**September 2022 DUR Board Meeting Minutes**

**Date: September 21, 2022**

**Members Present:** Barnhill, Anglim, Blank, Brown, Caldwell, Jost, McGrane

**Members Absent:** Blake, Maxwell, Nauts, Putsch, Stone

**Others Present:** Katie Hawkins, Shannon Sexauer, Dani Feist, (DPHHS); Artis, Bahny, Erickson, Miranda (MPQH); and representatives from the pharmaceutical industry.

**MPQH Update:** Sara Medley, CEO, announced her retirement from Mountain Pacific at the end of 2022.

**Public Comment**:

- Natalie Rose, Gilead – Hepatitis C treatment access
- Charlie Lovan, AbbVie – Rinvoq®
- Deb Profant, Jazz Pharmaceuticals – Xywav®
- Nila Stevens, Sanofi - Dupixent®

*The Department received a written request to revisit the PA requirements for atypical antipsychotic use in children. The Board voted to bring the discussion back at the November 9th, 2022 meeting.

**Meeting Minute Review:** The meeting minutes from the July 13, 2022 Drug Utilization Review Board Meeting were approved as written.

**Department Update:** No Department update.

**Board Discussion**

1. **REMS and Black Box warning place in PA Criteria**
   During the development phase of criteria, the Board agreed that criteria selected by MPQH and DPHHS for REMS drugs does not need to duplicate the REMS requirements for providers or members. However, they did request that the provider attests to being enrolled in the REMS program before these drugs will be considered or approved.

2. **Criteria Removal Discussion:**
   A. **TZD Class**
      - The Board approved the request to remove criteria requirements for this class.
   B. **Ondansetron**
      - The Board approved the request to remove all quantity limits and only enforce preferred/non-preferred status.
   C. **Iron Products**
      - The Board approved the request to remove PA requirements for iron products.

3. **Drug Criteria Review:**

**A. Zoryve® (roflumilast 0.3%)**

Initial Coverage Criteria

Member must meet all the following criteria:

- Member must have a diagnosis of plaque psoriasis
- Provider attests member does not have moderate to severe liver impairment (Child-Pugh B or C)
- Member is at least 12 years of age or older
- Member has tried and failed a preferred high potency topical steroid
- Member has tried and failed a preferred calcipotriene agent
- Subject to PDL requirements
- **Limitations:**
    - Maximum quantity is limited to one (1) 60gm tube per 28 days
    - Initial coverage authorization will be granted for 2 months

Renewal Coverage Criteria

Member must meet all the following criteria:

- Provider attests that the member has shown improvement in condition over baseline
- **Limitations:**
    - Maximum quantity is limited to one (1) 60gm tube per 28 days
    - Renewal authorization will be granted for 1 year

**B. Lemtrada® (alemtuzumab)**

Initial Coverage Criteria

Member must meet all the following criteria:

- Member is 17 years of age or older
- Member has one of the following relapsing forms of multiple sclerosis:
    - Relapsing-remitting MS
    - Active secondary-progressive MS
- Member must not have clinically isolated syndrome (CIS)
- Must be prescribed by, or in consult with a neurology specialist
- Member must have experienced at least two relapses during the two years prior and at least one relapse during the year prior to request
- Prescriber and patient must be enrolled in and meet the conditions of the Lemtrada® REMS program
- Provider attests to all the following:
    - Member has received baseline skin exam for melanoma
    - Member does not have any medical conditions that significantly compromise the immune system including HIV infection or AIDS, leukemia, lymphoma, or organ transplantation
    - Member does not have an active infection

    - Member must have labs completed at baseline (i.e. CBC with differential, serum creatinine levels, urinalysis with urine counts, TSH, etc.) and at periodic intervals for 48 months after the last dose
    - Provider will monitor for malignancies, including thyroid cancer, melanoma, and lymphoproliferative disorder
- Member has had an inadequate response, history of intolerance, or contraindication to at least two medications with different mechanisms of action indicated for the treatment of multiple sclerosis (one medication needs to be a high efficacy agent)
- Member is not receiving Lemtrada® in combination with another disease modifying agent for multiple sclerosis
- **Limitations:**
    - Maximum dose of 12mg IV daily on 5 consecutive days within 12 months
    - Initial coverage authorization will be granted for 1 year (one 5-day course)

Renewal Coverage Criteria

Member must meet all of the following criteria:

- Member has experienced a positive clinical response to therapy
- Member has been adherent to Lemtrada®
- Provider attests to all of the following:
    - Member is receiving ongoing laboratory monitoring (i.e. CBC with differential, serum creatinine levels, urinalysis with urine counts, TSH, etc.)
    - Member does not have any medical condition that significantly compromise the immune system including HIV infection or AIDS, leukemia, lymphoma, or organ transplantation
    - Member does not have an active infection
    - Provider is monitoring for malignancies, including thyroid cancer, melanoma, and lymphoproliferative disorder
- Annual specialist consult provided if prescriber not a specialist
- **Limitations:**
    - Maximum dose of 12mg IV daily on 3 consecutive days 12 months after first treatment course
    - Renewal authorization will be granted for 1 year (one 3-day course)

**C. Xyrem® (sodium oxybate)**

Member must meet all the following criteria:

- Member must be at least 7 years of age or older
- Member must have a diagnosis of narcolepsy with either cataplexy or excessive daytime sleepiness
- Diagnosis must be made using ICSD-3 or DSM-5 diagnostic criteria
- **Limitations:**
    - Initial and renewal authorization will be granted for 1 year

**D. Xywav® (calcium, magnesium, potassium, & sodium oxybates)**

Initial Coverage Criteria

Member must meet all the following criteria for applicable diagnosis:

**Narcolepsy with cataplexy or excessive daytime somnolence**

- Member must be at least 7 years of age or older
- Member must have a diagnosis of narcolepsy with either cataplexy or excessive daytime sleepiness
- Diagnosis must be made using ICSD-3 or DSM-5 diagnostic criteria
  **Limitations:**
  - Maximum daily approved dose is 9gm per night
  - Initial and renewal coverage authorization will be granted for 1 year

**Idiopathic Hypersomnia in Adults**

- Member must be at least 18 years of age or older
- Member must have a diagnosis idiopathic hypersomnia
- Diagnosis must be made using ICSD-3 or DSM-5 diagnostic criteria
- **Limitations:**
  - Maximum daily dose approved is 9gm per night
  - Initial and renewal coverage authorization will be granted for 1 year

**E. Daliresp® (roflumilast)**

Initial Coverage Criteria

Member must meet all the following criteria:

- Member must be 18 years of age and older
- Member must have a diagnosis of severe COPD **WITH** 2 or more exacerbations **OR** one exacerbation requiring hospitalization within the past year
- Member must be on, and compliant with, combination LABA/LAMA or triple combination LABA/LAMA/ICS inhaler
- Provider attests that an ICS has been considered and has either been prescribed, or provider has determined that an ICS would not be appropriate for the member
- Provider attests that member does not have hepatic impairment (Child Pugh B or C)
- **Limitations:**
  - Maximum dose limit is 1 tablet per day (500mcg daily)
  - Initial coverage authorization will be granted for 1 year

Renewal Coverage Criteria

Member must meet all the following criteria:

- Member must be on, and compliant with, combination LABA/LAMA or triple combination LABA/LAMA/ICS inhaler
- **Limitations:**
    - Maximum dose limit is 1 tablet per day (500mcg daily)
    - Renewal authorization will be granted for 1 year

**F. Cibinqo® (abrocitinib)**

Initial Coverage Criteria

Member must meet all the following criteria:

- Member must be 18 years of age or older
- Member must have a diagnosis of refractory moderate to severe atopic dermatitis
- Member has clinical documentation of functional impairment due to atopic dermatitis, which may include, but is not limited to, limitations to activities of daily living (ADLs), such as skin infections or sleep disturbances and a baseline assessment has been made to allow for documentation of positive clinical response
- Inadequate treatment response, intolerance, or contraindication to a preferred high potency topical corticosteroid
- Inadequate treatment response, intolerance, or contraindication to topical immunomodulator (i.e. tacrolimus, pimecrolimus)
- Inadequate treatment response, intolerance, or contraindication to other biologics with preferable safety profile (i.e. Dupixent®)
- Provider attests that member will not use Cibinqo® concomitantly with other biologics
- Provider attests that they have reviewed the black box warning associated with this drug
- **Limitations:**
    - Maximum daily dose is 200mg
    - Initial coverage authorization will be granted for 6 months

Renewal Coverage Criteria

Member must meet all the following criteria:

- Member has documentation of positive clinical response to therapy (e.g. reduction in body surface area involvement, reduction in pruritus severity or decrease in severity index using a scoring tool)
- **Limitations:**
    - Maximum daily dose is 200mg
    - Renewal authorization will be granted for 1 year

**G. Rinvoq ER® (upadacitinib)**

**General Criteria applying to ALL Immunomodulators, regardless of diagnosis**:

- Must be prescribed by an appropriate specialist for appropriate diagnosis per FDA indications OR
  - If not prescribed by appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization
- All agents are subject to PDL limitations unless preferred product does not have the appropriate indication, in which case, non-preferred requests will be reviewed on a case-by-case basis

Member must meet all the following criteria (in addition to what is listed above) for diagnosis:

**Rheumatoid Arthritis, Psoriatic Arthritis, Ulcerative Colitis, & Ankylosing Spondylitis**

- Provider attests that member will not use Rinvoq® concomitantly with other biologics
- Member must be 18 years of age or older
- Member must have a diagnosis of moderately to severely active rheumatoid arthritis; active psoriatic arthritis; moderately to severely active ulcerative colitis; or active ankylosing spondylitis
- Member must have tried and had an inadequate response or intolerance to a preferred TNF blocker
- Provider attests that they have reviewed the black box warning associated with this drug
- **Limitations:**
  - Maximum quantity limit is 1 tablet per day
  - Initial and renewal coverage authorization will be granted for 1 year

**Atopic Dermatitis**

- Provider attests that member will not use Rinvoq® concomitantly with other biologics
- Member must be 12 years of age or older
- Member must have a diagnosis of refractory, moderate to severe atopic dermatitis
- Member has clinical documentation of functional impairment due to atopic dermatitis, which may include, but is not limited to, limitations to activities of daily living (ADLs), such as skin infections or sleep disturbances and a baseline assessment has been made to allow for documentation of positive clinical response
- Inadequate treatment response, intolerance, or contraindication to a preferred high potency topical corticosteroid
- Inadequate treatment response, intolerance, or contraindication to topical immunomodulator (i.e. tacrolimus, pimecrolimus)
- Inadequate treatment response, intolerance, or contraindication to other biologics with preferable safety profile (i.e. Dupixent®)
- Provider attests that they have reviewed the black box warning associated with this drug
- **Limitations:**

- Maximum quantity limit is 1 tablet per day
- Initial coverage authorization will be granted for 6 months

Renewal Coverage Criteria (applies only to Atopic Dermatitis diagnosis)

Member must meet the following criteria:

- Member has documentation of positive clinical response to therapy (e.g. reduction in body surface area involvement, reduction in pruritus severity or decrease in severity index using a scoring tool)
- **Limitations**:
  - Maximum quantity limit is 1 tablet per day
  - Renewal authorization will be granted for 1 year

**The Board requested that a provider attestation be added to all JAK Inhibitors stating that they have reviewed the black box warnings for these drugs.

**H. Dupixent® (dubilumab)**

Initial Coverage Criteria for Eosinophilic Esophagitis

Member must meet all the following criteria:

- Must be prescribed by, or in consult with, an allergy or gastroenterology specialist
- Member must have a diagnosis of eosinophilic esophagitis with documentation of ≥15 intraepithelial eosinophils per high-power field (eos/hpf) AND symptoms of dysphagia as measured by the Dysphagia Symptom Questionnaire (DSQ)
- Member must be 12 years of age or older AND weigh at least 40 kg
- Member has a documented 4-week trial of swallowed topical corticosteroids (budesonide, fluticasone) in the prior 6 months
- Dupixent® will not be used concurrently with other biologics
- **Limitations:**
  - Maximum dose limit is 300mg weekly
  - Initial coverage authorization will be granted for 6 months

Renewal Coverage Criteria

Member must meet the following criteria:

- Member has documentation of positive clinical response to therapy by reduction in peak esophageal intraepithelial eosinophil count (<6=remission)
- Member has documentation of positive clinical response to therapy by reduction in DSQ score (Dysphagia Symptom Questionnaire)
- **Limitations:**
  - Maximum dose limit is 300mg weekly
  - Renewal authorization will be granted for 1 year

## I. Emgality® (galcanezumab)

Initial Coverage Criteria for Episodic Cluster Headache

Member must meet all the following criteria:

- Must be 18 years of age or older
- Member meets the International Classification of Headache Disorders diagnostic criteria for episodic cluster
- Member has experienced a minimum of one attack every other day, and at least 4 attacks during the baseline period. Member has had no more than 8 attacks per day
- Member has tried verapamil for 4 weeks unless it is contraindicated
- **Limitations:**
    - Maximum dose limit is 300mg (three consecutive SQ injections of 100mg each) at the onset of the cluster period, then monthly until the end of the cluster period, up to a limit of 8 total weeks
    - Initial coverage authorization will be granted for 2 months (8 weeks)

Renewal Coverage Criteria

- Emgality® will be approved for NO MORE than 8 consecutive weeks of therapy, so no continuation of therapy approvals will be granted. For new attacks, criteria above will have to be met again

## J. Nuedexta® (dextromethorphan/quinidine)

Initial Coverage Criteria

Member must meet all the following criteria:

- Member must have been diagnosed with pseudobulbar affect by a neurologist
- May be prescribed by any provider, but diagnosis of PBA from a neurologist must be included
- Approval will be granted only for patients with PBA secondary to neurological conditions or injuries (i.e., stroke, ALS, MS, TBI, etc.)
- Member does not have any of the following contraindications (all must be checked):
    - Concomitant use of quinidine, quinine, or mefloquine
    - Known hypersensitivity to dextromethorphan
    - Current MAOI use or within 14 days of stopping a MAOI
    - Prolonged QT interval, congenital long QT syndrome, history suggestive of torsades de pointes, or heart failure
    - Complete atrioventricular (AV) block without implanted pacemaker, or member at high risk of complete AV block
    - Concomitant use of drugs that both prolong QT interval and are metabolized by

CYP2D6 (e.g., paroxetine, fluoxetine, thioridazine, pimozide, risperidone, etc.)

- **Limitations:**
  - Maximum dose limit is 2 capsules daily
  - Initial coverage authorization will be granted for 6 months

Renewal Coverage Criteria

Member must meet all the following criteria:

- Subsequent authorization may be granted in 1-year intervals with documentation of efficacy (decrease in number of crying or laughing episodes, as well as other markers of improved emotional control)
- **Limitations:**
  - Maximum dose limit is 2 capsules daily
  - Renewal authorization will be granted for 1 year

**K. Qelbree® (vioxazine)**

Initial Coverage Criteria

Member must meet all the following criteria:

- Member is 6 years of age or older
- Member has a diagnosis of ADHD
- Member has had an appropriate trial (minimum of 8 weeks of therapy at maximum tolerated dose) on, and had an inadequate response or contraindication to atomoxetine (preferred SNRI for ADHD) **AND** either clonidine ER or guanfacine ER
- **Limitations:**
  - Pediatric Patients 6 to 17 years of age – maximum daily dose is 400mg once daily
  - Adult Patients – maximum daily dose is 600mg daily
  - Initial approval authorization will be granted for 2 months
  - Dose optimization is required after the titration period

Renewal Coverage Criteria

Member must meet all the following criteria:

- Prescriber must attest the patient has had a positive clinical response to therapy over baseline at 2 months
- **Limitations:**
  - Pediatric Patients 6 to 17 years of age – maximum daily dose is 400mg once daily
  - Adult Patients – maximum daily dose is 600mg daily
  - Renewal authorization will be granted for 1 year
  - Dose optimization is required after the titration period

**L. Hepatitis C PA Form Additions**

- **Provider Attestation Section:**

- I will test for current or prior HBV infection before initiation of HCV treatment. If HCV/HBV coinfected, I will monitor for HBV reactivation and hepatitis flare during HCV treatment and post-treatment follow-up

- **Member Attestation Section:**
  - For some hepatitis C treatment regimens, there are currently no FDA approved retreatment options for individuals who fail hepatitis C treatment. I understand that I may not be eligible for retreatment

**M. Entadfi® (tadalafil 5mg and finasteride 5mg)**

Initial Coverage Criteria

Member must meet all the following criteria:

- Subject to Preferred Drug List requirements
- Member is an adult with a diagnosis of BPH
- Member has trialed 3 other drugs approved for BPH, including finasteride alone (for a minimum of 3 months) with some, but inadequate response
- Member has trialed a combination of the individual medications, tadalafil 5mg and finasteride 5mg daily, and has a clinically compelling reason they cannot continue with the individual medications
- **Limitations:**
  - Maximum dose limit 1 capsule daily
  - Initial coverage authorization will be granted for 26 weeks of therapy (182 capsules)

Renewal Coverage Criteria

- Use is not recommended for greater than 26 weeks because the incremental benefit of tadalafil decreases from 4 weeks until 26 weeks, and the incremental benefit beyond 26 weeks is unknown. Because of this recommendation, renewals will not be authorized.

The Board also requested that the tadalafil criteria for BPH be updated to match by removing the requirements that the member be male, that the member have no history of erectile dysfunction, and adding that finasteride had been tried for a minimum of 3 months with some, but inadequate response.

**Open Discussion:**

- Discussion on MAT treatment in emergency rooms and opioid access limitations

The next meeting will be Wednesday, November 9th, 2022 in this same format. The meeting adjourned at 4:01pm.