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

Office of Pharmacy Service
Prior Authorization Criteria

LINZESS® (linaclotide)

Linzess® will be prior authorized if the following criteria are met:

1) Diagnosis of chronic idiopathic constipation, with less than three spontaneous bowel movements per week; **OR**
2) Diagnosis of Irritable Bowel Syndrome with Constipation (IBS-C);

AND EACH of the following:

3) Patient is eighteen (18) years of age or older; **AND**
4) Documented failure of an increase in dietary fiber/dietary modification; **AND**
5) Documented failure of at least fourteen (14) days of therapy **each** with osmotic and bulk forming laxatives; **AND**
6) Appropriate screening for colon cancer, history of bowel obstruction, hepatic or renal disease, hypothyroidism, pelvic floor abnormalities, and spinal cord abnormalities.

Note:

- Linzess is pregnancy category C; caution is advised when considering use during pregnancy.
- The initial approval will be authorized for a period of twelve (12) weeks. After follow-up with the prescriber, authorization may be granted for a period of twelve (12) months.

References

1) UpToDate (1/29/2015) – Management of Chronic Idiopathic Constipation
2) Linzess package insert 07/2014 revision
3) Lexi-Comp Clinical Application 1/29/2015
4) *Detail-Document;* Pharmacist's Letter December 2012; Vol: 28

Version 3 – DUR Board reviewed and approved (2-25-2015)
Version 3.2 - created 03-09-2015 (BMT)

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

Office of Pharmacy Service
Prior Authorization Criteria

EPANED® (enalapril powder for oral solution)

EPANED is powder formulation of the angiotensin-converting enzyme inhibitor enalapril and is indicated for the treatment of adults and children one 1 month of age or older, who have been diagnosed with hypertension, symptomatic heart failure and asymptomatic left ventricular dysfunction (to decrease the rate of development of overt heart failure and reduce hospitalization for heart failure).

Criteria for Approval

1) Diagnosis of hypertension, symptomatic heart failure or asymptomatic left ventricular dysfunction; **AND EITHER of the following:**
2) Patient is less than seven (7) years of age; **OR**
3) Patient is unable to ingest a solid dosage form (eg. an oral tablet or capsule) due to documented oral-motor difficulties or dysphagia.

References

1) Epaned package insert revised 9/2014
2) Lexi-Comp Clinical Application 02/12/2015

Version 2 - DUR Board reviewed and approved (02-25-2015)
Version 2.1 – created 03-09-2015 (BMT)

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

Office of Pharmacy Service
Prior Authorization Criteria

JUBLIA® (efinaconazole)

Julbia® is an azole antifungal indicated for the topical treatment of onychomycosis of the toenails due to *Trichophyton rubrum* and *Trichophyton mentagrophytes*.

Criteria for Approval

1) Diagnosis of onychomycosis of the toenail confirmed by KOH test or laboratory sensitivity; **and**
2) Patient must be eighteen (18) years of age or older; **and**
3) Treatment is requested due to medical condition and not for cosmetic purposes (e.g. patients with history of cellulitis of the lower extremity who have ipsilateral toenail onychomycosis, patients with diabetes who have additional risk factors for cellulitis, and patients who are otherwise immunocompromised). Supporting documentation must be submitted with the request; **and**
4) History of failure, contraindication, or intolerance to **one (1)** of the following oral antifungal agents (full treatment course of each is required):
    a. Itraconazole
    b. terbinafine

All approvals will be granted for 48 weeks.

References

1) Julbia package insert 6/2014
2) Lexi-Comp Clinical Application 01/23/2015

Version 4 – DUR Board reviewed and approved (2-25-2015)
Version 4.1- created 03-09-2015 (BMT)

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

Office of Pharmacy Service
Prior Authorization Criteria

ESBRIET® (perfenidone)

ESBRIET is indicated for the treatment of idiopathic pulmonary fibrosis (IPF).

Criteria for Approval

1) Diagnosis of idiopathic pulmonary fibrosis (IPF); **and**
2) Must be prescribed by or in conjunction with a pulmonologist; **and**
3) Patient must be eighteen (18) years of age or older; **and**
4) Patient must be enrolled in a smoking cessation program (or must indicate that they do not smoke); **and**
5) Liver function tests (ALT, AST, and bilirubin) should be conducted prior to the initiation of therapy, then monthly for the first six (6) months and every three (3) months thereafter. Lab results must be submitted with prior authorization request; **and**
6) Patient must not have ESRD or be on dialysis.

Note:

- Patient will be denied coverage if they have previously been treated with Esbriet and experienced greater than five (5) times the upper normal limit of ALT and/or AST.
- Esbriet is pregnancy category C; caution is advised when considering use in pregnant patients.

References

1) Esbriet package insert 10/28/2014
2) Lexi-Comp Clinical Application 11/26/2014
3) http://medlibrary.org/lib/rx/meds/esbriet/

Version 1 – DUR Board reviewed and approved (2-25-2015)
Version 1.1 – created 03-09-2015 (BMT)