November 2021 DUR Board Meeting Minutes

Date: November 9, 2021

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

Members Absent: Anglim, Jost

Others Present: Katie Hawkins, Shannon Sexauer, Dani Feist, (DPHHS); Artis, 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: A representative from the Little Hercules Foundation, an advocacy group for members with Duchenne Muscular Dystrophy, requested that the Board discuss at a future meeting the ability for public members (patients, caregivers, and expert providers) to speak on agenda items.

Meeting Minute Review: The September 22, 2021 Drug Utilization Review Board meeting minutes were reviewed, and an update on the Zeposia™ criteria (previously discussed) for ulcerative colitis was provided, explaining that a failure on a 5-ASA product and budesonide was not appropriate under the current guidelines. The Board agreed and the criteria was approved as follows:

Member must meet all of the following criteria:

Initial Coverage Criteria:

- Subject to Preferred Drug List (PDL) requirements
- Member must be 18 years of age or older
- Member must have a diagnosis of moderate to severe ulcerative colitis
- Must be prescribed by, or in consult with, a gastroenterology specialist
- Member must have had an inadequate treatment response, intolerance, or contraindication to a preferred TNF blocker
- Initial coverage authorization will be granted for 3 months
- Maximum dose is 0.23mg once daily days 1-4, then 0.46mg once daily days 5-7, and then 0.92mg once daily starting on day 8

Renewal Coverage Criteria

- Annual specialist consult required if prescriber is not a specialist
- Provider must provide documentation showing a positive clinical response (i.e., decreased stool frequency or rectal bleeding)
- Renewal coverage authorization will be granted for 1 year
- Maximum dose is 0.92mg daily

Department Update: Dani Feist introduced Katie Hawkins as the new Allied Health Services Bureau Chief, replacing Dan Petersen.

Board Discussion

Review of New Drug Criteria

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

A. Aduhelm™ (aducanumab)

Member must meet all of the following criteria:

Initial Coverage Criteria

- Member must be 50 years of age or older
- Must be prescribed by a neurology specialist
- Member has mild cognitive impairment due to Alzheimer's disease or has mild Alzheimer's dementia stage of disease as evidenced by all of the following:
    - Clinical Dementia Rating (CDR)-Global Score of 0.5
    - Repeatable Battery for Assessment of Neuropsychological Status (RBANS) delayed memory index score ≤85
    - Mini-Mental Status Exam (MMSE) score between 24 and 30
    - Objective evidence of cognitive impairment at screening
- Provider has ruled out any other medical or neurological conditions (other than Alzheimer's Disease) that may be contributing to member's cognitive impairment, including any medications that can substantially contribute to cognitive impairment (see Beer's List)
- Member must have had a positive amyloid Positron Emission Tomography (PET) scan
- Member must not have had a stroke or TIA within past year
- Member must not be currently taking blood thinners (platelet anti-aggregate or anti-coagulant properties) except for aspirin at a prophylactic dose
- Member must have had one adequate trial (at least 6 months) with a Montana Health Care Programs preferred Alzheimer's therapy (cholinesterase inhibitor) and the preferred drug was ineffective or caused intolerable side effects
- If member is taking medications to treat symptoms of Alzheimer disease, dosages must be stable for at least 8 weeks prior to starting Aduhelm™. Additional therapies may not be initiated during Aduhelm™ treatment
- Member must have recent brain MRI (within one year) prior to initiating treatment
- Member must have follow-up MRIs prior to the 7th and 12th infusions
    - If radiographic severe ARIA-H is observed, treatment may be continued with caution only after a clinical evaluation and follow-up MRI demonstrates radiographic stabilization (i.e., no increase in size or number of ARIA-H)
- Initial coverage authorization will be for 6 months
- Maximum dose is 10mg/kg IV every 4 weeks

Renewal Coverage Criteria

- Member has been adherent to Aduhelm™

- Must be prescribed by a neurology specialist
- Member obtained follow-up MRI prior to the 7th and 12th infusions and did not demonstrate radiographic severe ARIA-H
    - If radiographic severe ARIA-H observed, treatment may be continued with caution only after clinical evaluation and a follow-up MRI demonstrates radiographic stabilization (i.e., no increase in size or number of ARIA-H)
- Member is receiving a benefit from Aduhelm™ therapy, as demonstrated by an improvement or stabilization from baseline on the Clinical Dementia Rating (CDR) and Mini-Mental Status Exam (MMSE)
- Renewal coverage authorization will be granted for 6 months
- Maximum dose is 10mg/kg IV every 4 weeks

B. Qulipta™ (atogepant)

Member must meet all of the following criteria:

Initial Coverage Criteria

- Member must be 18 years of age or older
- Diagnosis of episodic migraine 4-14 migraine days/month and <15 headache days per month (cannot have diagnosis of chronic migraine)
- Used as a preventive medication, not for treatment of a migraine attack
- 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
- Trial of preferred CGRP with indication for prophylactic use
- Not to be used concomitantly with injectable CGRP
- Initial coverage authorization will be granted for 3 months
- Maximum dose is 1 tablet daily

Renewal Coverage Criteria

- Member has experienced a documented positive response to therapy, as demonstrated by a reduction in migraine frequency compared to the number of migraine days at baseline
- Renewal coverage authorization will be granted for 1 year
- Maximum dose is 1 tablet daily

B. Invega Hafyera™ (paliperidone palmitate)

Member must meet all of the following criteria:

Initial Coverage Criteria

- Subject to Preferred Drug List (PDL) requirements

- Member must be at least 18 years of age
- Member must have diagnosis of schizophrenia
- Must be prescribed by, or in consult with, a psychiatric specialist
- Member must have clinical rationale that oral therapy cannot be used
- Tolerability with corresponding oral molecule must be established prior to requesting approval for injectable therapy
- Member must have been treated with Invega Sustenna™ for at least 4 consecutive months or Invega Trinza™ for 1 3-month injection cycle
- Initial coverage authorization will be granted for 1 year
- Maximum dose is 1 injection every 6 months

Renewal Coverage Criteria:

- Member has been adherent to Invega Hafyera™
- Member has experienced a positive clinical response (stabilization or decrease in schizophrenia symptoms)
- Annual specialist consult required if prescriber is not a specialist
- Renewal coverage authorization will be granted for 1 year
- Maximum dose is 1 injection every 6 months

C. Opzelura™ (ruxolitinib)

Member must meet all of the following criteria:

Initial Coverage Criteria

- Member must be 12 years of age or older
- Diagnosis of mild to moderate atopic dermatitis
- Documented baseline assessment to allow for positive clinical response
- Inadequate treatment response, intolerance, or contraindication to a preferred low-mid potency topical corticosteroid
- If over age of 17, inadequate treatment response, intolerance, or contraindication to a preferred high potency topical corticosteroid
- Inadequate treatment response, intolerance, or contraindication to either pimecrolimus or tacrolimus
- Inadequate treatment response, intolerance, or contraindication to Eucrisa™ (crisaborole)
- Initial coverage authorization will be granted for 8 weeks
- Maximum dose is #4-60gm tubes per month

Renewal Coverage Criteria:

- Member must have documentation of positive clinical response to Opzelura™ therapy (e.g., reduction in body surface area involvement, reduction in pruritus severity or decrease in severity index using a scoring tool)
- Renewal coverage authorization will be granted for 6 months
- Maximum dose is #4-60gm tubes per month

D. Lybalvi™ (olanzapine and samidorphan)

Member must meet all of the following criteria:

Diagnosis of Schizophrenia

Initial Coverage Criteria:

- Member must be at least 18 years of age
- Member must have diagnosis schizophrenia
- Must be prescribed by, or in consult with, a psychiatric specialist
- Prior to initiating, there should be at least a 7-day opioid-free interval from last use of short-acting opioids, and at least a 14-day opioid-free interval from the last use of long-acting opioids
- Positive trial of olanzapine, but unacceptable weight gain (7%) seen within 12 weeks or less of treatment
- Documented trial with inadequate response (or contraindication) of two additional preferred antipsychotics at maximally tolerated doses for at least 4 weeks.
- Initial coverage authorization will be granted for 6 months
- Maximum dose is 1 tablet per day

Renewal Coverage Criteria:

- Member has been adherent to medication
- Member has shown a positive clinical outcome to medication (weight to have decreased or stabilized)
- Renewal coverage authorization will be granted for 1 year
- Maximum dose is 1 tablet per day

Diagnosis of Bipolar I Disorder

Initial Coverage Criteria:

- Member must be at least 18 years of age
- Member must have diagnosis Bipolar I Disorder
- Must be prescribed by, or in consult with, a psychiatric specialist
- Prior to initiating, there should be at least a 7-day opioid-free interval from last use of short-acting opioids, and at least a 14-day opioid-free interval from the last use of long-acting opioids
- Positive trial of olanzapine, but unacceptable weight gain (7%) seen after 12 weeks or less of treatment
- Documented trial with inadequate response (or contraindication) of two additional preferred antipsychotics at maximally tolerated doses for at least 4 weeks.
- Initial coverage authorization will be granted for 6 months
- Maximum dose is 1 tablet per day

Renewal Coverage Criteria:

- Member has been adherent to medication
- Member has shown a positive clinical outcome to medication (weight to have decreased or stabilized)
- Renewal coverage authorization will be granted for 1 year
- Maximum dose is 1 tablet per day

E. Perseris™ (risperidone)

Member must meet all of the following criteria:

Initial Coverage Criteria:

- Subject to Preferred Drug List (PDL) requirements
- Member must be at least 18 years of age
- Member must have diagnosis schizophrenia
- Must be prescribed by, or in consult with, a psychiatric specialist
- Member must have clinical rationale that oral therapy cannot be used
- Tolerability with corresponding oral molecule must be established prior to requesting approval for injectable therapy
- Initial coverage authorization will be granted for 1 year
- Maximum dose is 90mg or 120mg injection once monthly
    - 90mg = 3mg per day of oral risperidone
    - 120mg = 4mg per day of oral risperidone
    - Members on doses lower than 3mg per day, or higher than 4mg per day, may not be appropriate candidates for Perseris™

Renewal Coverage Criteria:

- Member has been adherent to Perseris™
- Member has experienced a positive clinical response
- Annual specialist consult required if prescriber is not a specialist
- Renewal coverage authorization will be granted for 1 year
- Maximum dose is 90mg or 120mg injection once monthly
    - 90mg = 3mg per day of oral risperidone
    - 120mg = 4mg per day of oral risperidone
    - Members on doses lower than 3mg per day, or higher than 4mg per day, may not be appropriate candidates for Perseris™

F. Evkeeza™ (evinacumab-dgnb)

Member must meet all of the following criteria:

Initial Coverage Criteria:

- Member must be at least 12 years of age or older
- Medication prescribed by, or in consult with, a cardiology specialist or endocrinology specialist

- Diagnosis of homozygous familial hypercholesterolemia (HoFH)
    - Confirmed by submitting genetic test results
- Member has an LDL-Cholesterol equal to or greater than 70 mg/dl
- Evkeeza™ will be used as adjunctive therapy and member meets ***ALL*** the following criteria:
    - Member must have trialed at least **2** high-intensity statins for at least 12 weeks each unless ineffective, not tolerated, or contraindicated
    - Member has trialed ezetimibe for at least 12 weeks and has been ineffective, not tolerated, or contraindicated
    - Member has trialed a PCSK-9 product for at least 12-weeks and has been ineffective, not tolerated, or contraindicated
- Member will continue background lipid-lowering therapies in combination with Evkeeza™
- *Females Only:* Provider attests that member of childbearing age has been counseled on use of contraception while using Evkeeza™ due to potential fetal harm
- Initial coverage authorization will be granted for 6 months
- Maximum dose is 15mg/kg every 4 weeks

Renewal Coverage Criteria:

- Provider must provide documentation showing positive clinical improvement
- Adherence to Evkeeza™ and all additional lipid lowering agents the member was taking at initiation of Evkeeza™ therapy
- Annual specialist consult required if prescriber is not a specialist
- Renewal coverage authorization will be granted for 1 year
- Maximum dose is 15mg/kg every 4 weeks

G. Vyepti™ (eptinezumab-jjmr)

Member must meet all of the following criteria:

Initial Coverage Criteria

- Member is 18 years of age or older
- Member has a diagnosis of one of the following conditions:
    - Episodic migraines: 4-14 migraine days per month AND <15 headache days per month
    - Chronic migraines: ≥8 migraine days per month AND ≥15 headache days per month
- Member must not be concurrently receiving Botox (onabotulinumtoxinA)
- Must have a history of inadequate response (trial of at least two-month duration), contraindication or intolerance to two conventional prophylactic therapies in at least two separate classes below:
    - Amitriptyline or venlafaxine
    - Atenolol, metoprolol, nadolol, or propranolol
    - Topiramate or divalproex
- Must have a history of inadequate response (trial of at least three-month duration), contraindication or intolerance to at least one preferred self-administered CGRP inhibitor for the same indication
- Vyepti™ must not be used concomitantly with other CGRP antagonists

- Initial coverage authorization will be granted for 6 months
- Maximum dose is 300mg IV every 3 months

Renewal Coverage Criteria:

- Member has been adherent to Vyepti™
- Member has experienced a positive clinical response, as demonstrated by a reduction in monthly migraine frequency compared to number of migraine days at baseline
- Renewal coverage authorization will be granted for 1 year
- Maximum dose is 300mg IV every 3 months

PDL/DURB Meeting Follow-Up Items:

1. Armodafinil/modafinil – 1 year review
    - In December 2020, the Board approved a request to remove criteria for armodafinil and modafinil but requested an update after a year to be sure the criteria removal was appropriate. In the past year, the Drug Prior Authorization Unit received 75 requests for armodafinil, with 65 of those requests being approved, and 210 requests for modafinil, with 181 of those requests being approved. These numbers are comparable to the previous year when criteria was required. The Board was satisfied with this information.

Closed Session: No cases to review.

The meeting adjourned at 3:35pm.