative Colitis:** Humira is approvable following failure or clinically significant adverse effects to a thirty (30) day course of aminosalicylates (e.g. sulfasalazine, mesalamine) requiring treatment for two (2) or more exacerbations using corticosteroids, such as prednisone. *Enbrel is not indicated for treatment of UC and will not be approved.*

- **Hidradenitis suppurativa:** Humira may be approved in patients 18 years of age or older who satisfy the following additional criteria:
    1. Has severe disease (Hurley stage III); **OR**
    2. Has moderate disease (Hurley state II) despite treatment with an oral formulary tetracycline (i.e., doxycycline) OR topical clindamycin.

- **Uveitis:** Humira may be approved in patients diagnosed with non-infectious uveitis who are at least 18 years of age and who have failed to respond adequately to corticosteroid therapy, or in whom corticosteroid therapy is inappropriate.

References

1) Lexi-Comp drug monographs for Humira and Enbrel (7/11/2016)
2) Humira Package Insert (7/2016)
3) Enbrel Package Insert
4) 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis
5) The 2012 BSR and BHPR guideline for the treatment of psoriatic arthritis with biologics
6) American College of Rheumatology/Spondylitis Association of America/Spondyloarhtritis Research and Treatment Network 2015 Recommendations for the Treatment of Anykylosing Spondylitis and Noradiographic Axial Spondyloarthritis
7) Crofford *Arthritis Research & Therapy* 2013, 15(Suppl 3):S2
8) J Braun *et al*. 2010 update of the ASAS/EULAR recommendations for the management of anykylosing spondylitis. Ann Rheum Dis 2011; 70:896-904
9) Scottish Intercollegiate Guidelines Network (SIGN). Diagnosis and management of psoriasis and psoriatic arthritis in adults. A national clinical guideline. Edinburgh (Scotland); Scottish Intercollegiate (SIGN), 2010 Oct (SIGN publication, no. 121 (217 references)
10) G Lichtenstein, S Hanauer *et al.* Management of Crohn's Disease in Adults. Am J Gastroenterol advance online publication, 6 January 2009
11) EDF Guideline for Hidradenitis Suppurativa / Acne Inversa (HS) - S1 Guideline – 2016-2017 (file:///C:/Users/E033601/Downloads/Guideline-on-Hidradenitis-suppurativa-S1.pdf)

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Office of Pharmacy Service
Prior Authorization Criteria

Growth Hormone for Children under 21 years of age

Effective 10/01/2016

Prior Authorization Request Form

Growth hormone will be approved for children meeting prior authorization criteria stated for the conditions listed below. In addition, all information and documentation requested on the prior authorization form, including height, weight, bone age, date of most current x-ray, stimulus test results, IGF-1 levels and a growth chart must be supplied.

Growth Hormone Deficiency

1) Standard deviation of 2.0 or more below mean height for chronological age; **AND**
2) No expanding intracranial lesion or tumor diagnosed. Growth rate below five (5) centimeters per year; **AND**
3) Failure of any two stimuli test to raise the serum growth hormone level above 10nanograms/milliliter; **AND**
4) Bone age 14-15 years or less in females and 15-16 years or less in males; **AND**
5) Epiphyses open.

Growth Retardation of Chronic Renal Insufficiency

1) Standard deviation of 2.0 or more below mean height for chronological age; **AND**
2) No expanding intracranial lesion or tumor diagnosed; **AND**
3) Growth rate below five (5) centimeters per year; **AND**
4) Irreversible renal insufficiency with a creatinine clearance less than 75 ml/min per 1.73m2 but pre-renal transplant; **AND**
5) Bone age 14-15 years or less in females and 15-16 years or less in males; **AND**
6) Epiphyses open.

Turner's Syndrome

1) Chromosomal abnormality showing Turner's syndrome; **AND**
2) Standard deviation of 2.0 or more below mean height for chronological age; **AND**
3) No expanding intracranial lesion or tumor diagnosed; **AND**
4) Growth rate below five (5) centimeters per year; **AND**
5) Bone age 14-15 year; **AND**
6) Epiphyses open.

Neurosecretory Growth Retardation

1) Standard deviation of 2.0 or more below mean height for chronological age; **AND**
2) No expanding intracranial lesion or tumor diagnosed; **AND**
3) Growth rate below five (5) centimeters per year; **AND**
4) Bone age 14-15 years or less in females and 15-16 years or less in males; **AND**
5) Epiphyses open; **AND**
6) Mixed or normal response to any two (2) stimuli test in raising serum growth hormone above 10nanograms/milliliter.

Idiopathic Short Stature

1) A standard deviation of 2.25 or more below mean height for chronological age; **AND**
2) No expanding intracranial lesion or tumor diagnosed; **AND**
3) Growth rate is below five (5) centimeters per year; **AND**
4) Bone age is 14-15 years or less in females and 15-16 years or less in males and epiphyses are open; **AND**
5) A mixed or normal response to any two stimuli tests in raising serum growth hormone above 10 nanograms/milliliter; **AND**
6) The child is proportionally shorter than the predicted rate of growth from the parents height; **AND**
7) Requests must come from a pediatric endocrinologist.

Prader Willi Syndrome, SHOX, or Noonan's Syndrome

1) Request must come from a pediatric endocrinologist; **AND**
2) Documentation and lab results must be submitted to support diagnosis (e.g., Prader-Willi Syndrome confirmed by genetic testing).

AND one of the following:

a) Child has severe growth retardation with height standard deviation score (SDS) more than 3 SDS below the mean for chronological age and sex; **OR**
b) Child has moderate growth retardation with height SDS between -2 and -3 SDS below the mean for chronological age and gender AND decreased growth rate (growth velocity measured over one year below 25th percentile for age and sex); **OR**
c) Child exhibits severe deceleration in growth rate (growth velocity measured over 1 year –2 SDS below the mean for age and gender)

Small for Gestational Age (SGA)

1) Request must come from a pediatric endocrinologist; **AND**
2) Documentation to support diagnosis defined as birth weight or length 2 or more standard deviations below the mean for gestational age.
3) Child fails to manifest catch up growth before 2 years of age, defined as height 2 or more standard deviations below the mean for age and gender.
4) Note: Review must include evaluation of growth curves from birth

References

12) Update to Guidelines for the Use of Growth Hormone in Children: The Lawson Wilkins Pediatric Endocrinology Society Drug and Therapeutics Committee https://www.pedsendo.org/education_training/healthcare_providers/consensus_statements/assets/sdarticle.pdf (2003)

13) A review of guidelines for use of growth hormone in pediatric and transition patients Pituitary. 2012 Sep;15(3):301-10. doi: 10.1007/s11102-011-0372-6.

14) Growth Hormone Therapy Guidelines: Clinical and Managed Care Perspectives - http://www.ajpb.com/journals/ajpb/2014/ajpb_septemberoctober2014/growth-hormone-therapy-guidelines-clinical-and-managed-care-perspectives

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Office of Pharmacy Service
Prior Authorization Criteria

Belbuca® (buprenorphine film)
Effective 10/01/2016

Prior Authorization Request Form

Belbuca is a buccal film containing buprenorphine, a partial opioid agonist. Belbuca is indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

To be eligible for prior-authorization of Belbuca, patients must satisfy all of the following criteria:

1) Recent medication history must indicate 6-day trials of Butrans patch and at least one other preferred agent; **AND**
2) A 6-day trial of another generic non-preferred agent; **AND**
3) The prescriber must indicate why they expect Belbuca to be effective when Butrans was not; **AND**
4) The patient must be titrated down to 30 mg of morphine equivalents daily (or less) to be eligible for approval of the initial dose of Belbuca.

The following table indicates approvable doses of Belbuca following a taper of the patient's current opioid requirement to ≤ 30 mg oral morphine sulfate equivalents (MSE):

Table 1: Initial BELBUCA Dose Based on Prior Opioid Expressed as Oral Morphine Sulfate Equivalents

Prior Daily Dose of Opioid Analgesic Before Taper to 30 mg Oral MSE	Initial BELBUCA Dose
Less than 30 mg oral MSE	BELBUCA 75 mcg once daily or every 12 hours
30 mg to 89 mg oral MSE	BELBUCA 150 mcg every 12 hours
90 mg to 160 mg oral MSE	BELBUCA 300 mcg every 12 hours
Greater than 160 mg oral MSE	Consider alternate analgesic

References

1) Belbuca Package insert 12/2015
2) Lexi-Comp drug monograph for Belbuca (9/06/2016)

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Prior Authorization Criteria

Albenza® (albendazole) and Emverm® (mebendazole)

Effective 10/01/2016

Prior Authorization Request Form

1.) Requests to treat an indication of *Enterobius vermicularis* (pin-worm) shall require documentation indicating failure of a recent treatment course of Pin-Ex (pyrantel pamoate). This treatment course shall consist of no fewer than 2 doses taken within 2 weeks of each other.

2.) Prior authorization requests for indications other than pinworm may be approved for FDA approved or common off-label indications. Diagnoses must accompany all requests; unrecognized off-label requests may require supporting literature references.

References

1.) Lexi-Comp drug monographs for Albenza, Emverm and Pin-EX (Reviewed 8/17/2016)
2.) PL Detail-Document, Pinworms (Enterobius vermicularis). Pharmacist's Letter/Prescriber's Letter. May 2016.
3.) CDC. Parasites – *Enterobiasis* (also known as pinworm infection). http://www.cdc.gov/parasites/pinworm/health_professionals/ (Reviewed 8/17/2016)

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Prior Authorization Criteria

Natpara® (parathyroid hormone)
Effective 10/01/2016

Prior Authorization Request Form

NATPARA is a parathyroid hormone indicated as an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism.

3.) Must be prescribed by an endocrinologist

4.) Diagnosis must be for hypocalcemia secondary to hypoparathyroidism

   a. Documentation must include parathyroid levels below the lower limit of normal range, recorded on 2 separate occasions within the past 12 months.

   b. Requests for Natpara will be denied if the patient has hypoparathyroidism caused by calcium-sensing mutations and in cases of an acute hypoparathyroidism caused by surgery.

5.) Hypocalcemia must not be correctable through the use of calcium supplementation and active forms of vitamin D alone.

6.) Initial serum calcium level must not be greater than 7.5 mg/dL.

7.) Continuation requests for Natpara should include clinical documentation indicating regular monitoring of the patient's serum calcium.

References

4.) Lexi-Comp drug monograph Natpara (Reviewed 9/08/2016)
5.) Natpara package insert, Shire Pharmaceuticals 7/2016

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Prior Authorization Criteria

Northera™ (droxidopa)
Effective 10/01/2016

Prior Authorization Request Form

Northera is indicated for the treatment of orthostatic dizziness, lightheadedness, or the "feeling that you are about to black out" in adult patients with symptomatic neurogenic orthostatic hypotension (nOH) caused by primary autonomic failure [Parkinson's disease, multiple system atrophy, and pure autonomic failure], dopamine beta-hydroxylase deficiency, and non-diabetic autonomic neuropathy. The continued effectiveness of Northera should be assessed periodically.

1.) Northera (droxidopa) must be prescribed by or in consultation with a specialist (i.e cardiologist or neurologist); AND

2.) Provider must document diagnosis of symptomatic neurogenic orthostatic hypotension (nOH) caused by primary autonomic failure associated with the following:
   a. Disease states such as Parkinson's disease, multiple-system atrophy, and pure autonomic failure OR
   b. Dopamine beta-hydroxylase deficiency OR
   c. Non-diabetic neuropathy

   AND

3.) Provider submits documentation that the member has tried and failed both midodrine and fludrocortisone due to inadequate response or adverse effects.

4.) Continuation requests for treatment beyond 2 weeks must be accompanied by documentation of efficacy including a decrease in patient symptoms and periodic assessment of blood pressure.

References

6.) Lexi-Comp drug monograph for (Reviewed 9/08/2016)
7.) Northera package insert (08/2014)