October 2020 DUR Board Meeting Minutes

Date: October 21, 2020

Members Present: Caldwell, King, McGrane, Jost, Brown, Stone, Nauts, Putsch

Members Absent: Anglim, Blank, Maxwell

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

Introductions:
Tony King opened the meeting and asked the Board, Mountain Pacific employees, and employees of Montana Department of Public Health and Human Services bureau to introduce themselves.

Public Comment:
There was no public comment.

Meeting Minute Review:
The meeting minutes from September 23, 2020 DUR were approved as written.

Department Update:
Dani Feist updated the Board about the Public Health Emergency (PHE). Earlier this week, the U.S. Department of Health and Human Services announced they will be extending the PHE for up to 90 days, effective October 23, 2020. However, it is not confirmed how long at this time, but if the PHE extended the full 90 days, the PHE would be through January 21, 2021.

Board Discussion

1. **PDL Meeting Follow-Up Discussion:**
   At the September DURB meeting, the Board asked to revisit three drug classes with a Magellan representative (present today) to determine if the decisions made in March were appropriate. After a therapeutic class review, the Board's final recommendations are as follows:
   - Hypoglycemics, Incretin Mimetics/Enhancers:
     - DPP-IV – Reaffirmed March 2019 PDL recommendations: Therapeutic alternatives, must have one single-ingredient agent.
       - Removed *do not add sitagliptin products* from March 2020 PDL recommendation.
     - GLP-1 – Reaffirmed March 2019 PDL recommendations: Therapeutic alternatives, must have one single-ingredient agent.
       - Reaffirmed part of March 2020 PDL recommendation: Must have an agent with cardiovascular benefit.
       - Removed *do not add exenatide* from recommendation.
   - Hypoglycemics, Insulins and Related Agents:
     - Reaffirmed March 2019 PDL recommendations: Class effect for each group. Must have one from each. (Human R, N, Rapid-acting, Long-Acting, Rapid/Intermediate, Reg/Intermediate Combos). Must have U-500 pen, do not add U-500 vial.
     - Removed *must add Toujeo or Tresiba* from March 2020 PDL recommendation.

2. **Multiple Sclerosis Agents**

Mountain-Pacific presented new proposed criteria for the MS agents indicated for relapsing forms of MS. The updated and approved criteria is as follows:

- Preferred Drug List is a starting point for treatment of newly diagnosed members
- Member must have a diagnosis of a Relapsing Form of MS (CIS, RRMS, SPMS)
    - Mavenclad does not have an FDA indication for CIS, so member ***must*** have a diagnosis of RRMS or SPMS
- Must be prescribed by, or in consult with, a neurologist
- Member must be 18 years of age or older
    - Gilenya (fingolimod) is indicated down to 12 years of age
- Prior authorization will be for one year
- Compliance will be verified, and provider notified if member has not been adherent to treatment

The Board questioned if the Preferred Drug List's current set up is appropriate. This conversation would need to be added to an agenda and discussed at a later PDL meeting.

3. **Specialty Clinic Discussion**

Mountain-Pacific requested clarification from the Board on who is considered as a specialist when there is no MD in the clinic, and what (if any) requirements there will be for these providers prescribing specialty medications. The Board discussed this and ultimately decided to put it on a later agenda and bring it back for further discussion. The primary cause of concern is what types of additional certifications are available for mid-level practitioners and what qualifications do they have to be considered a specialist in a particular field. MPQH will research more and present the information to the Board at a later date.

4. **Review of New Drug Criteria**

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

A. Fintepla™ (fenfluramine)

- Member must meet ***all of the following criteria***:
- Must have diagnosis of Dravet Syndrome
- Must be ≥2 years of age
- Must be prescribed by, or in consult with, a neurologist
- Member's seizures must have been inadequately controlled on at least 2 anti-epileptics for DS (valproic acid, topiramate, clobazam, levetiracetam)
- *Limitations:*
    - Max dose 26mg/day for members NOT on Diacomit
    - Max dose 17mg/day for members ON Diacomit or clobazam
- **Initial authorization** granted for 6 months, then obtain follow-up information from prescriber to ensure member is tolerating and adherent to therapy. Subsequent authorizations will be granted for 1 year.

B. Dayvigo™ (Lemborexant)

- Member must meet ***all of the following criteria***:
- Must be ≥18 years of age
- Must have a diagnosis of insomnia with NO history of narcolepsy
- Member should not have a history of substance use disorder (drug or alcohol), or a history of suicidal ideation
- Member must have had a documented trial on one preferred BZD (unless contraindicated) in the last 24 months
- Member must have a documented inadequate response or contraindication to all the following: zolpidem, eszopiclone, zaleplon, ramelteon, trazodone, mirtazapine, and doxepin ***within the last 24 months***
- Prescriber has considered or recommended clinic based or electronically delivered Cognitive Behavioral Therapy and Mindfulness for insomnia in the past 24 months
    - The Board asked to add this criteria to Belsomra as well
- Only one sedative hypnotic at a time allowed class wide
- Initial 15-day supply
- Maximum of 1 daily
- **Initial authorization** granted for 6 months, then obtain follow-up information from prescriber to ensure member is tolerating therapy. Subsequent authorizations will be granted for 1 year.

C. Evrysdi™ (risdiplam)

- Member must meet ***all of the following criteria***:
- Member must be 2 months of age or older
- Member must have a diagnosis of Spinal Muscular Atrophy Type 1, 2, or 3 (SMA1, SMA2, or SMA3) confirmed by genetic testing
- Genetic testing has confirmed chromosome 5q homozygous deletions or dysfunctional point mutations of the SMN1 gene and 2 to ≤4 copies of SMN2 gene
- Member must not have permanent ventilator dependence
- Evrysdi® is prescribed by a neurologist
- Prescriber must submit documentation of a baseline motor function milestone evaluation using at least one of the following age-appropriate screening tools:
    - HINE-2 (Hammersmith Infant Neurological Exam Part 2) - appropriate for children 2 to 24 months of age
    - CHOP-INTEND (Children's Hospital of Philadelphia Infant Test of Neuromuscular Diseases)- appropriate for infants, children, and older people with an infant's repertoire of motor skills
    - HFMSE (Hammersmith Functional Motor Scale Expanded)- appropriate for individuals over 24 months of age with later-onset SMA (Type 2 or Type 3)
    - RULM (Revised Upper Limb Module Test)- appropriate for assessing upper limb function of ambulatory and non-ambulatory individuals
    - 6MWT (6 Minute Walking Test)- appropriate for ambulatory members with later-onset SMA (Type 2 or Type 3)
    - BSID-III Gross Motor Scale (Bayley Scales of Infant and Toddler Development – Third Edition) – appropriate for children 1 to 42 months of age
    - MFM32 (Motor Function Measure 32) – appropriate for ambulatory and non-ambulatory children and adults aged 6-62 years and for all levels of severity of the disease

- Member has not previously received Zolgensma®, or member has previously received Zolgensma® and has experienced a worsening in clinical status
- Member is not concurrently using Spinraza™ (nusinersen)
- **Initial authorization** granted for 1 year, then obtain follow-up information from prescriber to ensure member is tolerating and adherent to therapy
- **Subsequent Approval Criteria:**
    - Reauthorization will be granted for 1 year if criteria (below) is met
    - Member has been compliant with Evrysdi® therapy
    - Member is receiving a benefit from Evrysdi® therapy, as demonstrated by improvement or maintenance of motor skills as compared to pre-treatment baseline using at least one of the following age appropriate screening tools:
        - HINE-2 (Hammersmith Infant Neurological Exam Part 2) - appropriate for children 2 to 24 months of age
        - CHOP-INTEND (Children's Hospital of Philadelphia Infant Test of Neuromuscular Diseases)- appropriate for infants, children, and older people with an infant's repertoire of motor skills
        - HFMSE (Hammersmith Functional Motor Scale Expanded)- appropriate for individuals over 24 months of age with later-onset SMA (Type 2 or Type 3)
        - RULM (Revised Upper Limb Module Test)- appropriate for assessing upper limb function of ambulatory and non-ambulatory individuals
        - 6MWT (6 Minute Walking Test)- appropriate for ambulatory member with later-onset SMA (Type 2 or Type 3)
        - BSID-III Gross Motor Scale (Bayley Scales of Infant and Toddler Development – Third Edition) – appropriate for children 1 to 42 months of age
        - MFM32 (Motor Function Measure 32) – appropriate for ambulatory and non-ambulatory children and adults aged 6-62 years and for all levels of severity of the disease
    - Member has not previously received Zolgensma®, or member has previously received Zolgensma® and has experienced a worsening in clinical status
    - Member is not concurrently using Spinraza™ (nusinersen)

5. Existing Criteria Updates

The following existing clinical criteria were reviewed, and the Board made the following recommendations:

A. Epidiolex™ (cannabidiol) – *New indication for Tuberous Sclerosis Complex (TSC)*

- Member must meet ***all of the following criteria***:
- Must have diagnosis Tuberous Sclerosis Complex (TSC)
- Must be 1 year of age or older
- Must be prescribed by or in consultation with a neurologist
- Member's seizures must have been inadequately controlled by trial of at least 3 other conventional anti-epileptic therapies
- Must be used as adjunctive therapy with at least one other anti-epileptic medication
- LIMITATIONS: Max dose 12.5mg/kg twice daily

- **Initial** authorization will be granted for 4 months, then obtain follow-up information from prescriber to ensure member is tolerating and adherent to therapy and experiencing a positive clinical response. Subsequent approvals granted for 1 year.

6. ***Physician Administered Drug Program (PAD)***

Existing Criteria for PAD Drugs

The following existing clinical criteria were reviewed, and the Board made the following recommendations:

A. Cinqair™ (reslizumab)

- Member must meet ***all of the following criteria***:
- Member must be 18 years of age or older
- Member has a diagnosis of severe asthma with an eosinophilic phenotype
- Prescriber practices in one of the following specialty clinics, or has an annual consult on file: Allergy, Pulmonology, or Immunology
- Initial baseline peripheral blood eosinophil count is provided
- Member has a history of severe asthma attacks despite treatment with BOTH an inhaled corticosteroid AND a Long-acting beta2-agonist at optimized doses in combination for 3 consecutive months
- Provider attests that member will not use Cinqair (reslizumab) concomitantly with other biologics (e.g., Fasenra, Dupixent, Nucala, Xolair)
- **Initial authorization** will be granted for 6 months, then obtain follow-up information from MD to ensure member is tolerating and adherent to therapy, experiencing positive response to therapy as demonstrated by a reduction in the frequency and/or severity of symptoms and exacerbations or medication dose reduction, and an updated annual consult if prescriber is not a specialist. Subsequent approvals will be granted for 1 year.

B. Exondys 51™ (eteplirsen)

- Member must meet ***all of the following criteria****:*
- Member must have Duchenne Muscular Dystrophy (DMD) with a confirmed mutation of the DMD gene that is amenable to exon 51 skipping. See Column 1 in attached Table 1 (last page of minutes) for DMD gene deletions that are potentially amenable to Exon 51 skipping. Genetic mutation test results must be submitted with request.
- Exondys 51 must be prescribed by, or in consult with, a specialist familiar with DMD (usually a neurologist)
- Member must be on a stable dose of corticosteroids (prednisone, prednisolone, etc.) prior to starting Exondys 51, unless corticosteroid use is contraindicated, or was discontinued due to unfavorable side effects.
- Corticosteroids (prednisone, prednisolone, etc.) must be used concurrently with Exondys 51, unless corticosteroid use is contraindicated, or was discontinued due to unfavorable side effects.
- Member must be ambulatory (able to walk with assistance, and not wheelchair dependent).

- **Initial authorization** will be granted for 6 months, then obtain follow-up information from prescriber to ensure member is tolerating and adherent to therapy, as well as still ambulatory (able to walk with assistance and not wheelchair dependent), and corticosteroid used concurrently, unless contraindicated or discontinued due to unfavorable side effects. Subsequent approvals will be granted in 6-month intervals.

C. Sublocade™ (buprenorphine extended release)

- Member must meet ***all of the following criteria***:
- Member is 18 years of age or older
- Diagnosis of moderate to severe Opioid Use Disorder (DSM-V criteria)
- Provider enrolled in SUBLOCADE REMS Program and X-DEA number provided
- Member has been stabilized on a buprenorphine transmucosal dose equivalent of 8-24 mg for a minimum of 7 days
- Provider has evaluated potential drug interactions (concurrent use of strong CYP inhibitors or inducers is not recommended)
- Clinical rationale provided documenting necessity to switch to injectable product
- Consideration will be made to offer member a naloxone rescue prescription and education
- Provider attests member Treatment Plan includes ***all*** of the following and ***will be documented*** in member chart (case notes do not need to be sent unless specifically requested)
    - Diagnosis of ***moderate to severe*** **Opioid Use Disorder** (DSM-V Criteria)
    - Member will be referred for counseling assessment and counseling
    - Proposed monitoring plan includes random urine drug screens (to include drugs of abuse *and* buprenorphine)
    - Treatment Contract has been signed by member ***and member understands:***
        - ***Concurrent opioids, tramadol, or carisoprodol will not be covered with buprenorphine-containing products***
        - If a member subsequently discontinues the buprenorphine-containing product, all opioids, tramadol formulations, and carisoprodol will remain on not-covered status. These medications will require Prior Authorization for any future prescriptions. Approval may be granted short-term for an acute injury, hospitalization, or other appropriate diagnosis *only* after the case is reviewed with the treating provider and the provider prescribing the buprenorphine-containing product.
    - ***If member is pregnant:***
        - Provide estimated due date
        - Risk/benefit has been discussed with member
        - Treatment provider attests that OB provider has been contacted to establish post-delivery plan (for treatment of neonatal withdrawal syndrome). OB provider name, phone, and date contacted must be submitted.
- **Initial authorization** will be granted for 6 months, then obtain follow-up information from prescriber to ensure member is tolerating and adherent to therapy, as well as making clinically meaningful progress towards treatment goals. Subsequent approvals will be granted for 1 year.

D. Xolair™ (omalizumab)

- **Allergic Asthma**
    - Member must meet ***all of the following criteria***:
    - Member must be 6 years of age or older
    - Member must have moderate/severe asthma and allergies
    - Prescriber must practice in an appropriate specialty clinic (Pulmonology, Allergy, or Immunology) **OR** have an annual consult on file
    - Member must be adherent to ICS
    - Pretreatment serum total IgE level and current body weight must be provided
    - **Initial authorization** will be granted for 1 year, then obtain follow-up information from prescriber to ensure member is tolerating and adherent to therapy. Member has shown a positive response to therapy as demonstrated by reduction in the frequency and/or severity of symptoms and exacerbations. Subsequent approvals will be granted for 1 year.
- **Chronic Idiopathic Urticaria**
    - Member must meet ***all of the following criteria***:
    - Member must be 12 years of age or older
    - Member must have a diagnosis of chronic idiopathic urticaria
    - Prescriber must practice in an appropriate specialty clinic (Allergy, Immunology, or Dermatology) OR have an annual consult on file
    - Member must have had an inadequate response to 2 different antihistamine trials of 4 weeks each
    - **Initial authorization** will be granted for 3 months, then obtain follow-up information from prescriber to ensure member is tolerating and adherent to therapy. If there is still insufficient control at that time, no further authorization will be approved. If member has had a positive response to therapy as demonstrated by reduction in the frequency and/or severity of symptoms, subsequent approvals will be granted in 6-month increments.

E. Vivitrol™ (naltrexone extended release)

- Member must meet ***all of the following criteria***:
- Opioid using or opioid dependent members should be opioid free for a minimum of 7-10 days or have demonstrated negative naltrexone or naloxone challenge (applies to both alcohol dependence therapy and opioid use disorder therapy)
- Member must demonstrate tolerability to oral naltrexone
- **Alcohol Dependence**
    - Member is 18 years of age or older
    - Screening/assessment supports a diagnosis of alcohol dependence
    - Clinical rationale submitted why oral naltrexone not appropriate
    - Provider attests behavioral health assessment and engagement in counselling will be recommended as part of treatment plan
    - **Initial authorization** will be granted for 1 year, then obtain follow-up information from prescriber to ensure member is adherent to treatment and making clinically meaningful progress towards treatment goals. Subsequent approvals granted for 1 year.
- **Opioid Use Disorder**
    - Member is 18 years of age or older

- Screening/assessment supports a diagnosis of opioid use disorder
- Clinical rationale submitted why Suboxone is not appropriate
- Provider attests behavioral health assessment and engagement in counselling will be recommended as part of treatment plan
- Member is aware that all opioids will be placed on drug non-covered status permanently. All future requests for opioids will require prior authorization.
- **Initial authorization** will be granted for 1 year, then obtain follow-up information from prescriber to ensure member is adherent to treatment and making clinically meaningful progress towards treatment goals. Subsequent approvals granted for 1 year.

F. Krystexxa™ (pegloticase)

- Member must meet ***all of the following criteria***:
- Member must be 18 years of age or older
- Must be prescribed by a Rheumatologist (or have a documented consult on file)
- Baseline serum uric acid level greater than 8mg/dL
- Member must have symptomatic gout with one or more of the following:
  - Chronic gouty arthritis **OR**
  - Three or more flares in the past 18 months **OR**
  - Presence of one or more tophi
- Member has a documented contraindication, intolerance to or failure after at least a 90-day course of allopurinol AND Uloric®(febuxostat)
- Member screened for G6PD deficiency
- Urate lowering medications have been discontinued and will not be used concurrently with Krystexxa®
- **Initial authorization** will be granted for 3 months, then obtain follow-up information from prescriber describing positive response to treatment and lack of serious side effects. Reauthorization ***will not*** be granted if member has more than 2 serum uric acid levels over 6mg/dL after initiation. Subsequent approvals granted for 1 year.

G. Nucala™ (mepolizumab)

- **Severe Eosinophilic Asthma**
  - Member must meet ***all of the following criteria****:*
  - Member must be 6 years of age or older
  - Prescriber must be specialist or have an annual consult on file (Pulmonology/Allergy/Immunology)
  - Diagnosis of severe uncontrolled asthma with an eosinophilic phenotype
  - Must provide baseline peripheral blood eosinophil count (Attach lab report with eosinophil count)
    - Criteria: 150 cells/microliter (past 6 weeks) or 300 cells/microliter (past year)
  - Member has a history of *severe* asthma attacks despite treatment with inhaled corticosteroid (ICS) in combination with long-acting beta$_2$-agonist (LABA) inhaler at optimized doses for 3 consecutive months
  - Provider attests that member will not use Nucala concomitantly with other biologics (e.g. Fasenra, Dupixent, Cinqair, Xolair)
  - **Initial authorization** will be granted for 6 months, then obtain follow-up information from prescriber to ensure member is tolerating and adherent to

therapy (including ICS/LABA use). Documentation submitted supporting positive response to therapy as demonstrated by a reduction in frequency and/or severity of symptoms and exacerbations or medication dose reduction. If not prescribed by appropriate specialist, annual specialist consult must be submitted. Subsequent approvals granted for 1 year.

- **EGPA**
  - Member must meet ***all of the following criteria***:
  - Member must be 18 years of age or older
  - Prescriber must be specialist or have an annual consult on file (Rheumatology/ Pulmonology/Immunology)
  - Diagnosis of eosinophilic granulomatosis with polyangiitis
  - Member is experiencing exacerbations while on stable dose of oral corticosteroids or during steroid taper
  - Immunosuppressive therapy has been ineffective, contraindicated, or not tolerated
  - **Initial authorization** will be granted for 6 months, then obtain follow-up information from prescriber to ensure member is tolerating and adherent to therapy. Documentation submitted supporting positive response to therapy as demonstrated by a reduction in frequency and/or severity of symptoms and exacerbations or medication dose reduction. If not prescribed by appropriate specialist, annual specialist consult must be submitted. Subsequent approvals granted for 1 year.

- **HES**
  - Member must meet ***all of the following criteria***:
  - Member must be 12 years of age or older
  - Prescriber must be a specialist (Allergy/Immunology/Pulmonology/Neurology/Cardiology/Dermatology) or have an annual consult on file
  - Diagnosis of hypereosinophilic syndrome for >6 months
  - **Initial authorization** will be granted for 6 months, then obtain follow-up information from prescriber to ensure member is tolerating and adherent to therapy. Documentation must be submitted supporting positive response to therapy as demonstrated by a reduction in frequency and/or severity of symptoms and exacerbations or medication dose reduction. If not prescribed by appropriate specialist, annual specialist consult must be submitted. Subsequent approvals granted for 1 year.

New Criteria for PAD Drugs

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

- ***Prolia™ (denosumab)***
  - Member must meet ***all of the following criteria***:
  - Member is 18 years of age or older

- Prolia® is being used for one of the following indications:
    - Treatment of postmenopausal women with osteoporosis at high risk for fracture
    - Treatment to increase bone mass in men with osteoporosis at high risk for fracture
    - Treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture
    - Treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer
    - Treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer
- Member is at high risk for fracture defined as meeting at least one of the following:
    - BMD T-score $\leq$-2.5 at femoral neck or spine
    - BMD T-score between -1 and -2.5 at the femoral neck or spine, AND one of the following:
        - a 10-year probability of hip fracture $\geq$3 percent (determined by FRAX) **OR**
        - a 10-year probability of any major osteoporosis-related fracture $\geq$20% (determined by FRAX) **OR**
        - History of low-trauma fragility fracture (particularly at the spine, hip, wrist, humerus, rib, and pelvis)
- Unless contraindicated, member had an adequate trial with a Montana Health Care Programs preferred drug (such as alendronate, ibandronate, raloxifene, or Forteo SQ) and the preferred drug was ineffective or caused intolerable side effects. An adequate trial is one year.
- Member does not have pre-existing hypocalcemia
- Member takes at least 1000 mg/day of calcium and at least 400 IU/day of Vitamin D (unless contraindicated) and any deficiencies have been corrected
- Member is not pregnant
- Member is not taking Xgeva®
- **Initial authorization** will be granted for 1 year, then obtain follow-up information from prescriber. Subsequent renewals will be approved for 1 year. For PA renewal, member must meet ***all*** the following criteria:
    - Member has been compliant and adherent with Prolia®
    - Member continues to take calcium and vitamin D (unless contraindicated)
    - Member has experienced a positive clinical response (e.g., T-score has increased or has not continued to decrease, absence of fracture, etc.)

- ***Entyvio™ (vedolizumab)***
    - Member must meet ***all of the following criteria***:
    - Member is 18 years of age or older.
    - Member has one of the approved indications listed below:
        - Moderately to severely active ulcerative colitis
        - 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 **both** of the following, unless contraindicated:

    - One of the conventional therapies [corticosteroid and/or immunomodulator (e.g., azathioprine, 6-mercaptopurine, methotrexate, etc.)]
    - A Montana Healthcare Programs preferred TNF blocker (e.g., Humira®)
- **Initial authorization** will be granted for 14 weeks, then obtain follow-up information from prescriber. Subsequent renewals will be approved for 1 year. For PA renewal, member must meet ***all*** the following criteria:
    - Yearly follow-up or consult with appropriate specialist
    - Evidence of continued therapeutic benefit
    - Compliance with Entyvio™

- ***Ocrevus™ (ocrelizumab)***
    - **Primary Progressive MS:**
        - Member must meet ***all of the following criteria***:
        - Member is 18 years of age or older
        - Member has a diagnosis of primary progressive multiple sclerosis (PPMS)
        - Member is ambulatory when therapy is **instituted** (not required for renewals)
        - Member is being treated by a neurologist or has a current neurology consult
        - Member has been screened for Hepatitis B and shown not to have active disease prior to initial dose
        - **Initial authorization** will be granted for 1 year, then obtain follow-up information from prescriber to ensure tolerability and adherence to therapy. Subsequent approvals will be granted for 1 year.

    - **Relapsing forms of MS:**
        - Member must meet ***all of the following criteria***:
        - Member has a relapsing form of multiple sclerosis:
            - clinically isolated syndrome (CIS) or
            - relapsing-remitting MS (RRMS) or
            - secondary progressive MS (SPMS)
        - Member has had an adequate trial, or provider has clinical rationale as to why the preferred molecules are not appropriate, with one (1) Montana Health Care Programs preferred drug:
            - interferon beta-1a (Avonex®, Rebif®)
            - interferon beta-1b (Betaseron®)
            - glatiramer acetate (Copaxone®)
            - fingolimod (Gilenya®)
        - Member is being treated by a neurologist or has a current neurology consult
        - Member has been screened for Hepatitis B and shown not to have active disease prior to initial dose
        - **Initial authorization** will be granted for 1 year, then obtain follow-up information from prescriber to ensure tolerability and adherence to therapy. Subsequent approvals will be granted for 1 year.

- ***Simponi Aria™ (golimumab infusion)***
    - **Moderately to severely active rheumatoid arthritis**
        - Member must meet ***all of the following criteria***:
        - Member is 18 years or older

- Medication is prescribed by or in consult with a rheumatologist (consultation must be made yearly)
- Member has failed one (1) oral DMARD (e.g. methotrexate) and one (1) Montana Healthcare Programs Preferred Drug List TNF inhibitor (Enbrel®, Humira®)
- Member will be taking Simponi Aria® in conjunction with methotrexate.
- **Initial authorization** will be granted for 6 months, then obtain follow-up information from prescriber to ensure tolerability and adherence to therapy. Yearly follow-up or consult with appropriate specialist, evidence of continued therapeutic benefit, and compliance with methotrexate therapy required. Subsequent approvals will be granted for 1 year.

- **Active psoriatic arthritis**
  - Member must meet ***all of the following criteria***:
  - Member is 2 years of age or older
  - Medication is prescribed by or in consult with a rheumatologist and/or dermatologist (consultation must be made yearly)
  - Member has failed or has contraindications to a non-steroidal anti-inflammatory (NSAID), and an oral DMARD
  - Member has failed a Montana Healthcare Program Preferred Drug List TNF inhibitor (Enbrel®, Humira®)
  - **Initial authorization** will be granted for 6 months, then obtain follow-up information from prescriber to ensure tolerability and adherence to therapy. Yearly follow-up or consult with appropriate specialist, and evidence of continued therapeutic benefit required. Subsequent approvals will be granted for 1 year.

- **Active ankylosing spondylitis**
  - Member must meet ***all of the following criteria***:
  - Member is 18 years or older
  - Medication is prescribed by or in consult with a rheumatologist (consultation must be made yearly)
  - Member has failed or has contraindications to a non-steroidal anti-inflammatory (NSAID), and an oral DMARD
  - Member has failed a Montana Healthcare Program Preferred Drug List TNF inhibitor (Enbrel®, Humira®)
  - **Initial authorization** will be granted for 6 months, then obtain follow-up information from prescriber to ensure tolerability and adherence to therapy. Yearly follow-up or consult with appropriate specialist, and evidence of continued therapeutic benefit required. Subsequent approvals will be granted for 1 year.

- **Active polyarticular juvenile idiopathic arthritis (pJIA)**
  - Member must meet ***all of the following criteria***:
  - Member is 2 years of age or older
  - Medication is prescribed by or in consult with a rheumatologist (consultation must be made yearly)

- Member has failed one (1) Montana Healthcare Program Preferred Drug List TNF inhibitor (Enbrel® and Humira® are indicated for pJIA in members 2 years of age and older)
- **Initial authorization** will be granted for 6 months, then obtain follow-up information from prescriber to ensure tolerability and adherence to therapy. Yearly follow-up or consult with appropriate specialist, and evidence of continued therapeutic benefit required. Subsequent approvals will be granted for 1 year.

- ***Evenity™ (romosozumab-aqqg)***
  - Member must meet ***all of the following criteria***:
  - Member is 18 years of age or older
  - Member is a postmenopausal woman with osteoporosis at high risk for fracture
  - Member is at high risk for fracture defined as meeting at least one of the following:
    - BMD T-score ≤ -2.5 at femoral neck or spine
    - BMD T-score between -1 and -2.5 at the femoral neck or spine, AND one of the following:
      - a 10-year probability of hip fracture ≥3 percent (determined by FRAX), **OR**
      - a 10-year probability of any major osteoporosis-related fracture ≥20% (determined by FRAX), **OR**
      - History of low-trauma fragility fracture (particularly at the spine, hip, wrist, humerus, rib, and pelvis)
  - Member has not had a myocardial infarction or stroke within previous year
  - Member has not previously used Evenity® (romosozumab) for a total duration of more than 12 months
  - Member does not have pre-existing hypocalcemia
  - Member should be adequately supplemented with calcium and vitamin D while on Evenity®, unless contraindicated
  - Member must have had an inadequate response, intolerance, or contraindication to **all** the following medications (an adequate trial duration is one year for each medication):
    - A Montana Health Care Programs preferred bisphosphonate **AND** Forteo SQ® (teriparatide)
    - Prolia® (denosumab)
  - **Initial authorization** is limited to a total of 12 monthly doses. Subsequent authorizations are not applicable as this therapy is not indicated past 12 monthly doses.

- ***Fasenra™ (benralizumab)***
  - Member must meet ***all of the following criteria****:*
  - Member must be 12 years of age or older
  - Prescriber must be specialist or have an annual consult on file (Pulmonology/ Allergy/Immunology)
  - Diagnosis of severe uncontrolled asthma with an eosinophilic phenotype
  - Must provide baseline peripheral blood eosinophil count (Attach lab report with eosinophil count) of ≥300 cells/microliter

- Member has a history of *severe* asthma attacks despite treatment with inhaled corticosteroid (ICS) in combination with long-acting beta$_2$-agonist (LABA) inhaler at optimized doses for 3 consecutive months
- Provider attests that member will not use Fasenra concomitantly with other biologics (e.g., Cinqair, Dupixent, Nucala, Xolair)
- **Initial authorization** will be granted for 6 months, then obtain follow-up information from prescriber to ensure tolerability and adherence to therapy. Subsequent renewals will be approved for 1 year. For PA renewal, member must meet ***all*** the following criteria:
    - Reauthorization will be approved based on compliance with Fasenra® injection and with ICS/LABA
    - Documentation is attached supporting positive response to therapy as demonstrated by a reduction in the frequency and/or severity of symptoms and exacerbations, or medication dose reduction
    - Annual specialist consult is attached if prescriber is not a specialist

- ***Xgeva™ (denosumab)***
    - Member must meet ***all of the following criteria***:
    - Xgeva® is being used for one of the following indications:
        - Prevention of skeletal-related events in members with multiple myeloma and in members with bone metastases from solid tumors
        - Treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity
        - Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy
    - Member is at least 18 years of age, unless has giant cell tumor of bone. If has giant cell tumor of bone, then must be an adult ($\geq$18 years old) or an adolescent at least 12 years of age and skeletally mature, defined by having at least 1 mature long bone (e.g., closed epiphyseal growth plate of the humerus) and a body weight $\geq$ 45 kg.
    - Member has used an IV bisphosphonate that has been ineffective or not tolerated, unless contraindicated. Exception: If member has Giant Cell Tumor of Bone, they do not have to try IV bisphosphonate first.
    - Member is not pregnant.
    - Member is not taking Prolia®
    - **Initial Approval Limitations:**
        - Initial coverage duration is one year
        - For Prevention of skeletal-related events in members with multiple myeloma and in members with bone metastases from solid tumors:
            - 120 mg every 4 weeks as subcutaneous injection
        - For treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity:
            - 120 mg every 4 weeks with additional 120 mg doses on day 8 and 15 of the first month of therapy administered by subcutaneous injection
        - For treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy:

        - 120 mg every 4 weeks with additional loading doses on day 8 and 15 of the first month of therapy administered by subcutaneous injection
    - **Subsequent authorizations** are granted for one year if the member has been compliant and adherent to therapy and has had a positive clinical response

- ***Spinraza™ (nusinersen)***
    - Member must meet ***all of the following criteria***:
    - Member must have a diagnosis of Spinal Muscular Atrophy Type 1, 2, or 3 (SMA1, SMA2, or SMA3) confirmed by genetic testing
    - Genetic testing has confirmed chromosome 5q homozygous deletions or dysfunctional point mutations of the SMN1 gene and 2 to ≤4 copies of SMN2 gene.
    - Member must not have permanent ventilator dependence
    - Spinraza® is prescribed by a neurologist
    - Prescriber must submit documentation of a baseline motor function milestone evaluation using at least one of the following age-appropriate screening tools:
        - HINE-2 (Hammersmith Infant Neurological Exam Part 2) - appropriate for children 2 to 24 months of age
        - CHOP-INTEND (Children's Hospital of Philadelphia Infant Test of Neuromuscular Diseases)- appropriate for infants, children, and older people with an infant's repertoire of motor skills
        - HFMSE (Hammersmith Functional Motor Scale Expanded)- appropriate for individuals over 24 months of age with later-onset SMA (Type 2 or Type 3)
        - RULM (Revised Upper Limb Module Test)- appropriate for assessing upper limb function of ambulatory and non-ambulatory individuals
        - 6MWT (6 Minute Walking Test)- appropriate for ambulatory members with later-onset SMA (Type 2 or Type 3)
    - Provider attests that the following laboratory tests will be performed at baseline and prior to each administration of Spinraza®: platelet count, coagulation test, quantitative spot urine protein test
    - Member has not previously received Zolgensma®, or member has previously received Zolgensma® and has experienced a worsening in clinical status
    - Member is not concurrently using Evrysdi™ (risdiplam)
    - **Initial Approval Limitations:**
        - Initial coverage may be approved for a total of 5 doses (five 12 mg/5 ml vials) for the first 6 months. This includes coverage through the 4 loading doses (to be administered as 1 vial every 14 days for 3 doses, then the 4th loading dose 30 days following the 3rd dose), plus the first maintenance dose (given 4 months after the 4th dose).
    - **Subsequent Approval Criteria:**
        - Reauthorization will be granted for 1 year for a max of three (12mg/5ml) vials (1 vial every 4 months)
        - Member has been compliant with Spinraza® therapy
        - Member is receiving a benefit from Spinraza® therapy, as demonstrated by improvement or maintenance of motor skills as compared to pre-treatment baseline using at least one of the following age appropriate screening tools:

        - HINE-2 (Hammersmith Infant Neurological Exam Part 2) - appropriate for children 2 to 24 months of age
        - CHOP-INTEND (Children's Hospital of Philadelphia Infant Test of Neuromuscular Diseases)- appropriate for infants, children, and older people with an infant's repertoire of motor skills
        - HFMSE (Hammersmith Functional Motor Scale Expanded)- appropriate for individuals over 24 months of age with later-onset SMA (Type 2 or Type 3)
        - RULM (Revised Upper Limb Module Test)- appropriate for assessing upper limb function of ambulatory and non-ambulatory individuals
        - 6MWT (6 Minute Walking Test)- appropriate for ambulatory members with later-onset SMA (Type 2 or Type 3)
    - Provider attests that the following laboratory tests are being performed prior to each administration of Spinraza®: platelet count, coagulation test, and quantitative spot urine test
    - Member has not received Zolgensma®, or member has previously received Zolgensma® and has experienced a worsening in clinical status
    - Member is not concurrently using Evrysdi™ (risdiplam)

7. PDL/DURB meeting follow-up items

- Tony King informed the Board that MPQH is working to create a Board Member Portal where meeting documents, as well as any internal changes to criteria (i.e. approved age changes, indication additions, etc.) would be accessible. No time frame for completion.
- Possible December DURB meeting 12/9/2020

8. Closed Session

No closed session.

Meeting adjourned
4:38pm

Table 1. Duchenne Gene Deletions Potentially Amenable to Exon Skipping*~

Exon 51 Skip-amenable (13% of Duchenne population)	Exon 53 Skip-amenable (8% of Duchenne population)	Exon 45 Skip-amenable (8% of Duchenne population)	Exon 44 Skip-amenable (6% of Duchenne population)	Exon 50 Skip-amenable (4% of Duchenne population)	Exon 52 Skip-amenable (4% of Duchenne population)	Exon 55 Skip-amenable (2% of Duchenne population)
17-50	19-52	12-44	10-43	20-49	20-51	21-54
19-50	21-52	18-44	11-43	22-49	22-51	23-54
21-50	23-52	44	13-43	51	51	24-54
23-50	24-52	46	14-43	51-53	53	25-54
24-50	25-52	46-47	15-43	51-55	53-55	26-54
25-50	26-52	46-48	16-43		53-57	27-54
26-50	27-52	46-49	17-43		53-59	28-54
27-50	28-52	46-51	19-43		53-60	29-54
28-50	29-52	46-53	21-43			30-54
29-50	30-52	46-55	23-43			31-54
30-50	31-52	46-57	24-43			32-54
31-50	32-52	46-59	25-43			33-54
32-50	33-52	46-60	26-43			34-54
33-50	34-52		27-43			35-54
34-50	35-52		28-43			36-54
35-50	36-52		29-43			37-54
36-50	37-52		30-43			38-54
37-50	38-52		31-43			39-54
38-50	39-52		32-43			40-54
39-50	40-52		33-43			41-54
40-50	41-52		34-43			42-54
41-50	42-52		35-43			43-54
42-50	43-52		36-43			45-54
43-50	45-52		37-43			47-54
45-50	47-52		38-43			48-54
47-50	48-52		39-43			49-54
48-50	49-52		40-43			50-54
49-50	50-52		41-43			52-54
50	52		42-43			54
52	54-58		43			56
52-58	54-61		45			56-62
52-61	54-63		45-54			
52-63			45-56			
			45-62			

* This table does not list all possible exon skipping compounds and the corresponding skip-amenable deletions. Exon skipping for other Duchenne gene exons is in development, including but not limited to exons 8, 35 and 43.

~ Exon skipping would in theory be expected to restore the reading frame allowing the production of a semi-functional dystrophin, but for many deletions listed above, this has never been confirmed.

Deletions potentially amenable to exon skipping were determined using the following sources:

- Leiden DMD Mutation Database. http://www/dmd.nl.
- White SJ, den Dunnen JT (2006). Copy number variation in the genome; the human DMD gene as an example. Cytogenet. Genome Res. 115: 240-246.
- Aartsma-Rus A (Thesis 2005). Development of antisense-mediated exon skipping therapy for Duchenne muscular dystrophy - making sense out of nonsense.
- Aartsma-Rus A et al (2006). Entries in the Leiden Duchenne muscular dystrophy mutation database: an overview of mutation types and paradoxical cases that confirm the reading-frame rule. Muscle Nerve 34(2):135-44.
- Aartsma-Rus A (2014). Dystrophin analysis in clinical trials. Journal of Neuromuscular Diseases 1(1): 41-53.