COUPE HEALTH

PHARMACY UTILIZATION MANAGEMENT (UM) PROGRAM CRITERIA ACTIVITY

Provider Notification

Policies Effective: 12/9/2022 Notification Posted: October 25, 2022

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Revisions are effective the first of the month following a 45-day notification and comment period.

NEW UM PROGRAM CRITERIA			
Elmiron (pentosan polysulfate sodium)			
Program Type:	☒ Prior Authorization	☒ Quantity Limit	☒ Step Therapy

Prior Authorization Approval Criteria

Elmiron (pentosan polysulfate sodium)

Generic name: Pentosan polysulfate sodium
Brand name: Elmiron
Medispan GPI: 56500060100110 MON
Medication class: Urinary analgesic
FDA-approved uses: **Interstitial cystitis**

Usual dose range:
Interstitial cystitis Initial: 100 mg three times daily

Duration of Authorization:
Initial: 4 months
Ongoing: 12 months

Estimated Cost: AWP $3,401 for three months

Criteria for use for interstitial cystitis

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan.
- Must be 16 years of age or older.
- Grandfather criteria allowed

- Please see policy and procedure "*14 – Grandfather Status Authorization*" for additional information.
- Patient is clinically diagnosed with interstitial cystitis
- Patient has failure, contraindication, or intolerance to an adequate trial of amitriptyline
- Due to the increased risk of pigmentary maculopathy with long-term use of Elmiron, plan requires annual screening by an optometrist/ophthalmologist for macular degeneration/dystrophy within 18 months of medication initiation for patients using medication chronically (greater than 12 months of therapy)

Criteria continuation of therapy

- Patient is tolerating and responding to medication and there continues to be a medical need for the medication.
- Updated chart notes or other clinical documentation confirming efficacy (decreased bladder pain, decreased frequency or urgency) and tolerability of the requested treatment will be required for all renewal reviews. Submitted clinical documentation must be from an encounter after the start date of the current approval.
- Patient demonstrates adequate compliance as defined as an MPR >80%.
- * Please included comment in Review* Due to the increased risk of pigmentary maculopathy with long-term use of Elmiron, plan requires annual screening by an optometrist/ophthalmologist for macular degeneration/dystrophy within 18 months of medication initiation for patients using medication chronically (greater than 12 months of therapy).

Contraindications:

- History of hypersensitivity to any of the product ingredients.

Not approved if:

- Patient does not meet any of the above criteria.
- Patient has a contraindication to treatment.

Special Considerations:

- Safety and efficacy have not been established in children under 16 years of age
- Pentosan polysulfate is a low-molecular weight heparin-like medication with anticoagulant and fibrinolytic effects so bleeding complications could occur. Evaluate patients with aneurysm, increased risk of bleeding, invasive procedures, HIT, bleeding disorders and hepatic impairment prior to use.
- Pigmentary changes in the retina have been reported with long-term use, but can also occur with short term use. Baseline comprehensive retinal exam is recommended prior to initiation therapy in patients with pre-existing ophthalmologic conditions.

References:

1. Elmiron (pentosan polysulfate sodium) [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals Inc; March 2021
2. Lexi Comp- abatacept. 8/30/22. https://online.lexi.com/Orencia; updated 7/7/22 accessed 9/20/22.

MedOne Clinical Review Subcommittee Approval: Date: 9/21/22

Initial adoption: 09/21/22
Revised: 09/21/22
09/21/22 1. Pricing updated based off of AWP (9/21/22)
Effective Date (most recent revisions): 12/9/2022

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NEW UM PROGRAM CRITERIA			
Fasenra (benralizumab)			
Program Type:	☒ Prior Authorization	☒ Quantity Limit	☒ Step Therapy

Prior Authorization Approval Criteria

Fasenra (benralizumab)

Generic name: benralizumab
Brand name: Fasenra
Medispan GPI: 4460402000D5** MON
Medication class: Interluekin-5 receptor antagonist, monoclonal antibody
FDA-approved uses: **Asthma, severe eosinophilic**

Usual dose range:

Severe Eosinophilic Asthma	Initial: 30 mg every 4 weeks for the first three doses	Maintenance: 30 mg every 8 weeks

Duration of Authorization:
Initial: 4 months
Ongoing: 12 months

Estimated Cost: AWP $6,421 per dose. First year annual cost $51,368 then $41,737 subsequent years

Criteria for use for Asthma, severe eosinophilic

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan.
- Grandfather criteria allowed
  - Please see policy and procedure "*14 – Grandfather Status Authorization*" for additional information.
- Must be 12 years of age or older.
- Must be prescribed by, or in consultation with a Board-Certified allergist, pulmonologist, or immunologist
- Patient is clinically diagnosed with severe asthma with eosinophilic phenotype
- Must have eosinophil blood count >150 cells µL within last 6 weeks -OR- >300 cells µL within the last 12 months
  - Use of Fasenra may be considered in patients who have a diagnosis of eosinophilic asthma who do not achieve the above laboratory parameters who are also oral corticosteroid dependent, defined as at least 1 month of continuous daily oral corticosteroid use within the last 3 months.
- Patient has failure, contraindication, or intolerance to at least once high dose inhaled corticosteroid in combination with long-acting beta agonist and has MPR>80% for at least 3 months -AND-
- Patient meets one of the following within past 12 months
  - One or more acute asthma related ED visits
  - One or more acute inpatient related asthma visits
  - Use of chronic systemic steroids due to severe asthma OR two or more acute asthma exacerbations requiring oral systemic steroids

-AND-

- Patient will use Fasenra with ONE of the following

- High dose combination inhaled corticosteroids/long-acting beta agonist (LABA)
- High dose combination inhaled corticosteroid /long-acting muscarinic agonist (LAMA)
  OR
- Both high dose ICS product AND one additional asthma controller medication

-AND-

- Patient is not a current smoker
- Patient will not use in combination with other specialty/biologic medications for asthma

Criteria continuation of therapy

- Patient is tolerating and responding to medication and there continues to be a medical need for the medication.
- Updated chart notes or other clinical documentation confirming efficacy and tolerability of the requested treatment will be required for all renewal reviews. Submitted clinical documentation must be from an encounter after the start date of the current approval.
- Response to Fasenra has been shown either by documented decreased asthma symptoms OR stable or reduced dose/ frequency of inhaled steroids OR stable or reduced exacerbations requiring oral steroids.
- Patient demonstrates adequate compliance as defined as an MPR >80% to ALL asthma therapies

Contraindications:

- History of hypersensitivity to any of the product ingredients.

Not approved if:

- Patient does not meet any of the above criteria.
- Patient has a contraindication to treatment.
- Patient is also using Xolair (omalizumab), Cinqair (reslizumab), Nucala (mepolizumab), Dupixent (dupilumab)
- Patient will be using as monotherapy
- Patients have a diagnosis of COPD
- Patients have demonstrated poor compliance with maintenance asthma treatments

Special Considerations:

- Patients with Helminth infections should be treated prior to starting Fasenra. Unknown how benralizumab will affect immune response against parasitic infections.
- Not used to treat acute asthma symptoms, or acute exacerbations or status asthmaticus.

References:

1. Fasenra (benralizumab) [prescribing information]. Wlmington, DE: AstraZeneca Pharmaceuticals LP; February 2021.
2. Global Initiative for Asthma (GINA). Global strategy for asthma management and prevention. . https://ginasthma.org/wp-content/uploads/2022/07/GINA-Main-Report-2022-FINAL-22-07-01-WMS.pdf Updated 2022. Accessed 9/21/22
3. Goldman M, Hirsch I, Zangrilli JG, et al. The association between blood eosinophil count and benralizumab efficacy for patients with severe, uncontrolled asthma: subanalyses of the Phase III SIROCCO and CALIMA studies. Curr Med Res Opin. 2017 Sep;33(9):1605-1613.
4. Bleecker ER, et.al; SIROCCO study investigators. Efficacy and safety of benralizumab for patients with severe asthma uncontrolled with high-dosage inhaled corticosteroids and long-acting β_2-agonists (SIROCCO): a randomised, multicentre, placebo-controlled phase 3 trial. Lancet. 2016 Oct 29;388(10056):2115-2127. doi: 10.1016/S0140-6736(16)31324-1. Epub 2016 Sep 5. PMID: 27609408.
5. Nair P, Wenzel S, Rabe KF, et al. Oral glucocorticoid-sparing effect of benralizumab in severe asthma. N Engl J Med. 2017;376(25):2448-2458.

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