COLORADO
Department of Health Care Policy & Financing

MINUTES OF THE QUARTERLY OPEN MEETING OF THE COLORADO MEDICAID DUR BOARD MEETING
Health First Colorado, Colorado Medicaid, Drug Utilization Review Board

Department of Health Care Policy and Financing

November 10, 2020
Open Session
1:00 pm – 5:00 pm

1. Call to Order

Board Chair M Noonan joined the meeting a few minutes late. In the absence of a Vice Chair *(see Department Updates below)*, M Wilkerson offered to act as Vice Chair. T Brubaker moved to approve Dr. Wilkerson as activing Vice Chair and the motion was seconded by S VanEyk. Motion passed unanimously. This virtual meeting was officially called to order at 1:10 pm by M Wilkerson.

2. Roll Call / Introductions and welcome to new members

All board members, HCPF staff, and CO DUR team members who were present introduced themselves. There were sufficient members for a quorum with nine voting members participating. Quorum is five members.

a. **Members Present:**, Michael Noonan, DO (Chair); Mary Wilkerson, MD (acting Vice-Chair); Scott VanEyk, MD; Allison Blackmer, PharmD; Miroslav Anguelov, PharmD; Liza Wilson Claus, PharmD; Alison Shmerling, MD; Todd Brubaker, DO; Patricia Lanius, MHA, BSPharm
b. **Members Absent:** W Lai (Industry Representative)
c. **Medicaid Pharmacy Staff:** Jeffrey Taylor, PharmD
d. **CO-DUR Team**: Robert Page, PharmD; Julia Rawlings, PharmD; Garth Wright, MPH

3. Reading of Rules for Public Testimony and Disclosure of Conflicts of Interest:

J Taylor read the following rules for Board members and speakers:

Rules for Speaker Testimony: Presentations shall be restricted to products being reviewed for prior authorization criteria. Presentations shall be limited to a maximum of three minutes per drug product. Only one presentation per product will be permitted for a manufacturer. Persons must sign up no later than 24 hours in advance with the DUR Account Manager in order to speak at the DUR Board Meeting. Persons will be called in the order in which they signed in for each set of prior authorization criteria. Presentations must be limited to verbal comments. No visual aids, other than designated handouts are permitted. Persons giving oral presentations must verbally disclose all relationships to pharmaceutical manufacturers.

DUR Board Conflicts of Interest: DUR Board Members must verbally disclose any conflicts of interest that would make it difficult to fulfill DUR Board duties in an objective manner. If a conflict of interest exists, members must recuse themselves from the applicable vote or discuss with the board during the meeting whether the situation rises to the level of an actual conflict. If a board member recuses himself or herself, they should not participate in the discussion of the agenda item or any vote regarding it.

4. Department Updates

J Taylor provided several updates:

- HCPF teams have been informed that they will be conducting their work virtually, at least through March 2021
- Dr. Lisa Latts recently left her position as Chief Medical Officer at HCPF. Her replacement has not yet been named
- Dr. Gosia Thomas recently accepted a new position within the pharmaceutical industry and therefore has resigned from the Board. Thank you to Dr. Thomas for her service as a Board member.
- After serving on the DUR Board for several years, Dr. Mary Wilkerson will be stepping down after today's meeting. Thank you to Dr. Wilkerson for her service as a Board member and for offering to serve as Vice Chair for today's meeting.
- Welcome to two new DUR Board members:
  - Pharmacist Patricia (Patte) Lanius
  - Physician Todd Brubaker
- Dr. Gosia Thomas was elected Vice Chair in February 2020, so the Board is now temporarily without a Vice Chair. The Department suggests postponing selection of a new Vice Chair until the normal cycle to select a Board Chair and Vice Chair during the February 2021 meeting. For the upcoming year, the Chair will be a pharmacist and the Vice Chair will be a physician. Members may nominate themselves or other Board members as candidates for these roles.

J Taylor announced that the next Board meeting is scheduled for Tuesday, February 9, 2021, 1:00 pm to 5:00 pm, on Zoom.

J Taylor announced that some therapeutic classes may be moved in (or out) of Mass Review during today's meeting.

J Rawlings requested that Board members state their names each time they make a motion or second a motion so that meeting minutes can be produced more easily. Quick hand raises and motions/seconds with no verbal identification of the speaker are challenging within the Zoom environment. M Noonan stated that raising hands on screen may be used for voting since it is more efficient. Abstentions and recusals will be verbal.

R Page presented the RDUR summary. There was discussion about a rising trend in members who are taking more than one benzodiazepine, particularly as it relates to the potential role of that drug class in suicide scenarios. G Wright clarified that patients with seizure disorder diagnosis codes are excluded from the >1 benzodiazepine RDUR report. Prescribers receive letters each quarter to identify their patients who have >1 concurrent benzodiazepine claim. However, in addition to letters, M Noonan and M Wilkerson suggested that the Department consider initiating telephone calls to specific prescribers who might benefit from further education in this area. J Taylor stated that another option is to implement a system edit that would move approvals for >1 benzodiazepine upstream as part of the prior authorization process.

R Page presented an update on the recent Quarterly Clinical Modules

- Characterization of Gabapentinoid Use within Colorado Medicaid Beneficiaries (final 9/30/2020)
- Characterization of Newer Diabetes Agents Use Within Colorado Medicaid Members (draft 9/30/2020)
- Availability of naloxone for members taking opioids on a chronic basis (draft due 12/30/2020)

T Brubaker asked if Clinical Modules ever explore pediatric topics. The CO-DUR team can share previous modules that have included the pediatric Medicaid population with Dr. Brubaker if he is interested in reviewing those documents.

R Page presented the Quarterly Drug Utilization Reports.

J Rawlings and R Page presented FDA Safety and New Drug updates. One safety highlight was the FDA's warning on 9/24/2020 about serious problems associated with the current "Benadryl challenge" trend involving misuse of high-dose diphenhydramine, especially among teens. The FDA Updates were inadvertently skipped over at their assigned spot on the meeting agenda, so this item was presented immediately after review of the PAH therapeutic drug class.

5. Updates on Business from Last Meeting:

J Taylor reported that the Department was able to meet the Board's motions from the August 2020 meeting and incorporate them into implemented criteria that became effective on October 1, 2020. Changes included some updates for valproic acid dosing, Fintepla (fenfluramine) dosing for pediatric age groups, changes to accommodate the use of methylphenidate IR use in younger pediatric patients, changes regarding the use of Eliquis (apixaban) in the setting of malignancy, and some changes to bisphosphonate language to include vertebral fractures.

6. Final Approval of Minutes from August 11, 2020 Meeting

M. Noonan asked if there were any changes to propose for minutes from the August 2020 DUR Board meeting. With no discussion, a motion to approve the minutes as written made by L Claus, seconded by A Shmerling. None opposed. Motion passed unanimously.

7. New Business

R Page and J Rawlings proceeded to New Business and presenting criteria proposals

Proposed Criteria

1. Non-Steroidal Anti-Inflammatories (NSAIDs), Oral

Preferred Products:

Celecoxib capsule
Diclofenac potassium tablet
Diclofenac sodium EC/DR tablet
Ibuprofen tablet, suspension (Rx)
Indomethacin capsule, ER capsule
Ketorolac tablet**
Meloxicam tablet
Nabumetone tablet
Naproxen IR, EC, DR/ER, suspension (Rx)
Sulindac tablet

**Ketorolac tablets quantity limit: 5 days of therapy for every 30 days Tablets: 20 tablets for 30 days

Non-preferred oral agents may be approved for members who have trialed and failed four preferred agents. (Failure is defined as: lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction.)

DUEXIS (ibuprofen/famotidine) or **VIMOVO (naproxen/esomeprazole)** may be approved if the member meets the following criteria:

- Trial and failure of all preferred NSAIDs at maximally tolerated doses **AND**
- Trial and failure of three preferred proton pump inhibitors in combination with NSAID within the last 6 months **AND**
- Have a documented history of gastrointestinal bleeding

(Failure is defined as: lack of efficacy, contraindication to therapy, allergy, intolerable side effects or significant drug-drug interactions)

Discussion

- No Board members reported a conflict of interest for this therapeutic class.
- Motion made by A Blackmer to accept criteria for this class as written. Seconded by L Claus. Motion passed unanimously.

2. Non-Steroidal Anti-Inflammatories (NSAIDs), Non-Oral

Preferred Products:

Diclofenac sodium 1.5% topical solution
VOLTAREN^{BNR} (diclofenac sodium) 1% gel (Rx)
Diclofenac sodium 1% gel (generic VOLTAREN) (Rx)

Non-preferred topical agents may be approved for members who have trialed and failed one preferred agent. Failure is defined as lack of efficacy with 14 day trial, allergy, intolerable side effects, or significant drug-drug interaction.

SPRIX (ketorolac) intranasal will be approved if the member meets the following criteria:

- Unable to tolerate, swallow or absorb oral NSAIDs **OR**
- Trial and failure of three preferred oral or topical NSAID agents (failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions)
- Quantity limit: 5-single day nasal spray bottles per 30 days

FLECTOR (diclofenac) patch quantity limit: 2 patches per day

SOLARAZE (diclofenac sodium) gel prior authorization criteria can be found on the Appendix P.

Discussion

- The Non-Oral NSAIDs therapeutic drug class was moved to Mass Review during this meeting.
- Current PDL criteria for the Non-Oral NSAIDs were inadvertently omitted from the proposed criteria document in the Board meeting binder. Therefore, those criteria were emailed to all Board members during the meeting and prior to the Mass Review agenda item.

3. Antibiotics, Inhaled

Preferred Products:
Tobramycin inhalation solution (ampule)
*CAYSTON (aztreonam) inhalation solution **2nd Line****

*The second-line preferred agent **CAYSTON (aztreonam) inhalation solution** may be approved if the following criteria are met:

1. Member has a history of trial and failure of tobramycin solution for inhalation **OR** provider attests that member cannot use tobramycin solution for inhalation. Failure is defined as lack of efficacy with a 4-week trial, contraindication to therapy, allergy, intolerable side effects or significant drug-drug interaction **AND**
2. Member is 7 years of age or older and has a documented diagnosis of cystic fibrosis (CF) with *Pseudomonas aeruginosa* **AND**
3. Member has FEV_1 25-75% of predicted **AND**
4. Member is not infected with *Burkholderia cepacia* **AND**
5. Member has prescription for inhaled beta agonist to use prior to nebulization of CAYSTON (short-acting: 15 minutes to 4 hours prior, long-acting: 30 minutes to 12 hours prior)

NOTE: To reduce the development of drug-resistant bacteria and maintain the effectiveness of CAYSTON and other antibacterial drugs, CAYSTON should be used only to treat members with CF known to have *Pseudomonas aeruginosa* in the lungs.

*Failure is defined as: lack of efficacy, contraindication to therapy, allergy, intolerable side effects or significant drug-drug interactions

	Age Range & Dosing	**Maximum Dose**
Tobramycin inhalation ampule	Age ≥ 6 years: 300 mg administered every 12 hours for 28 days, followed by 28 days off Doses are not adjusted based on weight or age Tobramycin inhalation solution should not be used concurrently with other drugs with neurotoxic, nephrotoxic, or ototoxic potential (such as ethacrynic acid, furosemide, urea or IV mannitol)	600 mg daily for 28 days

*CAYSTON (aztreonam) inhalation solution ****2nd Line****	Age ≥ 7 years: 75 mg administered 3 times a day for 28 days, followed by 28 days off Doses are not adjusted based on weight or age	225 mg daily for 28 days
ARIKAYCE (amikacin) nebulizer vial -**non-preferred**	Age ≥ 18 years: 590 mg administered one time daily	590 mg daily

Prior authorization for all **non-preferred inhaled antibiotics** may be approved after a 4-week trial and failure (due to lack of efficacy) of BOTH tobramycin inhalation ampule **AND** CAYSTON (aztreonam).

Grandfathering: Members currently stabilized on any medication in this class may receive approval to continue on that agent.

Quantity Limits for tobramycin and aztreonam: 28-day supply may be dispensed per 56-day period (dosing is 28 days on, 28 days off)

Discussion

- No Board members reported conflicts of interest for this therapeutic class.
- A Blackmer asked how inhaled antibiotics would be managed for non-CF and off-label indications such as chronic bronchiectasis or tracheitis where lower-dose therapy is often used. J Taylor clarified that the intent is for preferred agents in this class to be approved for any indication. Preferred products will be approved for on- and off-label uses as well as for standard and low-dose regimens.
- Motion made by M Wilkerson to accept criteria for this class, as written. Seconded by A Shmerling. Motion passed unanimously.

4. Hepatitis C Virus Treatments – Direct Acting Antiviral (DAAs)

PA Required for all agents in this class

Preferred Products:

EPCLUSA[BNR] (sofosbuvir/velpatasvir)
HARVONI[BNR] (sofosbuvir/ledipasvir)
Sofosbuvir/velpatasvir tablet (generic EPCLUSA) – *Asequa only*
Ledipasvir/sofosbuvir tablet (generic HARVONI) – *Asequa only*
MAVYRET (glecaprevir/pibrentasvir)
*HARVONI (sofosbuvir/ledipasvir) oral pellets
VOSEVI (sofosbuvir/velpatasvir/voxilaprevir) tablet ****2nd Line**

Preferred Hepatitis C Virus Treatment Regimens	
HARVONI (ledipasvir/sofosbuvir)	HARVONI may be approved for members 3 years or older with chronic HCV infection; GT 1, 4, 5 or 6; who are NC, have CC, or in combination with ribavirin in adults with DC; AND meet the below applicable criteria
MAVYRET (glecapravir/pibrentasvir)	MAVYRET may be approved for members 12 years and older or weighing at least 45 kg with chronic HCV infection, GT 1-6 who are NC or have CC (Child-Pugh A), AND meet the below applicable criteria
EPCLUSA (sofosbuvir/velpatasvir)	EPCLUSA may be approved for adult members 6 years and older or weighing at least 17 kg with chronic HCV infection, GT 1-6, who are NC, have CC (Child-Pugh A), or in combination with ribavirin in DC; AND meet the below applicable criteria

*(**GT**-Genotype, **NC**-Non-Cirrhotic, **CC**-Compensated Cirrhosis, **DC**-Decompensated Cirrhosis)*

All preferred agents may be granted prior authorization if the following criteria are met:

- Physician attests that one quantitative HCV RNA test result from 12-24 weeks post-treatment will be provided to document SVR (cure) **AND**
- Member has received, or is in the process of receiving, full courses of both Hepatitis A and Hepatitis B vaccinations, or has immunity; **AND**
- If a non-pan-genotypic DAA will be prescribed, then test for HCV genotype and subtype. Members must have genotyping results within 1 year prior to the anticipated therapy start date; **AND**
  ~~If member is abusing/misusing alcohol or controlled substances, member must be receiving or be enrolled in counseling or a substance use treatment program for at least 1 month prior to starting treatment; **AND**~~
- Agent must be prescribed by an infectious disease specialist, gastroenterologist, hepatologist **OR** prescribed by any primary care provider in consultation with an infectious disease specialist, gastroenterologist or hepatologist; **OR** for treatment naïve members without cirrhosis, prescribed by any primary care who has completed the hepatitis C (HCV) ECHO series (four 1-hour trainings); **AND** physician attests to the following:
  - Prescribers may utilize assessment tools to evaluate readiness of the member for treatment, some examples are available at: or Psychosocial Readiness Evaluation and Preparation for Hepatitis C Treatment (PREP-C) is available at: https://prepc.org/ **AND**
  - Provider has reviewed member's complete current medication list and attests that significant drug-drug interactions have been screened for and/or addressed before and during treatment. May use https://www.hep-druginteractions.org/ **AND**
  - If member is abusing/misusing alcohol or controlled substances, member is receiving counseling or will be enrolled in counseling or a substance use treatment program prior to initiation of treatment for HCV infection **AND**
  - Physician attests to Member has chronic HCV infection (presence of HCV RNA viral load for ≥ 6 months) to confirm infection is not acute **OR** there is evidence that the infection has spontaneously resolved **OR** physician attests that member needs to be treated for acute HCV infection in the setting of solid organ transplant

  AND

  - For women of reproductive age with HCV, pregnancy test results have been documented and, within 30 days prior to the expected direct-acting antiviral start date, counseling has been offered regarding pregnancy and breastfeeding **AND**
- For women of childbearing potential, serum pregnancy testing is conducted within 30 days of expected direct-acting antiviral start date **AND**
- The provider must provide the following laboratory tests and assessments within 6 months of initiating therapy:
  - Complete Blood Count (CBC)
  - Hepatic Function Panel, such as albumin, total and direct bilirubin, alanine aminotransferase (ALT), aspartate aminotransferase (AST), and alkaline phosphatase levels
  - Calculated glomerular filtration rate (GFR)
  - If cirrhosis is present, calculation of the Child-Turcotte-Pugh (CTP) Score
  - Transplant status as applicable (pre-, post-, N/A)

***HARVONI (ledipasvir/sofosbuvir) oral pellets** may be approved if the following criteria are met:

1. Member is 3 years of age or older with documented diagnosis of chronic HCV infection who is non-cirrhotic (NC) or has compensated cirrhosis (CC) (Child-Pugh A) **AND**
   - Genotypes 1, 4, 5 or 6 and NC or with CC **OR**
   - Genotype 1 with decompensated cirrhosis (DC), in combination with ribavirin
   - Members with genotype 1 or 4 who are liver transplant recipients, NC or with CC, in combination with ribavirin **AND**
2. Member meets applicable criteria for DAA therapy above **AND**
3. Member is unable to take/swallow ledipasvir/sofosbuvir oral tablets

Body Weight (kg)	**Dose of HARVONI Oral Pellets (**ledipasvir/sofosbuvir)	**Maximum Daily Dose**
at least 35	two 45mg/200mg packets once daily x 12 weeks	90mg/400 mg
17 to < 35	one 45mg/200mg packet once daily x 12 weeks	45mg/200mg
less than 17	one 33.75mg/150mg packet once daily x 12 weeks	33.75mg/150mg

****VOSEVI (sofosbuvir/velpatasvir/voxilaprevir)** may be approved if the following criteria are met:

1. Member is an adult (≥ 18 years of age) with documented diagnosis of chronic HCV infection who is non-cirrhotic or has compensated cirrhosis (Child-Pugh A) **AND**
   - Genotypes 1 through 6: has previously failed treatment with a regimen containing an NS5A inhibitor (such as ledipasvir, daclatasvir, or ombitasvir) **OR**
   - Genotype 1a or 3**:** has previously failed treatment with a regimen containing sofosbuvir without an NS5A inhibitor
2. **AND** member has been tested for evidence of active hepatitis B virus (HBV) infection and for evidence of prior HBV infection before initiating treatment with VOSEVI.

Non-Preferred Agents:
All non-preferred agents or treatment regimens may be granted prior authorization if the criteria for preferred agents above is satisfied **PLUS** documentation is provided indicating an acceptable rationale for not prescribing a preferred treatment regimen. (Acceptable rationale may include: member-specific medical contraindications to a preferred treatment, member has initiated treatment on a non-preferred drug and needs to complete therapy.)

Re-treatment:
All requests for HCV re-treatment for members who have failed therapy with a DAA will be reviewed on a case-by-case basis.

Additional information will be requested for retreatment requests including, but not limited to:

- Previous regimen medications and dates treated
- Genotype of previous HCV infection
- Any information regarding adherence to previously trialed regimen(s) and current chronic medications
- Adverse effects experienced from previous treatment regimen
- Provider has reviewed member's complete current medication list and attests that significant drug-drug interactions have been screened for and/or addressed before and during treatment. May use https://www.hep-druginteractions.org/
- Concomitant therapies during previous treatment regimen

For regimens ≥ 12 weeks in duration:

- Physician attests that if the week 4 HCV RNA is detectable (>25 copies) while on therapy, HCV RNA will be reassessed in 2 weeks. If the repeated HCV RNA level has not decreased (that is, >1 log10 IU/mL from nadir) all treatment will be discontinued unless documentation is provided which supports continuation of therapy; **AND**
- All approvals will initially be for an 8-week time period, with further approvals dependent on the submission of HCV RNA levels at treatment times of 4 weeks, 12 weeks, and 20 weeks as applicable to justify continuing drug therapy; **AND**
- Refills should be reauthorized in order to continue the appropriate treatment plan. The member MUST receive refills within one week of completing the previous fill. Please allow ample time for reauthorization after HCV RNA levels are submitted.

Grandfathering: Members currently receiving treatment with a non-preferred agent may receive approval to finish their treatment regimen, provided required documentation is sent via normal PAR process.

Hepatitis C treatment requests must be submitted via the Hepatitis C-specific PAR form, which can be accessed on the Pharmacy Resources page at: https://www.colorado.gov/hcpf/pharmacy-resources

- **Testimony presentations:**
  - A letter from Infectious Diseases and Gastroenterology physician leaders at UC Health
  - Nancy Steinfurth, Liver Health Connection – relinquished her time
  - Laura Hill, AbbVie (Mavyret) – relinquished her time
  - Sarah Rowan, HIV and Viral Hepatitis Prevention, Denver Health
  - David Wyles, Division of Infectious Diseases, Denver Health
  - Coleen Fong, Gilead (Epclusa) – relinquished her time

Discussion

- No Board members reported conflicts of interest for this therapeutic class.
- M Noonan asked Board members how they wanted to address chronicity (acute versus chronic disease) as a factor in HCV infection management.
- A Shmerling commented that the criteria need to allow primary care physicians who feel comfortable counseling members regarding alcohol or controlled substance abuse/misuse to provide that patient counseling themselves rather than requiring a referral for the patient to receive counseling through another provider or through a substance use treatment program.
- S VanEyk made a recommendation that PA criteria for this drug class be eliminated.
- A four-part motion made by M Wilkerson, seconded by S VanEyk, that included the following components:
  - A recommendation to remove prior authorization requirements for this therapeutic class in Colorado
  - Change language about the abuse/misuse of alcohol and controlled substances to say "If member is abusing/misusing alcohol or controlled substances, member has been counseled or will be enrolled in counseling or a substance use treatment program prior to initiation of treatment for HCV infection."
  - Edit last bullet at the bottom of Page 7 to read "Member has chronic HCV infection (presence of HCV RNA viral load for ≥ 6 months) **OR** there is evidence that the infection has spontaneously resolved **OR** physician attests that member needs to be treated for acute HCV infection."
  - To accept criteria for this class, as amended by the three bullet points above.

None opposed. The motion passed unanimously.

5. Pulmonary Arterial Hypertension (PAH) Therapies

◆ **PAH - Phosphodiesterase (PDE) Inhibitors**

Preferred Products:
***Must meet eligibility criteria**
*Sildenafil 20 mg tablet (generic REVATIO)
*Tadalafil 20mg tablet (generic ADCIRCA)

***Eligibility Criteria for all agents in the class**
Approval may be granted for a diagnosis of pulmonary hypertension.

Non-preferred products may be approved for members who have failed treatment with preferred sildenafil AND preferred tadalafil. Failure is defined as lack of efficacy with 4 week trial, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction.

REVATIO (sildenafil) suspension may be approved for members who are unable to take/swallow tablets.

Grandfathering: Members who have been previously stabilized on a non-preferred product can receive approval to continue on the medication.

- **PAH - Endothelin Antagonists**

  Preferred Products:

  ***Must meet eligibility criteria**

  *LETAIRIS[BNR] (ambrisentan) tablet

  *TRACLEER[BNR](bosentan) 62.5mg, 125mg tablet

***Eligibility Criteria for all agents in the class**

Approval may be granted for a diagnosis of pulmonary hypertension.

Member and prescriber should be enrolled in applicable REMS program for prescribed medication.

Non-preferred agents may be approved for members who have trialed and failed two preferred agents. Failure is defined as lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction.

Grandfathering: Members who have been previously stabilized on a non-preferred product can receive approval to continue on the medication.

- **PAH - Prostanoids**

  Preferred Products:

  ***Must meet eligibility criteria**

  *Epoprostenol vial (generic FLOLAN)

  *ORENITRAM (treprostinil) ER tablet

  *VENTAVIS (iloprost) inhalation solution

***Eligibility Criteria for all agents in the class**
Approval may be granted for a diagnosis of pulmonary hypertension.

Non-preferred products may be approved for members who have failed treatment with a Preferred Product. (Failure is defined as: lack of efficacy, contraindication to therapy, allergy, intolerable side effects, contraindication to IV therapy or significant drug-drug interaction)

Grandfathering: Members who have been previously stabilized on a non-preferred product can receive approval to continue on the medication.

- **PAH - Guanylate Cyclase (sGC) Stimulator**

  Preferred Products:

  NONE

ADEMPAS may be approved for members who meet the following criteria:

- Member is not a pregnant female and is able to receive monthly pregnancy tests while taking ADEMPAS and one month after stopping therapy **AND**
- Women of childbearing potential and their male partners must use one of the following contraceptive methods during treatment and one month after stopping treatment (such as IUD, contraceptive implants, tubal sterilization, a hormone method with a barrier method, two barrier methods, vasectomy with a hormone method, or vasectomy with a barrier method) **AND**
- Member is not receiving dialysis or has severe renal failure (such as CrCl <15 mL/min) **AND**
- Member does not have severe liver impairment (such as Child Pugh C) **AND**

- Prescriber must be enrolled with the ADEMPAS REMS Program **AND**
- Female members, regardless of reproductive potential, must be enrolled in the ADEMPAS REMS program prior to starting therapy **AND**
- Member has a diagnosis of persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH) (WHO Group 4) after surgical treatment or has inoperable CTEPH **OR**
- Member has a diagnosis of pulmonary hypertension and has failed treatment with a preferred product for pulmonary hypertension. (Failure is defined as a lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interactions).

- **Testimony presentations:**
  - E Hohman, Janssen (Opsumit)
  - E Hohman, Janssen (Uptravi)

Discussion

- No Board members reported conflicts of interest for this therapeutic class.
- S VanEyk observed that Opsumit and Uptravi have 30-36% market share even though they are not preferred products.
- Motion made by S VanEyk to accept criteria for this class as written. Seconded by M Wilkerson. None opposed. Motion passed unanimously.

6. Triptans and other Migraine Treatments, Oral & Non-Oral

- **Triptans and other Migraine Treatments – Oral**

  Preferred Products:

  No PA Required (monthly quantity limits may apply)

  Eletriptan tablet (generic RELPAX)
  Naratriptan tablet (generic AMERGE)
  Rizatriptan tablet, ODT (generic MAXALT)
  Sumatriptan tablet (generic IMITREX)

Non-preferred products may be approved for members who have trialed and failed three preferred oral products. Failure is defined as lack of efficacy with 4 week trial, contraindication to therapy, allergy, intolerable side effects or significant drug-drug interaction.

Oral Triptan Quantity Limits	
MAXALT (rizatriptan)	Maximum 12 tablets per 30 days
AMERGE (naraptriptan) FROVA (frovatriptan) IMITREX (sumatriptan) ZOMIG (zolmitriptan)	Maximum 9 tablets per 30 days
TREXIMET (sumatriptan/naproxen)	Maximum 9 tablets per 30 days
REYVOW (lasmiditan)	Maximum 8 tablets per 30 days
AXERT (almotriptan) RELPAX (eletriptan)	Maximum 6 tablets per 30 days

Triptans and other Migraine Treatments – Non-oral

Preferred Products:

No PA Required (monthly quantity limits may apply)

Sumatriptan vial

ZOMIG (zolmitriptan) nasal spray

IMITREX[BNR] nasal spray

Non-preferred non-oral products may be approved for members who have trialed and failed two preferred non-oral products. Failure is defined as lack of efficacy with 4 week trial, contraindication to therapy, allergy, intolerable side effects or significant drug-drug interactions, documented inability to tolerate dosage form.

ZOMIG (zolmitriptan) nasal spray may be approved for members after a 4-week trial and failure of IMITREX nasal spray. Failure is defined as lack of efficacy, contraindication to therapy, allergy, or intolerable side effects. For members taking concomitant cimetidine, ZOMIG nasal spray single doses should be limited to 2.5mg and the total dose should not exceed 5mg in any 24-hour period.

Grandfathering: Members currently stabilized on ZOMIG (zolmitriptan) nasal spray may receive approval to continue therapy with that product at the prescribed dose and not exceeding 6 inhalers per 30 days.

ZEMBRACE SYMTOUCH injection, TOSYMRA nasal spray, or ONZETRA XSAIL nasal powder may be approved for members who have trialed and failed two preferred non-oral triptan products **AND** have trialed and failed two oral triptan agents. Failure is defined as lack of efficacy with 4 week trial, contraindication to therapy, allergy, intolerable side effects or significant drug-drug interaction, documented inability to tolerate dosage form.

Non-Oral Triptan Quantity Limits	
IMITREX (sumatriptan) injection	Maximum 4 injectors per 30 days
IMITREX (sumatriptan) nasal spray	Maximum 6 injectors per 30 days
ZOMIG (zolmitriptan) nasal spray	Maximum 6 inhalers per 30 days
ZEMBRACE SYMTOUCH (sumatriptan) injection	Maximum 36 mg per 30 days
ONZETRA XSAIL (sumatriptan) nasal powder	Maximum 16 nosepieces per 30 days
TOSYMRA (sumatriptan) nasal spray	Maximum 12 nasal spray devices per 30 days

- **Testimony presentations:**
  - A letter from J Moon, MD, MPH, from Denver Neurological Clinic (Reyvow)
  - M Shepherd, Eli Lilly (Reyvow)

Discussion

- No Board members reported conflicts of interest for this therapeutic class.
- A Shmerling commented that it seems rather burdensome to go through three triptans before having access to some of the newer migraine medications. L Claus mentioned that sometimes there is benefit to patients when they switch triptan route of administration, and also that the American Headache Society (AHS) position statement recommends consideration of newer agents after the trial and failure of only two triptans.

- Motion made by A Shmerling to reduce the current trial and failure requirement from three triptans to two triptans. Seconded by L Claus. None opposed. Motion passed unanimously.
- Motion made by T Brubaker to accept criteria for this class, as amended. Seconded by M Wilkerson. Motion passed unanimously.

7. Antipsoriatics – Oral

Preferred Products:

SORIATANE[BNR] (acitretin) capsule

Acitretin capsule (generic SORIATANE)

Prior authorization for non-preferred oral agents may be approved with failure of two preferred anti-psoriatic agents, one of which must be a preferred oral agent. Failure is defined as lack of efficacy of a 4 week trial, contraindication to therapy, allergy, intolerable side effects or significant drug-drug interaction.

Discussion

- No Board members reported conflicts of interest for this therapeutic class.
- Motion made by M Anguelov to accept criteria for this class as written. Seconded by M Wilkerson. None opposed. Motion passed unanimously.

8. Antipsoriatics – Topical

Preferred Products:

Calcipotriene solution

DOVONEX[BNR] (calcipotriene) cream

TACLONEX SCALP[BNR] (calcipotriene/betamethasone) suspension

TACLONEX OINTMENT[BNR] (calcipotriene/betamethasone)

Prior authorization for non-preferred topical agents may be approved with failure of two preferred topical agents. If non-preferred topical agent being requested is a combination product, trial of two preferred agents must include a preferred combination agent. Failure is defined as lack of efficacy of a 4 week trial, contraindication to therapy, allergy, intolerable side effects or significant drug-drug interaction.

Preferred and non-preferred products that contain a corticosteroid ingredient (such as betamethasone) will be limited to 4 weeks of therapy. Continued use will require one week of steroid-free time in between treatment periods.

Members with >30% of their body surface area affected may not use ENSTILAR (calcipotriene/betamethasone DP) foam or TACLONEX (calcipotriene/betamethasone DP) ointment products as safety and efficacy have not been established.

Discussion

Motion made by T Brubaker to accept criteria for this class as written. Seconded by M Anguelov. None opposed. Motion passed unanimously.

9. Anti-Emetics

- **Anti-Emetics, Oral**

  Preferred Products:

  Ondansetron ODT, tablet
  *Ondansetron oral solution (members under 5 years)
  **Doxylamine succinate/pyridoxine HCl delayed-release tablets (generic DICLEGIS – *Analog Pharma only)*
  Meclizine tablet (Rx)
  Metoclopramide tablet, solution
  Prochlorperazine tablet
  Promethazine tablet, syrup
  Trimethobenzamide tablet

- **Anti-Emetics, Non-oral**

  Preferred Products:

  Prochlorperazine suppository
  Promethazine suppository 12.5mg, 25mg
  TRANSDERM-SCOP^{BNR} (scopolamine) patch

***Ondansetron oral solution** may be approved for members < 5 years of age and for members > 5 years of age who have a feeding tube.

****Pyridoxine HCl/doxylamine succinate delayed-release tablets** may be approved for members who meet the following criteria:

- Member has nausea and vomiting of pregnancy (NVP) **AND**
- Member does not have hyperemesis gravidarum **AND**
- Member has failed 7-day trial of OTC formulation of pyridoxine (Vitamin B6) at maximally tolerated dose of up to 200mg daily **AND**
- Member has failed 7-day combination trial of OTC formulations of doxylamine and pyridoxine (Vitamin B6) at maximum daily doses of doxylamine 40 mg and pyridoxine 40 mg **AND**
- Member has failed 7-day trial of an alternate antihistamine (diphenhydramine, dimenhydrinate, meclizine) **OR**
- Member has failed 7-day trial of a dopamine antagonist (metoclopramide, prochlorperazine, promethazine) **OR**
- Has failed 7-day trial of a serotonin antagonist (ondansetron, granisetron)

Failure is defined as lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction

Approval may be given for 9 months

EMEND (aprepitant) TriPack or **EMEND (aprepitant) powder kit** prior authorization may be approved for members who have trialed and failed one preferred product **AND** one other anti-emetic (for example: prochlorperazine, metoclopramide, promethazine) **AND** EMEND (aprepitant) capsule. Failure is defined as lack of efficacy with 14-day trial, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction.

DICLEGIS (doxylamine/pyridoxine) DR tablet or **BONJESTA (doxylamine/pyridoxine) ER tablet** may be approved for 9 months for members who meet the following criteria:

- Has nausea and vomiting associated with pregnancy **AND**

- Has failed* 7-day trial of OTC formulation of pyridoxine (Vitamin B6) at maximally tolerated dose of up to 200mg daily **AND**
- Has failed* 7-day combination trial of OTC formulations of doxylamine and pyridoxine (Vitamin B6) at maximum daily doses of doxylamine 40mg and pyridoxine 40mg **AND**
- Has failed* 7-day trial of alternate antihistamine (diphenhydramine, dimenhydrinate, meclizine) **OR**
- Has failed* 7-day trial of dopamine antagonist (metoclopramide, prochlorperazine, promethazine) **OR**
- Has failed 7-day trial of serotonin antagonist (ondansetron, granisetron).

*Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.

Dronabinol prior authorization may be approved for members meeting above non-preferred criteria **OR** via AutoPA for members with documented HIV diagnosis.

Discussion

- No Board members reported conflicts of interest for this therapeutic class.
- Motion made by A Blackmer to add "If unable to swallow Emend capsules, that requirement [to try and fail Emend capsules] is waived" at the end of the Emend paragraph in this section. Seconded by L Claus. None opposed. Motion passed unanimously.
- Motion made by A Shmerling to strike the bullet, "Member does not have hyperemesis gravidarum **AND**." Seconded by L Claus. None opposed. Motion passed unanimously.
- Motion made by A Shmerling to accept criteria for this class, as amended. Seconded by L Claus. None opposed. Motion passed unanimously.

10. *H. pylori* Treatments

Preferred Products:

PYLERA (bismuth subcitrate/metronidazole/tetracycline)

H. pylori treatments should be used as individual products unless one of the individual products is not commercially available then a PA for the combination product may be given.

PYLERA (bismuth subcitrate/metronidazole/tetracycline) must be used in combination with omeprazole 20mg twice a day after morning and evening meal for ten days.

Prior authorization for non-preferred agents may be approved after trial and failure of treatment with PYLERA (bismuth subcitrate/metronidazole/tetracycline) plus omeprazole. Failure is defined as lack of efficacy, contraindication to therapy, allergy, intolerable side effects or significant drug-drug interaction.

Discussion

- No Board members reported conflicts of interest for this therapeutic class.
- Motion made by M Wilkerson to accept criteria for this class as written. Seconded by T Brubaker. None opposed. Motion passed unanimously.

11. Methotrexate Products

Preferred Products:

Methotrexate tablet
Methotrexate vial
Methotrexate preservative free (PF) vial

OTREXUP or **RASUVO** methotrexate auto-injector may be approved for members who meet the following criteria:

1. Member has diagnosis of rheumatoid arthritis **AND**
2. Member cannot take methotrexate by mouth due to intolerable gastrointestinal side effects **AND**
3. Member unable to administer methotrexate vial by injection due to limited functional ability.

TREXALL oral tablet may be approved for members who meet the following criteria:

1. Member has trialed and failed preferred tablet formulation. Failure is defined as allergy or intolerable side effects.

XATMEP (methotrexate) oral solution may be approved for members who meet the following criteria:

1. Member is < 18 years of age
2. Member has a diagnosis of Acute Lymphoblastic Leukemia (ALL) **OR**
3. Member has a diagnosis of active polyarticular course juvenile idiopathic arthritis (pcJIA) and has had an insufficient therapeutic response to, or is intolerant to, an adequate trial of first-line therapy including full dose non-steroidal anti-inflammatory agents (NSAIDs), **AND**
4. Female members of reproductive age initiating XATMEP therapy for a non-malignant disease indication (pcJIA) have a documented negative pregnancy test within 2 weeks of **AND**
5. Female members of reproductive age initiating XATMEP (methotrexate) for Acute Lymphoblastic Leukemia (ALL) have been advised to use effective contraception during therapy and for 6 months after the final dose **AND**
6. Males with reproductive potential have been advised to use effective contraception during and for at least 3 months after the final methotrexate dose **AND**
7. Member has documented swallowing difficulty due to young age and/or a medical condition, and is unable to use the preferred methotrexate tablet formulation

Grandfathering: Members currently stabilized on a non-preferred methotrexate product may receive approval to continue on that agent.

Discussion

- No Board members reported conflicts of interest for this therapeutic class.
- Motion made by M Wilkerson to accept criteria for this class as written. Seconded by A Shmerling. None opposed. Motion passed unanimously.

12. Targeted Immune Modulators (TIMs)

Preferred Products:
ENBREL (etanercept) syringe, Mini, Sureclick, Kit
HUMIRA (adalimumab) subcutaneous injection
XELJANZ IR (tofacitinib) tablet
TALTZ (ixekizumab) subcutaneous injection ****2nd Line****

OTEZLA (apremilast) tablet ****2nd Line****
COSENTYX (secukinumab) subcutaneous injection

12.a TIMs: Rheumatoid Arthritis, Polyarticular Course Juvenile Idiopathic Arthritis, and Ankylosing Spondylitis

First line preferred agents (HUMIRA, ENBREL, and XELJANZ IR) may receive approval for use for FDA-labeled indications.

TALTZ (ixekizumab) may receive approval for use for FDA-labeled indications following trial and failure‡ of HUMIRA or ENBREL.

KEVZARA (sarilumab) may receive approval for use for FDA-labeled indications following trial and failure‡ of HUMIRA or ENBREL **AND** XELJANZ IR.

All other non-preferred agents may receive approval for FDA-labeled indications following trial and failure‡ of all indicated first line preferred agents (HUMIRA, ENBREL, and XELJANZ IR). Agents listed below must meet the following additional criteria for approval of that agent:

RINVOQ (upadacitinib) may receive approval if meeting non-preferred criteria listed above **AND** following trial and failure‡ of OLUMIANT.

XELJANZ (tofacitinib) XR approval will require verification of the clinically relevant reason for use of the XELJANZ XR formulation versus the XELJANZ IR formulation, in addition to meeting non-preferred criteria listed above.

XELJANZ (tofacitinib) oral solution may receive approval if meeting the following criteria:

1. Member is 2 years of age or older **AND**
2. Member has a diagnosis of active polyarticular course juvenile idiopathic arthritis **AND**
3. Member weighs less than 40 kg **AND**
4. Member is not using a concomitant biologic disease-modifying anti-rheumatic drug (bDMARD) such as HUMIRA or ENBREL

Body Weight	Dose of XELJANZ (tofacitinib) 1 mg/mL oral solution	Maximum Daily Dose
10 kg ≤ to < 20 kg	3.2 mg (3.2 mL oral solution) twice daily	6.4 mg
20 kg to <40 kg	4 mg (4 mL oral solution) twice daily	8 mg
≥ 40 kg	*Use oral tablet*	10 mg

ACTEMRA (tocilizumab) may receive approval for treatment for FDA-labeled indications following trial and failure‡ of HUMIRA or ENBREL.

12.b TIMs: Plaque Psoriasis

First line preferred agents (HUMIRA, ENBREL) may receive approval for plaque psoriasis indication.

Second line preferred agents (TALTZ, OTEZLA) may receive approval for plaque psoriasis indication following trial and failure‡ of HUMIRA OR ENBREL.

Non-preferred agents may receive approval for plaque psoriasis indication following trial and failure‡ of one indicated first line agent (HUMIRA, ENBREL) AND two second line agents (TALTZ, OTEZLA). Agents listed below must meet the following additional criteria for approval of that agent:

STELARA (ustekinumab): Loading dose administration prior to approval of STELARA for maintenance therapy using the above criteria should be avoided and will not result in an automatic approval of STELARA maintenance therapy. Prior authorization approval may be given for an initial 16 weeks and authorization approval for continuation may be provided based on clinical response. STELARA IV vial formulation may receive approval under the pharmacy benefit if meeting non-preferred criteria listed above AND if being administered in a long-term care facility or the member's home by a home health provider (initial 16 week authorization may be placed for both IV and subcutaneous formulations at time of STELARA IV vial approval).

12.c TIMs: Psoriatic Arthritis

First line preferred agents (HUMIRA, ENBREL, XELJANZ IR) may receive approval for psoriatic arthritis indication.

TALTZ may receive approval for psoriatic arthritis indication following trial and failure‡ of HUMIRA or ENBREL **AND** XELJANZ IR or OTEZLA.

OTEZLA may receive approval for psoriatic arthritis indication following trial and failure‡ of HUMIRA or ENBREL **AND** XELJANZ IR or TALTZ.

Non-preferred agents may receive approval for psoriatic arthritis following trial and failure‡ of HUMIRA or ENBREL AND XELJANZ IR AND TALTZ or OTEZLA. Agents listed below must meet the following additional criteria for approval of that agent:

STELARA (ustekinumab): Loading dose administration prior to approval of STELARA for maintenance therapy using the above criteria should be avoided and will not result in an automatic approval of STELARA maintenance therapy. Prior authorization approval may be given for an initial 16 weeks and authorization approval for continuation may be provided based on clinical response. STELARA IV vial formulation may receive approval under the pharmacy benefit if meeting non-preferred criteria listed above AND if being administered in a long-term care facility or the member's home by a home health provider (initial 16 week authorization may be placed for both IV and subcutaneous formulations at time of Stelara IV vial approval).

XELJANZ (tofacitinib) XR approval will require verification of the clinically relevant reason for use of the XELJANZ XR formulation versus the XELJANZ IR formulation, in addition to meeting non-preferred criteria listed above.

12.d TIMs: Crohn's Disease and Ulcerative Colitis

First line preferred agents (HUMIRA) may receive approval for Crohn's disease and ulcerative colitis indications.

XELJANZ IR may receive approval for ulcerative colitis indication following trial and failure‡ of HUMIRA.

Non-preferred agents may receive approval for FDA-labeled indications following trial and failure‡ of all indicated first line preferred agents. Agents listed below must meet the following additional criteria for approval of that agent:

STELARA (ustekinumab): Loading dose administration prior to approval of STELARA for maintenance therapy using the above criteria should be avoided and will not result in an automatic approval of STELARA maintenance therapy. STELARA may be approved for treatment of moderately-to-severely active Crohn's disease following trial and failure‡ of HUMIRA **AND** XELJANZ IR **AND** CIMZIA. Prior authorization approval may be given for an initial 16 week supply and authorization approval for continuation may be provided based on clinical response. STELARA IV vial formulation may receive approval under the pharmacy benefit if meeting non-preferred criteria listed above AND if being administered in a long-term care facility or the member's home by a home health provider (initial 16 week authorization may be placed for both IV and subcutaneous formulations at time of STELARA IV vial approval).

XELJANZ (tofacitinib) XR approval will require verification of the clinically relevant reason for use of the XELJANZ XR formulation versus the XELJANZ IR formulation, in addition to meeting non-preferred criteria listed above.

12.e TIMs: Other Indications

First line preferred agents (HUMIRA, ENBREL, and XELJANZ IR) may receive approval for use for FDA-labeled indications.

Non-preferred agents may receive approval for FDA-labeled indications following trial and failure‡ of all indicated preferred first line agents (ENBREL, HUMIRA, XELJANZ IR). Agents listed below must meet the following additional criteria for approval of that agent:

ARCALYST (rilonacept) initial approval will be given for 12 weeks, and approval for continuation will be provided based on clinical response.

ILARIS (canakinumab) may receive approval for the following autoinflammatory periodic fever syndromes (approval for all other indications is subject to meeting non-preferred criteria listed above):

- Adult-Onset Still's Disease (AOSD)
- Cryopyrin-associated Autoinflammatory Syndrome (CAPS), including:
  - Familial Cold Autoinflammatory Syndrome (FCAS)
  - Muckle-Wells Syndrome (MWS)
- Familial Mediterranean fever (FMF)
- Hyperimmunoglobulinemia D syndrome (HIDS)
- Mevalonate Kinase Deficiency (MKD)
- Neonatal onset multisystem inflammatory disease (NOMID)
- Systemic Juvenile Idiopathic Arthritis (sJIA)
- TNF Receptor Associated Periodic Syndrome (TRAPS)

KINERET (anakinra): Prior authorization approval may be given the treatment of Familial Mediterranean Fever (FMF) and Cryopyrin-associated Autoinflammatory Syndrome (CAPS)/ Neonatal onset multisystem inflammatory disease (NOMID). Approval for all other indications is subject to meeting non-preferred criteria listed above.

Grandfathering: Members with current prior authorization approval on file for COSENTYX on file may receive approval to continue on that agent.

Quantity Limit: XELJANZ IR is limited to 2 tablets per day or 60 tablets for a 30 day supply

‡Failure is defined as lack of efficacy with a three-month trial, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction.

The Department would like to remind providers that many products are associated with patient-centered programs that are available to assist with drug administration, education, and emotional support related to our members' various disease states.

COSENTYX may receive approval for FDA-labeled indications following trial and failure of HUMIRA (failure is defined as lack of efficacy of a three-month trial, contraindication to therapy, allergy, intolerable side effects or significant drug-drug interaction).

XELJANZ IR may receive approval for ulcerative colitis following trial and failure of HUMIRA and (failure is defined as lack of efficacy of a three-month trial, contraindication to therapy, allergy, intolerable side effects, significant drug-drug interaction or XELJANZ IR may receive approval with no trial and failure required for rheumatoid arthritis and psoriatic arthritis.. Quantity Limits: 2 tablets per day or 60 tablets for a 30 day supply.

Non-preferred Agents may receive prior authorization approval for FDA-labeled indications following trial and failure ALL preferred agents (ENBREL, HUMIRA, COSENTYX, TALTZ and XELJANZ IR) that are FDA-labeled for use for the same prescribed indication (failure is defined as lack of efficacy of a three-month trial, contraindication to therapy, allergy, intolerable side effects or significant drug-drug interaction). Agents listed below must meet the following additional criteria for approval of that agent:

SILIQ (brodalumab), SKYRIZI (risankizumab-rzaa), or **TREMFYA (guselkumab**) may receive approval if meeting non-preferred criteria listed above **AND** following trial and failure of OTEZLA (apremilast). Failure is defined as lack of efficacy of a three-month trial, contraindication to therapy, allergy, intolerable side effects or significant drug-drug interaction.

TALTZ (ixekizumab): Prior authorization approval may be given for an initial 12 weeks and authorization approval for continuation will be provided based on clinical response.

Testimony presentations were provided by:

- K Schlageter, Bristol Myers Squibb (Orencia)
- L Hill, AbbVie (Skyrizi) – relinquished her time
- L Hill, AbbVie (Rinvoq)
- C Brandmeyer, Amgen (Otezla)
- M Shepherd, Eli Lilly (Taltz)

Discussion

- No Board members reported conflicts of interest for this therapeutic class
- S VanEyk asked why Rinvoq requires a trial and failure of Olumiant. J Taylor explained that while the DUR Board focuses primarily on safety and efficacy aspects of the proposed criteria, the Department takes several other factors, including cost and stakeholder input, into consideration.
- M Noonan commented that proposed criteria for canakinumab and anakinra are intended to be used 2nd line following trial and failure of methotrexate for treatment of FMF, etc. J Taylor clarified that if a first-line treatment is indicated for a particular condition included in the TIMS Other Indications section, then it should be used first. If another agent is not indicated as first-line therapy before a TIM agent, the TIM should be used first. M Noonan suggested that consideration be given to clarifying this point in the final criteria.
- Motion made by S VanEyk to remove the special section of criteria regarding Rinvoq [on Page 18] and allow Rinvoq to fall into the "all other non-preferred agents" section. Seconded by M Wilkerson. None opposed. Motion passed unanimously.
- Motion made by M Wilkerson to accept criteria for this class as amended. Seconded by L Claus. None opposed. Motion passed unanimously.

13. Antihyperuricemics

Preferred Products:

Allopurinol tablet
Colchicine capsule
MITIGARE[BNR] (colchicine) capsule
Probenecid tablet
Probenecid/colchicine tablet

Prior authorization for non-preferred xanthine oxidase inhibitor products (allopurinol or febuxostat formulations) may be approved after trial and failure of preferred allopurinol. Failure is defined as lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction.

If member has tested positive for the HLA-B*58:01 allele, it is not recommended that they try allopurinol. A positive result on this genetic test will count as a failure of allopurinol.

Prior authorization for all other (non-xanthine oxidase inhibitors) non-preferred agents may be approved after trial and failure of two preferred products. Failure is defined as lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction.

Prior authorization for colchicine capsules may be approved for members requiring treatment of gout flares.

Colchicine tablet quantity limits:

- Chronic hyperuricemia/gout prophylaxis: 60 tablets per 30 days
- Familial Mediterranean Fever: 120 tablets per 30 days

Discussion

- The Antihyperuricemics therapeutic drug class was initially moved to Mass Review during this meeting, then removed for further discussion the request of A Blackmer.
- No Board members reported conflicts of interest for this therapeutic class.

- A Blackmer reported that she had received feedback from the Children's Hospital Colorado pediatric rheumatology group regarding colchicine tablets in that (1) it is not very clear which indications colchicine is approved for. For clarity, consider also listing the indications under quality limits in the main body of the criteria, (2) a request to give approval of Gloperba oral solution for patients requiring doses < 0.6 mg or those who cannot swallow tablets or capsules., and (3) approve for off-label uses of colchicine such as aphthous ulcers, pericarditis and others.
- L Claus suggested that the statement to "Prior authorization for colchicine capsules may be approved for members requiring treatment of gout flares" should say colchicine "tablets" now that the preferred product is a capsule.
- Motion made by A Blackmer to:
    - Change final bullet point in this section to "Prior authorization for colchicine tablets may be approved for members requiring treatment of gout flares."
    - Accept criteria for this therapeutic class as amended

  Motion was seconded by L Claus. None opposed. Motion passed unanimously.
- Motion made by A Blackmer to approve Gloperba oral solution for patients requiring colchicine doses < 0.6 mg and for those who cannot swallow tablets or capsules." Seconded by L Claus. None opposed. Motion passed unanimously.

14. Mass Review Drug Classes*:

a. Antiherpetic Agents, Oral and Topical
b. Fluoroquinolones, Oral
c. Hepatitis C Virus Treatments – Ribavirin Products
d. Newer Generation Antidepressants
e. Monoamine Oxidase Inhibitors (MAOIs)
f. Tricyclic Antidepressants (TCAs)
g. Pancreatic Enzymes
h. Proton Pump Inhibitors
i. Non-Biologic Ulcerative Colitis Agents, Oral & Rectal
j. Antiplatelet Agents
k. Epinephrine (self-administered) Products

** Proposed criteria for drug classes designated for mass review will not be read aloud at the time of DUR Board review, as there are no proposed changes to criteria currently implemented for these designated classes. The DUR Board may determine if designated mass review drug classes will undergo full review based on Board vote.*

14.a Antiherpetic Agents, Oral and Topical

- **Antiherpetic Agents - Oral**

  Preferred Products:

  Acyclovir tablet, capsule
  Acyclovir suspension *(members under 5 years of age or with a feeding tube)*
  Valacyclovir tablet
  Famciclovir tablet

Non-preferred products may be approved for members who have failed an adequate trial with oral acyclovir **AND** valacyclovir. Failure is defined as lack of efficacy with 14 day trial, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction.

SITAVIG (acyclovir) buccal tablet may be approved for diagnosis of recurrent herpes labialis (cold sores) if member meets non-preferred criteria listed above **AND** has failed trial with oral acyclovir suspension. Failure is defined as lack of efficacy with 14 day trial, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction.

For members with a diagnosis of Bell's palsy, valacyclovir 1000 mg three times daily may be approved for 7 days if member presents with severe facial palsy.

Acyclovir suspension may be approved for:

- Members under 5 years of age **OR**
- Members with a feeding tube **OR**
- Members meeting non-preferred criteria listed above

Maximum Dose Table		
	Adult	**Pediatric**
Acyclovir	4000 mg daily	1200mg 3200 mg daily
Valacyclovir	4000 mg daily	Age 2-11 years: 3000 mg daily Age ≥ 12 years: 4000 mg daily

- **Antiherpetic Agents, Topical**

  Preferred Products:

  DENAVIR (penciclovir) cream 1%
  ZOVIRAX[BNR] (acyclovir) cream
  ZOVIRAX[BNR] (acyclovir) ointment

Generic acyclovir ointment/cream may be approved for members who have failed an adequate trial with ZOVIRAX ointment/cream (diagnosis, dose and duration) as deemed by approved compendium. (Failure is defined as: lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction).

XERESE (acyclovir/hydrocortisone) prior authorization may be approved for members that meet the following criteria:

- Documented diagnosis of recurrent herpes labialis **AND**
- Member is immunocompetent **AND**
- Member has failed treatment of at least 10 days with acyclovir (Failure is defined as significant drug-drug interaction, lack of efficacy, contraindication to therapy or intolerable side effects) **AND**
- Member has failed treatment of at least one day with famciclovir 1500 mg **OR** valacyclovir 2 grams twice daily (Failure is defined as significant drug-drug interaction, lack of efficacy, contraindication to therapy or intolerable side effects)

14.b Fluoroquinolones - Oral

Preferred Products:

CIPRO[BNR] (ciprofloxacin) oral suspension (< 5 years old)
Ciprofloxacin oral suspension (< 5 years old)
Ciprofloxacin tablet
Levofloxacin tablet

Non-preferred products may be approved for members who have failed an adequate trial (7 days) with at least one preferred product. (Failure is defined as: lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction.)

CIPRO/ciprofloxacin suspension approved for members < 5 years of age without PA

For members ≥ 5 years of age, CIPRO/ciprofloxacin suspension will only be approved for those members who cannot swallow a whole or crushed tablet.

Levofloxacin solution may be approved for members who require administration via feeding tube **OR** who have failed an adequate trial (7 days) of ciprofloxacin suspension. (Failure is defined as: lack of efficacy, presence of feeding tube, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction.)

14.c Hepatitis C Virus Treatments – Ribavirin Products

Preferred Products:

Ribavirin capsule
Ribavirin tablet

For ribavirin-containing regimens only:

- Member is not a pregnant female or a male with a pregnant female partner **AND**
- Women of childbearing potential and their male partners must attest that they will use two forms of effective (non-hormonal) contraception during treatment **AND**
- Member does not meet any of the following ineligibility criteria for use of ribavirin:
    - Pregnant women and men whose female partners are pregnant
    - Known hypersensitivity to ribavirin
    - Autoimmune hepatitis
    - Hemoglobinopathies
    - Creatinine clearance < 50 mL/min
    - Co-administered with didanosine

14.d Newer Generation Anti-Depressants

Preferred Products:

Bupropion IR 75mg, 100mg
Bupropion ER 100mg 150mg, 200mg, 300mg
Bupropion SR, XL
Citalopram tablet, solution
Desvenlafaxine succinate ER tablet (generic PRISTIQ)
Duloxetine capsule (generic CYMBALTA)
Escitalopram tablet
Fluoxetine capsules, solution

Fluvoxamine IR tablet (generic LUVOX)
Mirtazapine tablet, ODT
Paroxetine IR tablet
Sertraline tablet, solution
Trazodone tablet
Venlafaxine IR tablet
Venlafaxine ER capsule

Prior authorization for FETZIMA, TRINTELLIX, or VIIBRYD may be approved for members who have failed an adequate trial with four preferred newer generation anti-depressant products (failure is defined as lack of efficacy with 6 week trial, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction).

All non-preferred products not listed above may be approved for members who have failed adequate trial with three preferred newer generation anti-depressant products. If three preferred newer generation anti-depressant products are not available for indication being treated, approval of prior authorization for non-preferred products will require adequate trial of all preferred products FDA approved for that indication (failure is defined as lack of efficacy with 6 week trial, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction).

Citalopram doses higher than 40 mg/day for ≤60 years of age and 20mg for >60 years of age will require prior authorization. Please see the FDA guidance at: https://www.fda.gov/drugs/drugsafety/ucm297391.htm for important safety information.

Grandfathering: Members currently stabilized on a non-preferred newer generation antidepressant can receive approval to continue on that agent for one year if medically necessary. **Verification may be provided from the prescriber or the pharmacy.**

14.e Monoamine Oxidase Inhibitors (MAOis)

Preferred Products:

NONE

Non-preferred products may be approved for members who have failed adequate trial (8 weeks) with three preferred anti-depressant products. If three preferred anti-depressant products are not available for indication being treated, approval of prior authorization for non-preferred products will require adequate trial of all preferred anti-depressant products FDA approved for that indication. (Failure is defined as: lack of efficacy after 8 week trial, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction)

Grandfathering: Members currently stabilized on a non-preferred MAOi antidepressant can receive approval to continue on that agent for one year if medically necessary. **Verification may be provided from the prescriber or the pharmacy.**

14.f Tricyclic Anti-Depressants (TCAs)

Preferred Products:

Amitriptyline tablet
Doxepin 10mg, 25mg, 50mg, 75mg, 100mg, 150mg capsule
Doxepin solution
Imipramine HCl tablet
Nortriptyline capsule, solution

Non-preferred products may be approved for members who have failed adequate trial (8 weeks) with three preferred tricyclic products. If three preferred products are not available for indication being treated, approval of prior authorization for non-preferred products will require adequate trial of all tricyclic preferred products FDA approved for that indication. (Failure is defined as: lack of efficacy after 8 week trial, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction)

Grandfathering: Members currently stabilized on a non-preferred tricyclic antidepressant (TCA) may receive approval to continue on that agent for one year if medically necessary. **Verification may be provided from the prescriber or the pharmacy.**

SILENOR (doxepin 3mg, 6mg) approval criteria can be found on the Appendix P

14.g Pancreatic Enzymes

Preferred Products:

CREON (pancrelipase) DR capsule
ZENPEP (pancrelipase) DR capsule

Non-preferred products may be approved for members who have failed an adequate trial (4 weeks) with at least two preferred products. (Failure is defined as lack of efficacy, contraindication to therapy, allergy, intolerable side effects or significant drug-drug interaction.)

Grandfathering: Members currently stabilized on a non-preferred pancreatic enzyme can receive approval to continue on that agent for one year if medically necessary.

14.h Proton Pump Inhibitors

Preferred Products:

Esomeprazole magnesium DR capsule (generic NEXIUM) (Rx)
Lansoprazole DR capsule (generic PREVACID) (Rx)
NEXIUM^{BNR} (esomeprazole) packets
Omeprazole capsule
Pantoprazole tablet
PREVACID Solutab^{BNR} (lansoprazole) (members <2 years of age)

For members treating GERD symptoms that are controlled on PPI therapy, it is recommended that the dose of the PPI be re-evaluated or stepped-down with an H2 blocker (such as famotidine or ranitidine) be trialed in order to reduce long-term PPI use.

Prior authorization for non-preferred proton pump inhibitors may be approved if all of the following criteria are met:

- Member has a qualifying diagnosis (below) **AND**
- Member has trailed and failed therapy with three preferred agents within the last 24 months. (Failure is defined as: lack of efficacy following 4 week trial, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction) **AND**
- Member has been diagnosed using one of the following diagnostic methods:
    - Diagnosis made by GI specialist
    - Endoscopy
    - X-ray

- Biopsy
- Blood test
- Breath Test

Qualifying Diagnoses:
Barrett's esophagus, duodenal ulcer, erosive esophagitis, gastric ulcer, GERD, GI Bleed, *H. pylori* infection, hypersecretory conditions (Zollinger-Ellison), NSAID-induced ulcer, pediatric esophagitis, requiring mechanical ventilation, requiring a feeding tube

Quantity Limits:
All agents will be limited to once daily dosing except when used for the following diagnoses: Barrett's esophagus, GI Bleed, *H. pylori*, hypersecretory conditions (Zollinger-Ellison), or members who have Spinal Cord Injury and associated acid reflux.

Adult members with GERD on once daily, high-dose PPI therapy who continue to experience symptoms may receive initial prior authorization approval for a 4-week trial of twice daily, high-dose PPI therapy. Continuation of the twice daily dosing regimen for GERD beyond 4 weeks will require additional prior authorization approval verifying adequate member response to the dosing regimen and approval may be placed for one year. If a member with symptomatic GERD does not respond to twice daily, high-dose PPI therapy, this should be considered a treatment failure.

Pediatric members (< 18 years of age) on once daily dosing of a PPI who continue to experience symptoms may receive one-year prior authorization approval for twice daily PPI therapy.

Age Limits:
NEXIUM 24H and **ZEGERID** will not be approved for members less than 18 years of age.

PREVACID Solutab may be approved for members < 2 years of age OR for members ≥ 2 years of age with a feeding tube

14.i Non-Biologic Ulcerative Colitis Agents, Oral & Rectal

- **Ulcerative Colitis Agents – Oral**

Preferred Products:
No PA Required
APRISO ER (mesalamine) capsule
LIALDA (mesalamine DR) tablet
PENTASA (mesalamine) capsule
Sulfasalazine IR tablet, DR tablet

Prior authorization for non-preferred oral formulations will require trial and failure of two preferred oral products with different active ingredients **AND** a preferred rectal product. If inflammation is not within reach of topical therapy, trial of preferred rectal product is not required. Failure is defined as lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction.

UCERIS (budesonide) tablet: If the above criteria is met, UCERIS (budesonide) tablet prior authorization may be approved for 8 weeks. Further prior authorization may be approved if 7 days of steroid-free time has elapsed and member continues to meet the above criteria.

- **Ulcerative Colitis Agents – Rectal**

  Preferred Products:

  No PA Required

  Mesalamine suppository (generic CANASA)

  sf ROWASA (sulfite-free mesalamine) enema

Prior authorization for non-preferred rectal formulations will require trial and failure of one preferred rectal formulation and one preferred oral formulation (Failure is defined as lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction).

UCERIS (budesonide) foam: If the above criteria is met, UCERIS (budesonide) foam prior authorization may be approved for 6 weeks. Further prior authorization may be approved if 7 days of steroid-free time has elapsed and member continues to meet the above criteria

14.j. Antiplatelet Agents

Preferred Products:

AGGRENOX^{BNR} (aspirin/dipyridamole) capsule
Aspirin/dipyridamole ER capsule
BRILINTA (tigacrelor) tablet
Cilostazol tablet
Clopidogrel tablet
Dipyridamole tablet
Pentoxifylline ER tablet
Prasugrel tablet

Members taking **BRILINTA (ticagrelor)** must also be taking a maintenance dose of aspirin not exceeding 100 mg/day.

Ticlopidine should only be considered for members who can be monitored for neutropenia and thrombocytopenia during the first three months of therapy.

ZONTIVITY (vorapaxar) may be approved for members with a diagnosis of myocardial infarction or peripheral artery disease without a history of stroke, transient ischemic attack, intracranial bleeding, or active pathological bleeding. Members must also be taking aspirin and/or clopidogrel concomitantly.

Non-preferred products without criteria will be reviewed on a case-by-case basis.

14.k Epinephrine Products

Preferred Products:

Epinephrine 0.15mg/0.3mL, 0.3mg/0.3mL auto-injector (generic EPIPEN) - *Mylan only*

Non-preferred products may be approved if the member has failed treatment with one of the preferred products. Failure is defined as allergy to ingredients in product or intolerable side effects. Quantity limit: 4 auto injectors per year unless used / damaged / lost

Discussion

- In addition to the therapeutic classes included in Items 14.a-k, Non-Oral NSAIDs and Antihyperuricemics were added to Mass Review during the meeting.
- J Taylor clarified that even though some preferred product changes have occurred within the Mass Review agents, the DUR Board is looking at the criteria from a clinical impact perspective or if there have been any changes to the evidence supporting current criteria. Classes included in Mass Review reflect those with a low probability of requiring changes to existing PDL criteria. Board members may request that any classes be pulled from Mass Review if needed.
- No Board members reported conflicts of interest for the therapeutic classes included in Mass Review.
- A Blackmer requested that Antihyperuricemics be pulled from Mass Review for further discussion.
- T Brubaker mentioned the relative difficulty in obtaining oral liquid PPIs for pediatric patients. A Blackmer commented that oral PPI suspensions are usually prepared by a compounding pharmacies. The only commercially available oral liquid PPI products are kits and those products probably do not participate in the Medicaid drug rebate program. A Blackmer suggested that if the Department finds that some commercially available liquid kits do participate in the rebate program, the Colorado P&T Committee should consider adding one or more of those products to the PPI preferred list.
- T Brubaker suggested addition of levofloxacin oral solution to the Cipro oral suspension section of criteria to help avoid delays in therapy in situations when patients who need to be treated with levofloxacin and the Board discussed further.
- Motion made by T Brubaker to edit the Fluoroquinolone bullet point [on Page 25] to say "CIPRO/ciprofloxacin suspension and levofloxacin suspension approved for members < 5 years of age without PA." Seconded by A Blackmer. None opposed. Motion passed unanimously.
- Motion made by L Claus to accept the Mass Review criteria, as amended. Seconded by T Brubaker. None Opposed. Motion passed unanimously.

15. Proposed ProDUR and Prior Authorization Criteria for Other Selected Products:

a. EVRYSDI (risdiplam)
b. XYWAV (calcium, magnesium, potassium, sodium oxybates)
c. ENSPRYNG (satralizumab-mwge)
d. JYNARQUE (tolvaptan)
e. UPLIZNA (inebilizumab)
f. VILTEPSO (viltolarsen)
g. LAMPIT (nifurtimox)
h. BYNFEZIA (octreotide acetate)
i. HEMADY (dexamethasone)

15.a **EVRISDI (rizdiplam)** oral solution

EVRYSDI (risdiplam) may be approved for members meeting the following criteria:

1. Member is between 2 months of age and 25 years old **AND**

2. Member has documented diagnosis of 5q-autosomal recessive spinal muscular atrophy (SMA) by genetic testing and SMN1 mutation **AND** two or more SMN2 gene copies must be specified **AND**

3. Treating and prescribing provider(s) include a neurologist or pediatrician experienced in treatment of SMA **AND**

4. The prescriber attests that the member will be assessed by at least one of the following exam scales at baseline and during subsequent office visits:

a. Hammersmith Infant Neurological Examination Module 2 (HINE2)
b. Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)
c. Hammersmith Functional Motor Scale Expanded (HFMSE)
d. Bayley Scales of Infant and Toddler Development, Third Edition (BSID-III)
e. Motor Function Measure (MFM-32)
f. Revised Upper Limb Module (RULM)

AND

5. Prior to the start of EVRYSDI treatment, the provider attests that the member meets all of the following requirements:

a. Female members of childbearing potential have a documented negative pregnancy test within 2 weeks of initiating EVRYSDI therapy **AND**
b. Female members of childbearing potential have been instructed to use effective contraception during treatment with EVRYSDI and for at least 1 month after discontinuing treatment **AND**
c. Male members have been advised prior to initiation of therapy that their fertility may be compromised while being treated with EVRYSDI **AND**
d. Provider confirms that member has baseline Liver Function Panel drawn and does not have hepatic impairment (EVRYSDI is extensively metabolized by the liver) **AND**
e. Drug-drug interactions, including but not limited to MATE substrates such as metformin, cimetidine, and acyclovir, have been screened for, addressed if needed, and will be continually monitored

AND

6. Member must not have any of the following:

a. Treatment plan which includes concomitant or previous treatment with ZOLGENSMA (onasemnogene abeparvovec-xioi) or SPINRAZA (nusinersen)
b. Presence of advanced SMA such as permanent ventilation dependence (permanent defined as greater than 16 hours per day) or tracheostomy
c. Hospitalization for a pulmonary event within 2 months prior to initiation of EVRYSDI
d. Surgery for scoliosis within 1 year prior to initiation of EVRYSDI

AND

7. Member weight is provided and meets recommended daily dosing:

Age and Body Weight	Recommended Daily Dosage
2 months to less than 2 years of age	0.2 mg/kg
2 years and older, weighing less than 20 kg	0.25 mg/kg
2 years and older, weighing 20 kg or more	5 mg

Reauthorization criteria: After 15 months, member may receive approval to continue therapy if the following criteria are met:

1. Member has shown no adverse events to EVRYSDI treatment **AND**
2. Member has no presence of advanced SMA, such as permanent ventilation dependence (permanent defined as greater than 16 hours per day) or tracheostomy **AND**
3. Member has demonstrated response to treatment by showing significant clinical improvement or no decline documented using quantitative scores using the same exam scale(s) used prior to initiating EVRYSDI treatment (please see number 4 of initial authorization criteria). Improvement of SMA-related symptoms must be compared to the baseline assessment and motor function must be measured against the degenerative effects of SMA **AND**
4. The prescriber provides the following information:
    a. A brief explanation, including the provider name, must be submitted if a provider other than the one who initially performed the motor exam completes any follow-up exam(s) **AND**
    b. A brief explanation must be submitted if an exam scale other than the scale used for initial authorization is used for reassessment

AND

5. Member weight is provided and meets recommended daily dosing:

Age and Body Weight	Recommended Daily Dosage
2 months to less than 2 years of age	0.2 mg/kg
2 years and older, weighing less than 20 kg	0.25 mg/kg
2 years and older, weighing 20 kg or more	5 mg

AND

6. Member does not have hepatic impairment

Maximum dose: 5mg/day

Above coverage standards will continue to be reviewed and evaluated for any applicable changes due to the evolving nature of factors including disease course, available treatment options, and available peer-reviewed medical literature and clinical evidence.

Testimony presentations for risdiplam were provided by:

- Letter from Cure SMA
- M Puyear, Genentech
- J Parsons, Children's Hospital Colorado, Pediatrics and Neurology
- S Dixon, Assistant Professor of Neurology, CU Anschutz

Discussion

- No Board members reported conflicts of interest for the review of this product.
- Motion made by S VanEyk to change criteria age limit wording to "member is 2 months of age or older." Seconded by A Blackmer. None opposed. Motion passed unanimously.
- Motion made by S VanEyk to remove the four bulleted criteria items included in item 6 above:
    6. Member must not have any of the following:
        a. Treatment plan which includes concomitant or previous treatment with ZOLGENSMA (onasemnogene abeparvovec-xioi) or SPINRAZA (nusinersen)

b. Presence of advanced SMA such as permanent ventilation dependence (permanent defined as greater than 16 hours per day) or tracheostomy
c. Hospitalization for a pulmonary event within 2 months prior to initiation of EVRYSDI
d. Surgery for scoliosis within 1 year prior to initiation of EVRYSDI

Seconded by A Blackmer. None opposed. Motion passed unanimously.

- Motion by M Wilkerson to approve Evrysdi (risdiplam) criteria as amended. Seconded by T Brubaker. None opposed. Motion passed unanimously.

15.c **ENGSPYNG (satralizumab-mwge)** subcutaneous injection

ENGSPYNG (satralizumab-mwge) may be approved when the following criteria are met:

1. Member is an adult (≥ 18 years of age) **AND** has a positive serologic test for anti-aquaporin-4 (AQP4) antibodies **AND** has a documented diagnosis of neuromyelitis optica spectrum disorder (NMOSD) **AND**
2. Member has a past medical history of at least one of the following:
   - Optic neuritis
   - Acute myelitis
   - Area postrema syndrome; episode of otherwise unexplained hiccups or nausea and vomiting
   - Acute brainstem syndrome
   - Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions
   - Symptomatic cerebral syndrome with NMOSD-typical brain lesions
3. Member does not have any active infections, including localized infections **AND**
4. Member does not have active Hepatitis B infection, as confirmed by negative surface antigen [HBsAg] and anti-HBV tests **AND**
5. Member does not have active or untreated latent tuberculosis **AND**
6. Provider confirms that member has a baseline Liver Function Panel drawn prior to initiation of ENGSPYNG treatment and member does not has an AST or ALT level greater than 1.5 times the upper limit of normal **AND**
7. Provider confirms that neutrophil counts will be checked 4 to 8 weeks after initiation of ENSPRYNG therapy, and thereafter at regular clinically determined intervals to monitor for decreased neutrophil counts
8. Provider has screened for immunizations the member is due to receive according to immunization guidelines **AND**
   - any live or live-attenuated vaccines will be administered at least 4 weeks prior to initiation of ENSPRYNG **AND**
   - any non-live vaccines will be administered at least 2 weeks prior to initiation of ENSPRYNG (whenever possible)

   AND
9. ENSPRYNG is prescribed by or in conjunction with a neurologist

Maximum dose: 120 mg subcutaneously every 2 weeks for three doses, followed by 120 mg subcutaneously every 4 weeks maintenance dose

Reauthorization criteria: After six months of treatment with EYNSPRYNG, member may receive approval to continue therapy for one year if the following criteria are met:

1. Member has shown no adverse effects to ENGSPYNG treatment at a maintenance dose of 120 mg subcutaneously every 4 weeks **AND**
2. Member does not have any active infections, including localized infections **AND**
3. Member does not has an AST or ALT level greater than 1.5 times the upper limit of normal **AND**
4. Provider confirms that neutrophil counts are currently within normal limits and will continue to be monitored at clinically determined intervals during ENSPRYNG therapy

Scheduled testimony presentation:

- M Puyear, Genentech – relinquished her time

Discussion

- Motion made by M Wilkerson to approve Enspryng criteria as written. Seconded by M Anguelov. None opposed. Motion passed unanimously.

Seven medications included in the ProDUR/Other Selected Products section were not reviewed during this meeting due to time limitations. J Taylor and M Noonan proposed, and the Board unanimously agreed, to complete reviews of the proposed criteria for EVRYSDI and ENSRYNG during this meeting and defer XYWAV (calcium, magnesium, potassium, sodium oxybates), JYNARQUE (tolvaptan), UPLIZNA (inebilizumab), VILTEPSO (viltolarsen), LAMPIT (nifurtimox), BYNFEZIA (octreotide acetate) and HEMADY (dexamethasone) until the next meeting in February 2021.

M Noonan reminded attendees that the next Board meeting is scheduled for Tuesday, February 9, starting at 1:00 pm.

R Page, on behalf of the entire CO-DUR team, thanked Dr. Mary Wilkerson for her service to the DUR Board.

Motion to adjourn made by S VanEyk and seconded by A Blackmer. The meeting was adjourned at 5:22 pm.