September 2021 DUR Board Meeting Minutes

Date: September 22, 2021

Members Present: King, Anglim, Blake, Blank, Brown, Caldwell, Jost, Maxwell, McGrane, Nauts, Putsch, Stone

Members Absent:

Others Present: Dan Peterson, Shannon Sexauer, Dani Feist, (DPHHS); Bahny, Barnhill, Doppler, Erickson, Opitz, Woodmansey (MPQH); representatives of the pharmaceutical industry.

Introductions: Tony King opened the meeting and provided opportunity for public comment.

Public Comment: No comment(s) presented.

Meeting Minute Review: The meeting minutes from the July 21, 2021 Drug Utilization Review Board meeting were reviewed, and were amended to include the criteria for Apokyn™ (mirroring the Kynmobi™ criteria) that was requested by the Board during that meeting; as well as, appending the language on the Entresto criteria from "If member is on an ACE or ARB, it must be discontinued at least 36 hours in advance of starting Entresto" to "ACEI or ARB must be discontinued if approved. ACEI must be discontinued at least 36 hours in advance of starting Entresto." The July meeting minutes were updated with these changes.

Department Update: No Department update. Congratulated Dan Peterson on his retirement.

Board Discussion

1. The Board agreed that for all medications that require a specialist or specialty consult, the requirement should apply to both the initial coverage criteria and the renewal coverage criteria. The Board has given Mountain-Pacific approval to make this update on all previously approved criteria, as well as any future criteria.

2. **Existing Drug Criteria Updates**

   A. **Synagis™ (palivizumab)**

   - Epidemiological information for both national and Montana trends was provided to the Board members, and based on the information available, the Montana Healthcare Programs initiated the season early, with dates of coverage being set from August 25th, 2021 through April 30th, 2022. The Board approved the Department's request to open and close the RSV season coverage dates as appropriate for state trends.

   B. **Linezolid**

   - The Board recommended removing criteria requirements and requested a follow up in a year to reevaluate usage and appropriateness.

   C. **Growth Hormone Therapy with Turner Syndrome**

Member must meet all of the following criteria:

- Must be prescribed by, or in consult with, an endocrinologist
- Height of female is below the 5th percentile for age on the normal female growth chart
    - Note: this usually occurs between two and five years of age
- Open epiphyses required
- Bone age <14-15 years required

*The Board also requested that ALL growth hormone therapies be prescribed by, or in consult with, an endocrinologist. All indications for growth hormone will be updated with this specialist requirement.

D. Zeposia™ (ozanimod) – Criteria for Moderate to Severe Ulcerative Colitis

- Criteria discussion tabled until future meeting

E. Xolair™ (omalizumab) – Criteria for Nasal Polyps

Member must meet all of the following criteria:

Initial Coverage Criteria

- Member must be 18 years of age or older
- Medication must be prescribed by, or in consultation with, an allergist, immunologist, or otolaryngologist
- Member must have clinical documentation of chronic rhinosinusitis with nasal polyps as evidenced by CT scan or endoscopy
- Member must have had an inadequate treatment response, intolerance, or contraindication to both of the following:
    - Two different intranasal corticosteroids (must be adherent to each therapy and used at optimized doses for at least 3 months) AND
    - Systemic corticosteroid trial (must be within last year) AND/OR sino-nasal surgery
- Member must concurrently be using an intranasal corticosteroid unless contraindicated
- Provider must include pretreatment serum total IgE level and current body weight for dose calculation/verification
- Max dose is 600mg sub-q every 2 weeks (refer to dosage chart in package insert
- Initial coverage authorization will be granted for 6 months

Renewal Coverage Criteria

- Member has been adherent to Xolair
- Member has been adherent to concurrent intranasal corticosteroids
- Documentation is provided supporting positive response to therapy as demonstrated by a reduction in severity of sino-nasal symptoms or systemic steroid reduction (if using)
- Annual specialist consult provided if prescriber is not a specialist
- Max dose is 600mg sub-q every 2 weeks (refer to dosage chart in package insert)
- Renewal authorizations will be granted for 1 year

F. Lemtrada™ (alemtuzumab)

Member must meet all of the following criteria:

Initial Coverage 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 member must be enrolled in, and meet the conditions of, the Lemtrada™ REMS program
- Provider attests to all of 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 infections or AIDS, leukemia, lymphoma, or an organ transplant
  - 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 of the following classes:
  - **Interferon:** interferon β-1a (Avonex® or Rebif®), interferon β-1b (Betaseron® or Extavia®), peginterferon beta-1a (Plegridy™)
  - **Glatiramer:** glatiramer acetate (Copaxone® or Glatopa®)
  - **Fumaric Acid Derivative**: dimethyl fumarate (Tecfidera®), monomethyl fumarate (Bafiertam®), diroximel fumarate (Vumerity®)
  - **Pyrimidine Synthesis Inhibitor:** teriflunomide (Aubagio®)
  - **Sphingosine 1-Phosphate Receptor Modulator:** siponimod (Mayzent®), ozanimod (Zeposia®), fingolimod (Gilenya®)
  - **Purine Analog:** cladribine (Mavenclad®)
  - **Anti-CD20 Monoclonal Antibody:** ofatumumab (Kesimpta®), ocrelizumab (Ocrevus®)
  - **CD20-directed Antibody:** rituximab (Rituxan®, Riabni™, Truxima®, Ruxience™)
  - **Selective Adhesion-Molecule Inhibitor**: natalizumab (Tysabri®)
- Member is not receiving Lemtrada in combination with another disease modifying agent for multiple sclerosis
- Initial quantity limits: Max 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 (stabilization or improvement)
- 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 an organ transplant.
    - Member does not have an active infection
    - Provider is monitoring for malignancies, including thyroid cancer, melanoma, and lymphoproliferative disorder
- Must be prescribed by, or in consult with, a neurology specialist
- Renewal quantity limits: Max of 12mg IV daily on 3 consecutive days within 12 months after first treatment course
- Renewal authorizations will be granted for 1 year (one 3-day course)

3. Review of New Drug Criteria

The following clinical criteria were reviewed and the Board recommended approval and implementation as follows:

A. <u>Hetlioz™ (tasimelteon) – Criteria for Smith-Magenis Syndrome (SMS)</u>

Member must meet all of the following criteria:

<u>Initial Coverage Criteria</u>

- Subject to Preferred Drug List
- Member must be 3 years of age or older
- Member must have diagnosis of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS)
- Must be prescribed by, or in consult with (within the previous year), a sleep specialist
- Member must have trialed other therapies (timed melatonin or planned social/physical activities) and found inadequate for improving functional impairment
- Provide documentation member has microdeletions or mutations of RAI1
- Initial coverage authorization will be granted for 6 months
- Maximum dose allowed is 20mg/day
- Oral suspension only approved for members 3-15 years of age

<u>Renewal Coverage Criteria</u>

- Provider attests positive clinical outcome as evidenced by sleep diaries (e.g., increase in number of hours slept or decrease in the number of worst nights slept)
- Renewal authorizations will be granted for 1 year

- Maximum dose allowed is 20mg/day
- Oral suspension only approved for members 3-15 years of age

B. Kerendia™ (finerenone)

Member must meet all of the following criteria:

Initial Coverage Criteria

- Member must be 18 years of age or older
- Must be prescribed by, or in consult with, a nephrologist
- Member is not pregnant
- Member has a diagnosis of chronic kidney disease associated with Type II diabetes AND an A1C less than 8%
- Member has undergone a recent trial (within the past 90 days) of an SGLT2 inhibitor with the same indication
- Member is currently receiving a maximally tolerated ACE or ARB, unless contraindicated
- Prior to the initiation of Kerendia®, member meets all of the following:
    - EGFR ≥25ml/min/1.73m2 and <75ml/min/1.73m2
        - 2 most recent eGFR labs at baseline
    - Urine albumin-to-creatinine ratio ≥30 mg/g
    - Serum potassium level ≤5.0 mEq/L
- Initial coverage authorization will be granted for 6 months
- Maximum dose is 1 tablet daily

Renewal Coverage Criteria

- Must be prescribed by, or in consult with, a nephrologist
- Provider must provide documentation showing positive clinical improvement (e.g., eGFR decline has been slowed)
- Renewal authorizations will be granted for 1 year
- Maximum dose is 1 tablet daily

PDL/DURB Meeting Follow-Up Items:

- Gabapentin Edits
    - Montana Healthcare Programs is going to enact quantity limits for gabapentin and limit the daily doses to the FDA indicated limit of 3600mg per day. Providers with patients exceeding the upper limit will receive notification and a white paper from Mountain-Pacific Quality Health (MPQH) outlining the research and guidelines of gabapentin utilization. Providers will have the opportunity to attest their acknowledgement of the guidelines and to maintain their patients at the current dosage or to engage in an action plan to decrease the dosage to 3600mg per day. No new patients will be allowed above the 3600mg dosing limit.

- Morphine Milligram Equivalent (MME) Update
    - Brief update provided and MPQH continues to review high dose MME cases and will continue to report back to the Board.

- Atypical Antipsychotics – Fellowship Trained Pediatric Psychiatrist (FTPP) discussion
    - The Board unanimously agreed to remove the existing policy allowing FTPP providers to bypass the lab monitoring requirement that is required for all non-FTPP providers. This was due to poor adherence by FTPPs to the American Academy of Child and Adolescent Psychiatry guidelines regarding metabolic monitoring. The procedure for removing the FTPP bypass list is as follows:
        - For members currently receiving an atypical antipsychotic, he/she will be grandfathered for 6-months, allowing time for the provider to submit the required lab information for ongoing approval.
        - Outreach to the FTPP providers will be completed prior to implementation.

Closed Session:

The meeting adjourned at 3:07pm.