July 2021 DUR Board Meeting Minutes

Date: July 21, 2021

Members Present: King, Anglim, Blank, Brown, Caldwell, Jost, Maxwell, McGrane, Nauts, Putsch, Stone (arrived 1:30pm)

Members Absent: Blake

Others Present: Shannon Sexauer, Dani Feist, (DPHHS); Artis, Bahny, Barnhill, Doppler, 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 May 26, 2021 Preferred Drug List (PDL) Meeting were approved as written.

Department Update: No Department update.

Board Discussion

A. Existing Drug Criteria Updates

A. Xofluza™ (baloxavir marboxil)

- The Board recommended removing criteria and keeping as preferred.

B. Nurtec™ ODT (rimegepant) – preventative treatment of episodic migraine in adults

Member must meet all of the following criteria:

- Must have a history of inadequate response (trial of at least 2 months duration), contraindication, or intolerance to 2 prophylactic conventional therapies **that include at least 2 separate therapeutic classes** from the following below:
    - Amitriptyline or venlafaxine
    - Atenolol, metoprolol, nadolol, or propranolol
    - Topiramate or divalproex
- Limitations: #15 tablets per month (approved for every other day dosing)
- Initial authorization is 3 months
- Reauthorization
    - Patient has documented response to therapy as demonstrated by reduction in migraine frequency compared to number of migraine days at baseline
    - Reauthorization approved x 12-month intervals

C. Invega Trinza™ (paliperidone palmitate)

Member must meet all of the following criteria:

- Subject to PDL requirements
- Member must be at least 18 years of age or older
- Member must have a diagnosis of schizophrenia
- Member must have been treated with Invega Sustenna for at least **4 months**

D. Clonidine ER

- The Board recommended removing criteria and moving to preferred.

E. Entresto™ (sacubitril/valsartan)

Member must meet all of the following criteria:

- Member must have a diagnosis of symptomatic chronic heart failure with reduced ejection fraction (HFrEF): LVEF ≤40%
- Concurrently taking an evidence-based beta-blocker (metoprolol succinate, carvedilol, or bisoprolol), unless contraindicated
- ACEI or ARB must be discontinued if approved. ACEI must be discontinued at least 36 hours in advance of starting Entresto
- Max Daily Dose (MDD) is 2 tablets

B. Review of New Drug Criteria

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

A. Nexlizet™ (bempedoic acid and ezetimibe)

Initial Coverage Criteria (member must meet *all of the following criteria*):

- Member is 18 years of age or older
- Must be prescribed by, or in consult with, a cardiologist, endocrinologist, or lipidologist
- Member has an LDL-cholesterol equal to or greater than 70mg/dl
- Member has diagnosis of either:
  - Heterozygous familial hypercholesterolemia (HeFH)
  - Atherosclerotic cardiovascular disease (ASCVD)
- Member must have trialed at least **2** high-intensity statins for at least 12 weeks **and** will continue receiving maximally tolerated high-intensity statin therapy unless ineffective or contraindicated
- Member has trialed ezetimibe for at least 12 weeks and has had an inadequate therapeutic response
- Member has trialed a PCSK-9 product for at least 12-weeks and has been ineffective or contraindicated
- Initial authorization granted for 6 months
- Maximum daily dose is 180mg/day

Renewal Coverage Criteria:

- Provider must provide documentation showing positive clinical improvement and adherence to therapy
- Renewal authorization granted for 1 year and maximum daily dose is 180mg/day

B. Lupkynis™ (voclosporin)

Initial Coverage Criteria (member must meet *all of the following criteria*):

- Member is 18 years of age or older
- Must be prescribed by a nephrologist or rheumatologist
- Member must have a diagnosis of active lupus nephritis
- Member must have a blood pressure <165/105 mmHg
- Member must have an estimated glomerular filtration rate (eGFR) ≥ 45/ml/min/1.73 m^2
- Provider must submit clinical documentation of functional impairment due to poor control, which may include, but is not limited to, limitation of activities of daily living (ADLs) due to pain, impaired ambulation, or missing school and/or work
- Member is currently on therapy for SLE, and *all of the following are met:*
    - Member requires daily use of oral corticosteroids, unless contraindicated, ineffective, or not tolerated
    - Member is on therapeutic dose of mycophenolate mofetil (MMF)
    - Member is not currently on IV administered cyclophosphamide
- Initial approval granted for 6 months with max of 180 capsules per month

Renewal Coverage Criteria:

- Provider must provide documentation showing stabilization of disease or an absence of disease progression AND absence of unacceptable toxicity from the medication
- Renewal authorization granted for 1 year

C. Verquvo™ (vericiguat)

Initial Coverage Criteria (member must meet *all of the following criteria*):

- Member is 18 years of age or older
- Member must not be pregnant or nursing
- Must be prescribed by, or in consult with, a cardiologist
- Not taking soluble guanylate cyclase stimulators (e.g., riociguat).
- Not taking phosphodiesterase type 5 inhibitors (e.g., sildenafil, tadalafil, vardenafil).
- Diagnosed with chronic heart failure with an ejection fraction 45% or less who are NYHA class II-IV and either:
    - Hospitalized due to heart failure within the last 6 months. OR
    - Required IV diuretics as an outpatient within the previous 3 months.
- Concurrently receiving the maximum tolerated or target dose of guideline-directed medical therapy for heart failure, unless not tolerated or contraindicated:
    - Beta-blockers (carvedilol, metoprolol succinate, or bisoprolol).
    - Angiotensin antagonist (ARNI, ACEI, ARB)
    - Mineralocorticoid receptor antagonist (e.g., spironolactone) if LVEF < 35% or LVEF ≤ 40% with diabetes mellitus or post myocardial infarction with HF symptoms.
- Initial approval granted for 6 months with dose limitation of 300mg/month

Renewal Coverage Criteria:

- Provider must provide documentation showing positive clinical improvement and adherence to therapy
- Renewal authorization granted for 1 year

D. <u>Kynmobi™ (apomorphine HCl)</u>

Initial Coverage Criteria (member must meet *<u>all of the following criteria</u>*):

- Must be prescribed by, or in consultation with, a neurologist
- Member has a diagnosis of advanced Parkinson's disease
- Member is experiencing "off" episodes (return of Parkinson's symptoms) while receiving a carbidopa/levodopa regimen where:
    - Attempts have been made to adjust the carbidopa/levodopa's dose and/or formulation in order to manage symptoms without success
    - Provider attests to discussing dietary intake with member to optimize the effects of carbidopa/levodopa
    - Member will continue receiving carbidopa/levodopa in combination with Kynmobi
- Member has had previous inadequate responses to or has been intolerant of at least ONE different class of medications for the treatment of Parkinson's disease (e.g., monoamine oxidase type B [MAO-B] inhibitors, dopamine agonists, catechol-O-methyl transferase [COMT] inhibitors, etc.), unless contraindicated
- Member is not concurrently taking a 5-HT3 antagonist (i.e., ondansetron, granisetron, dolasetron, palonosetron or alosetron)
- Initial approval granted for 6 months with dose limitation of 150 sublingual films per month

Renewal Coverage Criteria:

- Provider must provide documentation showing stabilization of disease or absence of disease progression AND absence of unacceptable toxicity from the medication
- Renewal authorization granted for 1 year

E. <u>Apokyn™ (apomorphine HCl)</u>

- Discussion for this drug not listed on agenda but after criteria discussion was had on Kynmobi™ (oral apomorphine), the DUR Board felt that the injectable agent should have criteria requirements as well. Criteria expected to match Kynmobi™ (with exception of quantity limits). The following criteria were approved, in conjunction with these meeting minutes, at the September DUR meeting.

Initial Coverage Criteria (member must meet *<u>all of the following criteria</u>*):

- Must be prescribed by, or in consultation with, a neurologist
- Member has a diagnosis of advanced Parkinson's disease
- Member is experiencing "off" episodes (return of Parkinson's symptoms) while receiving a carbidopa/levodopa regimen where:
    - Attempts have been made to adjust the carbidopa/levodopa's dose and/or formulation in order to manage symptoms without success
    - Provider attests to discussing dietary intake with member to optimize the effects of carbidopa/levodopa

    - Member will continue receiving carbidopa/levodopa in combination with Apokyn
- Member has had previous inadequate responses to or has been intolerant of at least ONE different class of medications for the treatment of Parkinson's disease (e.g., monoamine oxidase type B [MAO-B] inhibitors, dopamine agonists, catechol-O-methyl transferase [COMT] inhibitors, etc.), unless contraindicated
- Member is not concurrently taking a 5-HT3 antagonist (i.e., ondansetron, granisetron, dolasetron, palonosetron or alosetron)
- Initial approval granted for 6 months

Renewal Coverage Criteria:
- Provider must provide documentation showing stabilization of disease or absence of disease progression AND absence of unacceptable toxicity from the medication
- Renewal authorization granted for 1 year

Dosing Limits:
- 1.8 mL/day

C. Physician Administered Drugs (PAD):

A. <u>Entyvio™ (vedolizumab)</u>

Initial Coverage Criteria (member must meet *<u>all of the following criteria specific for diagnosis</u>*):

- **<u>Crohn's Disease</u>**
    - Member is 18 years of age or older
    - Member must have a diagnosis of moderately to severely active Crohn's disease
    - Medication is prescribed by, or in consult with, an appropriate specialist (gastroenterologist)
    - Member must have had an inadequate response with, lost response to, or was intolerant to a Montana Healthcare Programs preferred TNF blocker (e.g., Humira®), unless contraindicated

- **<u>Ulcerative Colitis</u>**
    - Member is 18 years of age or older.
    - Member must have a diagnosis of moderately to severely active ulcerative colitis
    - Medication is prescribed by, or in consult with, an appropriate specialist (gastroenterologist)

Initial Coverage Duration and Quantity Limitations:
- Approval Duration: 14 weeks
- Quantity Limitations: Max 300mg IV at 0, 2, and 6 weeks, then every 8 weeks thereafter

Renewal Coverage Criteria:
Member must meet all the following criteria:
- Member has been adherent to Entyvio®
- Member has experienced a positive clinical response
- Annual specialist consult provided if prescriber not a specialist

- Approval duration: 1 year

B. Lemtrada™ (alemtuzumab)

Initial Coverage Criteria (member must meet *all of the following criteria*):

- Diagnosis of relapsing forms of multiple sclerosis (MS) (e.g., relapsing-remitting MS, active secondary-progressive MS)
- Member must not have clinically isolated syndrome (CIS)
- Must be prescribed by a neurologist or a practitioner specializing in the treatment of MS
- Member must have experienced at least 2 relapses during the 2 years prior to, AND at least 1 relapse during the year prior to request
- Prescriber and patient must be enrolled in and meet the conditions of the Lemtrada ™ REMS program
- Member has intolerance, or contraindication OR history of failure following an adequate trial of at least one agent from three of the following categories:
    - **Interferons/glatiramer:** Interferon β-1a (Avonex® or Rebif®), Interferon β-1b (Betaseron® or Extavia®), Glatiramer acetate (Copaxone® or Glatopa®), Peginterferon beta-1a (Plegridy™)
    - **Fumaric Acid Derivative**: Dimethyl fumarate (Tecfidera®), Monomethyl fumarate (Bafiertam®), Vumerity® (diroximel fumarate)
    - **Pyrimidine Synthesis Inhibitor:** Teriflunomide (Aubagio®)
    - **Sphingosine 1-Phosphate Receptor Modulators:** Diponimod (Mayzent®), Ozanimod (Zeposia®), fingolimod (Gilenya®)
    - **Purine Analog:** Cladribine (Mavenclad®)
    - **Monoclonal Antibody:** Ofatumumab (Kesimpta®), Ocrelizumab (Ocrevus®)
    - **Other Infusion**: Natalizumab (Tysabri®), Rituximab (Rituxan®, Riabni™, Truxima®, Ruxience™)
- Member is not receiving alemtuzumab in combination with another disease modifying agent for multiple sclerosis (e.g., interferon beta preparations, glatiramer acetate, natalizumab, fingolimod, teriflunomide, ocrelizumab, etc.)

Initial Coverage Duration and Quantity Limitations:

- Approval Duration: 12 months
- Quantity Limitations: 12mg intravenously daily for 5 consecutive days initially and 12mg IV daily for 3 consecutive days once within 12 months afterwards.

Renewal Coverage Criteria:

Member must meet all the following criteria:

- Documentation of disease response to therapy (stabilization or improvement)
- Documentation member has not experienced any of the following: Intolerable adverse effects or drug toxicity, persistent and uncorrectable problems with adherence to treatment (i.e., member was not compliant in taking the medication as scheduled), poor response to treatment as evidenced by physical findings and/or clinical symptoms
- Prescribed by neurology specialist or have annual consult
- Quantity Limitations: 12mg intravenously daily for 3 consecutive days

C. **<u>Amondys 45™ (casimersen), Exondys 51™ (eteplirsen), & Vyondys 53™ (golodirsen)</u>**
    - Criteria pending. Will be re-reviewed and finalized at future meeting.

PDL/DURB Meeting Follow-Up Items:

- Gabapentin/Neuropathic Pain
    - Gabapentin currently not monitored through the Montana Prescription Drug Registry (MPDR) as current MT statute does not allow tracking for non-controlled medications.
- Board Portal
    - Tony is working with MPQH IT staff to set up secure portal for DUR Board members.
- MME/State Report

Closed Session: No cases to present.

The meeting adjourned at 3:30pm.