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

August 11, 2020
Open Session
1:00 pm – 5:00 pm

1. Call to Order
This virtual meeting was officially called to order at 1:02 pm by M Noonan.

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 eight voting members participating. Quorum is five members.

Julia Rawlings, PharmD, introduced herself as the new faculty liaison for the CO DUR Program, replacing Dr. Brandon Utter.

a. **Members Present:**, Michael Noonan, MD (Chair); Gosia Thomas, PharmD (Vice-Chair); Scott VanEyk, MD; Allison Blackmer, PharmD; Mary Wilkerson, MD; Miroslav Anguelov, PharmD; Liza Wilson Claus, PharmD; Alison Shmerling, MD; William Lai, PharmD (Industry Representative)
b. **Members Absent:** None
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 Rawlings provided an update regarding the recruitment of a second Pain Management Specialist physician to conduct peer-to-peer consultations.

J Taylor reported that Colorado's annual CMS report for FFY 2019 is in progress. The due date for submission was delayed from June 30 to September 30 due to the COVID-19 pandemic. The Colorado CMS report will be publically posted after the September 30 submission date.

J Taylor reported that based on stakeholder outreach regarding Substance Use Disorder (SUD), the Department intends to make SUD care easier for Members to access and also minimize delays in treatment. Implementation of an Automatic PA is planned for Fall 2020 to allow oral buprenorphine products to be automatically approved by the claims system when Members meet criteria.

M Noonan suggested adding an update about the Auto PA for oral buprenorphine products to the November 2020 Board meeting agenda.

J Taylor announced that the next DUR Board meeting is scheduled for Tuesday, November 10, 2020, 1:00 pm to 5:00 pm.

R Page presented RDUR criteria and data.

R Page presented an update on the draft (gabapentin) and final (PPI) Quarterly Clinical Modules.

R Page presented the quarterly drug utilization reports

J Rawlings and DUR Intern Londyn Caton presented FDA Safety and New Drug updates.

5. Updates on Business from Last Meeting:

J Taylor reported that final criteria from the May 2020 review have been implemented and are available on the Colorado HCPF department website (https://www.colorado.gov/hcpf/). Motions from the last Board meeting were accommodated.

6. Final Approval of Minutes from May 12, 2020 Meeting

M. Noonan asked if there were any changes with the minutes from the May 2020 DUR Board meeting. With no discussion, a motion to approve the minutes as written was made by G Thomas, seconded by A Blackmer. None opposed. Motion passed unanimously.

7. New Business

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

Yellow highlights are add/change proposals
AND
Red highlights are removal proposals

Proposed Criteria

1. Anticonvulsants, Oral

Preferred:

Carbamazepine IR tablet, ER tablet, chewable, ER capsule
Clobazam tablet
Clonazepam tablet, ODT
Divalproex capsule IR tablet, ER tablet
DILANTIN[BNR] (phenytoin) 30 mg capsules
Ethosuximide capsule, solution
FELBATOL[BNR] (felbamate) tablet, suspension
Lamotrigine tablet, chewable/disperse tabs
Levetiracetam IR, ER tablet, solution
Oxcarbazepine tablet, suspension
Phenobarbital elixir, solution, tab
PHENYTEK[BNR] (phenytoin ER)
Phenytoin suspension, chewable, ER capsule
Primidone tablet
TEGRETOL[BNR] (carbamazepine) suspension
Topiramate tablet, sprinkle cap
Valproic acid capsule, solution
Zonisamide capsule

Non-Preferred Products:

Prior Authorization for members currently stabilized (in outpatient or acute care settings) on any non-preferred medication may be approved.

Non-preferred brand name medications do not require a prior authorization when the equivalent generic is preferred and “dispense as written” is indicated on the prescription.

Non-Preferred Products Newly Started for Treating Seizure Disorder or Convulsions:

- Non-preferred medications newly started for members with a diagnosis of seizure disorder/convulsions may be approved if meeting the following criteria:

- The medication is being prescribed by a neurologist OR
  - The medication is being prescribed in conjunction with prescriber consultation by a neurologist and meets the following:
    - The prescription meets minimum age and maximum dose limits listed in Table 1 **AND**
  - For medications indicated for use as adjunctive therapy, the medication is being used in conjunction with another anticonvulsant medication

AND

- The prescription meets additional criteria listed for any of the following:

SYMPAZAN (clobazam) film:
- Member has history of trial and failure‡ of clobazam tablet or solution **OR**
- Provider attests that member cannot take clobazam tablet or solution

EPIDIOLEX (cannabidiol):
- Member has diagnosis of Lennox-Gastaut syndrome (LGS) **OR**
- Member has diagnosis of Dravet Syndrome **OR**
- Member is ≥1 year of age and has a diagnosis of seizures associated with tuberous sclerosis complex (TSC)

BRIVIACT (brivaracetam) **tablets and oral solution**
- Member is ≥ 4 years of age **AND**
- Member has history of trial and failure‡ of any levetiracetam-containing product

APTIOM (eslicarbazepine):
- Member has history of trial and failure‡ of any carbamazepine-containing product

DIACOMIT (stiripentol):
- Member is concomitantly taking clobazam **AND**
- Member has diagnosis of seizures associated with Dravet syndrome

ONFI (clobazam) **suspension**
- Member is ≥ 2 years of age **AND**
- Member has diagnosis of Lennox-Gastaut syndrome (LGS) **AND**
- Member has documented swallowing difficulty due to young age and/or a medical condition and therefore is unable to use an alternative dosing method with preferred tablet and capsule formulations **AND**

- Member is not taking a concomitant opioid, unless alternative treatment options have been shown to be inadequate

Non-Preferred Products Newly Started for Non-Seizure Disorder Diagnoses:

- Non-preferred medications newly started for non-seizure disorder diagnoses may be approved if meeting the following criteria:
  - Member has history of trial and failure‡ of two preferred agents **AND**
  - The prescription meets minimum age and maximum dose limits listed in Table 1

‡Failure is defined as lack of efficacy, allergy, intolerable side effects, significant drug-drug interaction, or documented contraindication to therapy, or inability to take preferred formulation. Members identified as HLA-B*15:02 positive, carbamazepine and oxcarbazepine should be avoided per Clinical Pharmacogenetics Implementation Consortium (CPIC) Guidelines. This may be considered a trial for prior authorization approvals of a non-preferred agent.

Discussion

- No Board members reported conflicts of interest for this therapeutic class
- J Taylor introduced the discussion for this class and highlighted changes made to this class as the result of previous reviews, including addressing clinical needs, improving access and providing a fairly extensive preferred agent list. In addition, DAW-1 designations for brand versions of preferred agents in this class for preferred agents do not require PA. provided a reminder that the role of the DUR Board does not include selection of preferred products.
- Testimony presentations were provided by
  - M Malik from SK Life Science, Inc. (Xcopri)
  - S Klein, representing the Epilepsy Foundation of Colorado (along with a letter in the Board meeting binder)
  - B Yaeger, UCB Pharma (Briviact and Vimpat)
  - S Kennedy from Greenwich Biosciences (Epidiolex)
  - G Mills from Swedish Medical Center Epilepsy and Movement Disorder Program
  - B O'Neal from Sunovion (Aptiom)
  - M Maruscak from Zogenix (Fintepla)
  - A letter from UC Health
- A Blackmer asked for clarification on minimum ages in Table 1 for Depakote, Depakene and generic divalproex and valproic acid products. Is the ≥10 years age limit applicable to all valproic acid-containing products? J Rawlings and R Page will research this question further and follow up.
- Motion was made by M Wilkerson to change EPIDIOLEX (cannabidiol) criteria so that all bullet points, for consistency, include the phrase "diagnosis of seizures associated with" for Lennox-Gastaut and Dravet syndromes, in order to match FDA-approved language. Seconded by A Blackmer. None opposed. Motion passed.
- Motion was made by A Blackmer to create a separate section of criteria spelled out for FINTEPLA (fenfluramine) to be consistent with other anticonvulsants indicated for the management of seizures associated with Dravet syndrome. Two bullet points: (1) Member is > 2 years of age and (2) FINTEPLA is being used for the treatment of

seizures associated with Dravet syndrome. Seconded by G Thomas.None opposed. Motion passed.

- M Noonan mentioned that there is value in consultations with providers at National Jewish Health and UCHealth when making therapeutic decisions involving agents in this drug class. Consultation process creates a system of checks and balances between primary care providers and specialists.
- M Noonan asked for clarification about new information released from a Phase IV trial with Aptiom (eslicarbazepine) that was mentioned by the speaker from Sunovion. Clarified that this trial has not yet been peer reviewed or published, so the Board will not consider any changes to criteria at this time. Once the paper is peer reviewed and published, the Board can consider making changes in the future.
- M Noonan mentioned that there is value in primary care physicians participating in consultations with specialty providers at National Jewish Health and UC Health when making therapeutic decisions involving preferred and non-preferred agents in this drug class. A Blackmer emphasized that the intention is not to limit access to critical lifesaving medication. G Thomas highlighted that the consultation process for non-preferred agents creates a system of checks and balances between primary care providers and specialists.
- Motion was made by L Claus to change language in criteria for non-preferred, newly-started anticonvulsants to be “prescribed by or in consultation with a neurologist and meets the following:” Seconded by A Blackmer. None opposed. Motion passed.
- Motion was made by M Wilkerson to accept criteria for this class, as amended. Seconded by L Claus. Motion passed unanimously.

Table 1: Non-preferred Anticonvulsant Product Table		
	Minimum Age**	**Maximum Dose****
MYSOLINE (primidone)		2000 mg per day
DILANTIN (phenytoin ER)		1000 mg per loading day 600 mg maintenance dose
PEGANONE (ethotoin)		3000 mg per day
CELONTIN (methsuximide)		Not listed
ZARONTIN (ethosuximide)		Not listed
KLONOPIN (clonazepam)		
ONFI (clobazam)	1 year	40 mg per day
Clobazam suspension	1 years	40 mg per day
DIACOMIT (stiripentol)	2 years	50mg/kg/day
APTIOM (eslicarbazepine)	4 years	1600 mg per day
CARBATROL (carbamazepine ER)		1600 mg per day
EPITOL (carbamazepine)		1600 mg per day
EQUETRO (carbamazepine ER)		1600 mg per day
OXTELLAR XR (oxcarbazepine ER)		Not listed
TEGRETOL (carbamazepine) all except suspension		Not listed
TEGRETOL XR (carbamazepine ER)		Not listed
TRILEPTAL (oxcarbazepine)		Not listed
DEPAKENE (valproic acid)	10 years	
DEPAKOTE (divalproex DR)	10 years	
DEPAKOTE ER (divalproex ER)	10 years	
DEPAKOTE SPRINKLE (divalproex DR)	10 years	
LAMICTAL (lamotrigine)	2 years	400 mg per day
LAMICTAL ODT (lamotrigine)	2 years	400 mg per day
LAMICTAL XR (lamotrigine ER)	13 years	600 mg per day
QUDEXY XR (topiramate ER)	2 years	400 mg per day
TOPAMAX (topiramate)		400 mg per day
TROKENDI XR (topiramate ER)	6 years	400 mg per day
BRIVIACT (brivaracetam)	4 years	200 mg per day
GABITRIL (tiagabine)	12 years	64 mg per day
tiagabine	12 years	64 mg per day
VIMPAT (lacosamide)	4 years	400 mg per day
BANZEL (rufinamide)	1 year	3200 mg per day
felbamate	18 years	
FYCOMPA (perampanel)	4 years	12 mg per day
SABRIL (vigabatrin)	1 month	3000 mg per day
SPRITAM (levetiracetam)	4 years	3000 mg per day
vigabatrin	1 month	3000 mg per day
ZONEGRAN (zonisamide)	16 years	600 mg per day
KEPPRA (levetiracetam)	1 month	3000 mg per day
KEPPRA XR (levetiracetam ER)	12 years	3000 mg per day
EPIDIOLEX (cannabidiol)	2 years	20 mg/kg/day
SYMPAZAN (clobazam film)	2 years	40 mg per day
**Limits based on data from FDA package insert. Approval for age/dosing that falls outside of the indicated range may be evaluated on a case-by-case basis		

2. Stimulants and other ADHD Agents

Preferred:

ADDERAL XL[BNR] (dextroamphetamine-amphetamine, extended-release)
Armodafinil (generic NUVIGIL)
Atomoxetine (generic STRATTERA)
Mixed-amphetamine salts (generic ADDERALL IR)
Mixed-Amphetamine salts ER (generic ADDERALL XR)
CONCERTA[BNR] (Methylphenidate ER) tablet
Dexmethylphenidate IR (generic FOCALIN)
FOCALIN XR[BNR] (dexmethylphenidate ER)
Guanfacine ER
Methylphenidate IR (generic RITALIN IR)
Modafinil (generic PROVIGIL)
VYVANSE (lisdexamfetamine) capsules, chewables

*Preferred medications may be approved through AutoPA for indications listed in Table 1 (preferred medications may also receive approval for off-label use for fatigue associated with multiple sclerosis).

Prior authorization for non-preferred medications used for indications listed in Table 1 may be approved for members meeting the following criteria (For SUNOSI (solriamfetol), refer to criteria listed below):

- Member has documented failure with three preferred products in the last 24 months if age ≥6 years or documented failure with one preferred product in the last 24 months if age 3 –5 years (Failure is defined as: lack of efficacy with a four week trial, allergy, intolerable side effects, or significant drug-drug interaction). Trial and failure of preferred agents will not be required for members meeting the following:

- For DAYTRANA, METHYLIN solution, QUILLICHEW, QUILLIVANT XR and DYANAVEL XR, one preferred trial must include VYVANSE chewable tablet, FOCALIN XR, VYVANSE capsules or mixed amphetamine salts ER (generic ADDERALL XR) and member must have a documented difficulty swallowing that are unable to utilize alternative dosing with preferred tablet and capsule formulations.

Table 1: Indication and Age

- Approval for medically accepted indications not listed in Table 1 may be given with prior authorization review and may require submission of peer-reviewed literature or medical compendia showing safety and efficacy of the medication used for the prescribed indication.
- Medications may also receive approval for off-label use for fatigue associated with multiple sclerosis if meeting all other criteria for approval.
- Prior authorization will be required for doses that are higher than the FDA approved maximum doses**
- **Bolded Drug names are Preferred**

Drug	Indications
Stimulants–Immediate Release	
amphetamine sulfate (EVEKEO)	ADHD (Age ≥ 3 years), Narcolepsy (Age ≥ 6 years)
armodafinil (NUVIGIL)	Excessive sleepiness associated with narcolepsy, OSA, and SWD for age ≥ 18 years
dexmethylphenidate IR (FOCALIN)	ADHD (Age ≥ 6 years)
dextroamphetamine IR (ZENZEDI)	ADHD (Age 3 to≤ 16 years), Narcolepsy (Age ≥ 6 years)
dextroamphetamine solution (PROCENTRA)	ADHD (Age 3 to ≤ 16 years), Narcolepsy (Age ≥ 6 years)
methamphetamine (DESOXYN)	ADHD (Age ≥ 6 years)
methylphenidate IR (METHYLIN, RITALIN)	ADHD (Age ≥ 6 years), Narcolepsy (Age ≥ 6 years), OSA
methylphenidate XR ODT (CONTEMPLA XR ODT)	ADHD (Age ≥ 6 years)
mixed amphetamine salts IR (ADDERALL)	ADHD (Age ≥ 3 years), Narcolepsy (Age ≥ 6 years)
modafinil (PROVIGIL)	Excessive sleepiness associated with narcolepsy, OSA, and SWD for age ≥ 18 years, adjunct therapy to treat fatigue and sleepiness in patients with major depressive disorder (MDD)
solriamfetol (SUNOSI)	Excessive sleepiness associated with narcolepsy, OSA for age ≥ 18 years
pitolisant (WAKIX)	Excessive sleepiness associated with narcolepsy for age ≥ 18 years
Stimulants –Extended-Release	
amphetamine ER (ADZENYS XR-ODT and ADZENYS ER suspension)	ADHD (Age ≥ 6 years)
amphetamine ER (DYANAVEL XR)	ADHD (Age ≥ 6 years)
mixed-amphetamine salts ER (generic ADDERALL XR)	ADHD (Age ≥ 6 years)
dexmethylphenidate ER **(Focalin XR)**	ADHD (Age ≥ 6 years)
dextroamphetamine ER (DEXEDRINE)	ADHD (Age 3 to ≤ 16 years), Narcolepsy (Age ≥ 6 years)

dextroamphetamine ER/amphetamine ER (MYDAYIS ER)	ADHD (Age ≥ 13 years)
lisdexamfetamine dimesylate (**VYVANSE capsule and VYVANSE chewable**)	ADHD (Age ≥ 6 years), Moderate to severe binge eating disorder in adults (Age ≥ 18 years)
methylphenidate ER OROS (CONCERTA)	ADHD (Age ≥ 6 years), Narcolepsy (Age ≥ 6 years), OSA
methylphenidate SR (METADATE ER)	ADHD (Age ≥ 6 years), Narcolepsy (Age ≥ 6 years)
methylphenidate ER† (METADATE CD)	ADHD (Age ≥ 6 years)
methylphenidate ER (QUILLICHEW ER)	ADHD (Age ≥ 6 years), Narcolepsy (Age ≥ 6 years)
methylphenidate ER (QUILLIVANT XR)	ADHD (Age ≥ 6 years), Narcolepsy (Age ≥ 6 years)
methylphenidate ER (RITALIN LA)	ADHD (Age ≥ 6 years)
methylphenidate ER (APTENSIO XR)	ADHD (Age ≥ 6 years)
methylphenidate XR ODT (CONTEMPLA XR ODT)	ADHD (Age ≥ 6 years)
Methylphenidate ER (JORNAY PM)	ADHD (Age ≥ 6 years)
Non-Stimulants	
atomoxetine (STRATTERA)	ADHD (Age ≥ 6 years)
clonidine ER (KAPVAY)	ADHD (Age ≥ 6 years), Treatment of ADHD as adjunct to stimulants
guanfacine ER (INTUNIV)	ADHD (Age ≥ 6 years), Treatment of ADHD as adjunct to stimulant
KEY: ADHD–attention-deficit/hyperactivity disorder, **OSA**–obstructive sleep apnea, SSRI—selective serotonin reuptake inhibitor, **SWD**–shift work disorder	

Max Dose: Prior authorization may be approved for doses that are higher than the listed maximum dose (Table 2) if member meets all of the following criteria:

- Member is taking medication for indicated use listed in table 1 **AND**
- Member has 30 day trial or failure of three different preferred or non-preferred agents at maximum doses listed in table 2 **AND**
- Documentation of member's symptom response to maximum doses of three other agents is provided **AND**
- Member is not taking a sedative hypnotic medication (from the Sedative Hypnotics PDL therapeutic drug class, such as temazepam, triazolam, or zolpidem)

Table 2: Maximum Daily Dose	
Medication	**Maximum Daily Dose**
ADDERALL	60 mg/day
ADDERALL XR	60mg/day
ADZENYS XR ODT ADZENYS ER suspension	18.8 mg/day (age 6-12) 12.5 mg/day (age ≥ 13)
amphetamine salts	40 mg/day
CONCERTA	54 mg/day (age 6-12) or 72 mg/day (≥ age 13)
COTEMPLA XR-ODT	51.8mg/day
DESOXYN	25mg/day
DEXEDRINE	40mg/day
DEXTROSTAT	40mg/day
DYANAVEL XR	20mg/day
FOCALIN	20 mg/day
FOCALIN XR	40 mg/day
methylphenidate ER	60 mg/day
MYDAYIS ER	25 mg/day (age 13-17) |50 mg/day (age ≥ 18)
INTUNIV ER	4 mg/day
RITALIN IR	60 mg/day
RITALIN SR	60 mg/day
RITALIN LA	60 mg/day
STRATTERA	100 mg/day
VYVANSE capsules and chewable tablets	70 mg/day
d-amphetamine ER	40 mg/day
DAYTRANA	30 mg/day
EVEKEO	40 mg/day
KAPVAY ER	0.4 mg/day
METHYLIN ER	60 mg/day
METHYLIN	60 mg/day
METHYLIN suspension	60 mg/day
METADATE CD	60mg/day
METADATE ER	60mg/day
methylphenidate	60 mg/day
PROVIGIL	400 mg/day
NUVIGIL	250 mg/day
QUILLIVANT	60 mg/day
ZENZEDI	40 mg/day
SUNOSI	150 mg/day
JORNAY PM	100 mg/day

- **SUNOSI** (solriamfetol) prior authorization may be approved if member meets the following criteria:
  - Member is 18 years of age or older **AND**
  - Member has diagnosis of either narcolepsy or obstructive sleep apnea (OSA) and is experiencing excessive daytime sleepiness **AND**
  - Member does not have end stage renal disease **AND**
  - If SUNOSI is being prescribed for OSA, member has 1 month trial of CPAP **AND**
  - Member has trial and failure of modafinil **AND** armodafinil **AND** one other agent in stimulant PDL class (Failure is defined as lack of efficacy with 4 week trial, allergy, intolerable side effects, or significant drug-drug interaction.)

- **WAKIX** (pitolisant) prior authorization may be approved if member meets the following criteria:
  - Member is 18 years of age or older **AND**
  - Member has diagnosis of narcolepsy and is experiencing excessive daytime sleepiness **AND**
  - Member does not have end stage renal disease (eGFR <15 mL/minute) **AND**
  - Member does not have severe hepatic impairment **AND**
  - Member does not have a history of prolonged QT interval prolongation
  - Member has trial and failure of modafinil **AND** armodafinil **AND** one other agent in stimulant PDL class (Failure is defined as: lack of efficacy with 4 week trial, allergy, intolerable side effects, or significant drug-drug interaction.) AND
  - Member has been instructed that WAKIX may reduce the efficacy of hormonal contraceptives **AND**
  - Members using a hormonal contraceptive have been counseled to use an alternative non-hormonal contraceptive method of contraception during WAKIX therapy and for at least 21 days after discontinuing treatment.

Discussion

- No Board members reported conflicts of interest for this therapeutic class.
- Table 1 (non-preferred), Table 1 (Indication & Age) and Table 2 (Maximum Daily Dose) have all been updated.
- A testimony presentation was provided by Justin Barnes from Ironshore Pharmaceuticals (Jornay PM)
- Motion was made by A Blackmer to create PA criteria to allow for the use of methylphenidate IR for 4 and 5 year old members whose ADHD symptoms are not controlled despite adequate behavior interventions.This request was based on the American Academy of Pediatrics ADHD Practice Guideline published in October 2019 and widely circulated this month. Motion seconded by A Shmerling. None opposed. Motion passed.
- M Wilkerson ask for comments from the Board regarding possibly making changes in the criteria for Journay PM. Board decided to wait until more data becomes available for that product.
- Motion was made by M Wilkerson to accept criteria for this class, as amended. Seconded by M Angeulov. None opposed. Motion passed unanimously.

3. Contraceptives, Oral

Preferred:

Monophasic 28:
Altavera 28 0.15-30
Alyacen 28 1-35
Apri 28 0.15-30
Aubra EQ-28 0.1-20
Aviane 28 0.1-20
Balziva 28 0.4-35
Chateal 28 0.15-30
Chateal EQ 28 0.15-30
Cryselle 28 0.3-30
Cyclafem 28 1-35
Dasetta 28 1-35
Drosperinone-Eth Estradiol 28 3-30
Elinest 28 0.3-30
Enskyce 28 0.15-30
Estarylla 28 0.25-35
Ethynodiol-Eth Estra 28 1-35
Ethynodiol-Eth Estra 28 1-50
Falmina 28 0.1-20
Femynor 28 0.25-35
Isibloom 28 0.15-30
Juleber 28 0.15-30
Kelnor 28 1-35
Kurvelo 28 0.15-30
Larissia 28 0.1-20
Lessina 28 0.1-20
Levonor-Eth Estrad 28 0.1-20
Levonor-Eth Estrad 28 0.15-30
Levora 28 0.15-30
Lillow 28 0.15-30
Low-Ogestrel 28 0.3-30
Lutera 28 0.1-20
Marlissa 28 0.15-30
Mili 28 0.25-35
Mono-Linyah 28 0.25-35
Mononessa 28 0.25-35
Norg-Ethin Estra 28 0.25-35
Nortrel 28 0.5-35
Nortrel 28 1-35
Ocella 28 3-30
Philith 28 0.4-35
Pirmella 28 1-35
Portia 28 0.15-30
Previfem 28 0.25-35
Reclipsen 28 0.15-30
Sprintec 28 0.25-35
Sronyx 28 0.1-20
Syeda 28 3-30
Vienva 28 0.1-20
Vyfemla 28 0.4-35

Monophasic 21:
Larin 21 1-20
Larin 21 1.5-30
Norethind-Eth Estrad 21 1-20
Nortrel 21 1-35
All other rebateable products are non-preferred

Biphasic:
Azurette 28
Bekyree 28
Desogest-Eth Estra 28
Kariva 28
Lo Loestrin FE 28 1-10
Mircette 28
Viorele 28

Triphasic:
Alyacen 7-7-7 28
Cyclafem 7-7-7 28
Dasetta 7-7-7 28
Enpresse 28
Levonest 28
Levonor-Eth Estrad Triphasic 28
Norgestimate-Eth estrad 0.18-0.215-0.25/0.025
Norgestimate-Eth estrad 0.18-0.215-0.25/0.035
Pirmella 7-7-7
Tri-Estarylla 28
Tri-Femynor 28
Tri-Linyah 28
Tri-Lo Estarylla 28
Tri-Lo Marzia 28
Tri-Lo Sprintec 28
Trinessa 28
Tri-Sprintec 28
Tri-Vylibra Lo 28

Norethindrone (progestin) Only:
Camila 28 0.35
Deblitane 28 0.35
Errin 28 0.35
Heather 28 0.35
Jencycla 28 0.35
Jolivette 28 0.35
Norethindrone 28 0.35
Norlyda 28 0.35
Sharobel 28 0.35

Extended Cycle:
Amethia 91 0.03–0.15–0.01
Ashlyna 91 0.15-10-30
Introvale 91 0.15-30
Jolessa 91 0.15-30
Levonorgest-Eth Estrad 0.09-20
Levonorgest-Eth Estrad 91 0.1-10-20
Levonorgest-Eth Estrad 91 0.15-0.03
Levonorgest-Eth Estrad 91 0.15-0.03-0.01
Levonorgest-Eth Estrad 91 0.15-20-25-30
Quasense 91 0.15-30
Setlakin 91 0.15-30

Continuous Cycle:
Aurovela FE 1-20
Aurovela FE 1.5-30
Blisovi FE 1-20
Blisovi FE 1.5-30
Jasmiel 3-20
Junel FE 1-20
Junel FE 24 1-20
Junel FE 1.5-30
Larin FE 1-20
Larin FE 24 1-20
Larin FE 1.5-30
Loryna 3-20
Minastrin FE 24 1-20
Nikki 3-20
Noreth-Eth Estrad-FE 24 1-20
Noreth-Eth Estrad-FE 1-20
Tarina FE 24 1-20
Tarina FE 1-20
Tarina FE 1-20 EQ

Non-preferred oral contraceptive products may be approved if member fails one-month trial with four preferred agents **OR** if preferred products with medically necessary ingredients and/or doses are unavailable. (Failure is defined as allergy, intolerable side effects, or significant drug-drug interaction) Initial fills may be dispensed for three-month supply to establish tolerance (i.e., lack of adverse effects). After established tolerance on the same agent for 3 months, a 12-month supply (365 days) may be dispensed (as one fill).

Discussion

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

4. Diabetes Management Classes – DPP-4 Inhibitors

Preferred:

*JANUMET (sitagliptin and metformin)
*JANUMET XR (sitagliptin and metformin XR)
*JANUVIA (sitagliptin)
*TRADJENTA (linagliptin)

Prior Authorization Criteria:

*Approval for preferred products require a 3-month trial of (or documented contraindication to) metformin therapy prior to initiation of therapy. Non-preferred DPP-4 inhibitors may be approved after a member has failed a 3-month trial of metformin **AND** a three month trial of two preferred products. Failure is defined as lack of efficacy (e.g., hemoglobin A1C ≥ 7%), allergy, intolerable side effects, or a significant drug-drug interaction. For all products, prior authorization will be required for dosing above the FDA approved maximum dosing listed in the following table:

DPP-4 Inhibitor	FDA Approved Maximum Dose
alogliptin (generic NESINA)	25 mg/day
JANUVIA (sitagliptan)	100 mg/day
NESINA (alogliptan)	25 mg/day
ONGLYZA (saxagliptan)	5 mg/day
TRADJENTA (linagliptan)	5 mg/day

*Approval for preferred combination agent products require a 3-month trial of (or documented contraindication to) metformin therapy prior to initiation of therapy.

Non-preferred combination products may be approved for members who have been stable on the two individual ingredients of the requested combination for three months **AND** have had adequate three-month trial and failure of a preferred combination agent. Failure is defined as lack of efficacy (e.g., hemoglobin A1C ≥ 7%), allergy, intolerable side effects, or a significant drug-drug interaction.

Discussion

- No Board members reported conflicts of interest for this therapeutic class.
- Motion was made by G Thomas to accept criteria for this class, as written. Seconded by M Anguelov. Motion passed unanimously.

5. Diabetes Management Classes – GLP-1 Analogues

Preferred:

*BYETTA (exenatide)
*BYDUREON (exenatide ER)
*VICTOZA (liraglutide)

Prior Authorization Criteria:

*Approval for preferred products requires a 3-month trial of (or documented contraindication to) metformin therapy prior to initiation of therapy. Non-preferred products may be approved following trial and failure of a 3-month trial of metformin **AND** a three month trial of two preferred products. Failure is defined as lack of efficacy (e.g., hemoglobin A1C ≥ 7%), allergy, intolerable side effects, or a significant drug-drug interaction. Maximum Dose: Prior authorization is required for all products exceeding maximum dose listed in product package labeling.

GLP-1 Recpetor Agonist	FDA Approved Maximum Dose
ADLYXIN (lixisenatide)	20 mcg per day
BYDUREON (exenatide)	2 mg weekly
BYDUREON BCISE (exenatide)	2 mg weekly
BYETTA (exenatide)	20 mcg per day
OZEMPIC (semaglutide)	1 mg weekly
TRULICITY (dulaglutide)	1.5 mg weekly
VICTOZA (liaglutide)	1.8 mg per day

Discussion

- No Board members reported conflicts of interest for this therapeutic class
- Testimony presentations were provided by R Flugge from Novo Nordisk (Rybelsus) and A Wheeler from Eli Lilly (Trulicity)
- M Wilkerson commented that it is compelling to have a GPL-1 medication available to Members who are not able to use an injectable dosage form. Since many GLP-1 analogues are delivered via a pen, it is important to consider physical inability to use a pen delivery system (such as lack of manual dexterity) as a treatment “failure.”
- Motion was made by M Wilkerson to add “inability to self-administer due to dexterity limitations” to the list that defines failures. Seconded by M Angeulov. None opposed. Motion passed.
- Motion was made by M Wilkerson to accept criteria for this class, as amended. Seconded by M Anguelov. Motion passed unanimously.

6. Diabetes Management Classes – Hypoglycemic Combos

Preferred:

NONE

Prior Authorization Criteria:

Non-preferred products may be approved for members who have been stable on each of the individual ingredients in the requested combination for 3 months (including cases where the ingredients are taken as two separate 3-month trials or when taken in combination for at least 3 months).

Discussion

- No Board members reported conflicts of interest for this therapeutic class
- Motion was made by G Thomas to accept criteria for this class, as written. Seconded by M Anguelov. Motion passed unanimously.

7. Diabetes Management Classes – SGLT-2 Inhibitors

Preferred:

*FARXIGA (dapagliflozin)
*INVOKAMET (canagliflozin/metformin)
*INVOKANA (canagliflozin)
*JARDIANCE (empagliflozin)
*XIGDUO XR (dapagliflozin/metformin extended-release)

Prior Authorization Criteria:

*Approval for preferred products requires a 3-month trial of (or documented contraindication to) metformin therapy prior to initiation of therapy.

Non-preferred products may receive approval following trial and failure with a 3-month trial of metformin **AND** a 3-month trial of two preferred products. Failure is defined as lack of efficacy with 3-month trial (e.g., hemoglobin A1C ≥ 7%) allergy, intolerable side effects, or a significant drug-drug interaction

Maximum Dose: Prior authorization is required for all products exceeding maximum dose listed in product package labeling.

Discussion

- No Board members reported conflicts of interest for this therapeutic class
- Discussion regarding new evidence regarding the benefits of SGLT-2 inhibitors (dapagliflozin and empagliflozin) in heart failure, with or without concomitant diabetes. Based on this evidence, the requirement for a 3-month trial of metformin will be removed from current criteria.
- Motion was made by M Wilkerson to accept criteria for this class, as written. Seconded by M Anguelov. Motion passed unanimously.

8. GI Motility, Chronic

Discussion

- Since there are no proposed changes to the criteria and no scheduled speakers, J Taylor requested to move this class to the Mass Review section of the agenda
- The Board will have the opportunity to discuss the Chronic GI Motility criteria, along with any other criteria included in Mass Review, during that section of the agenda.
- All Board members present agreed with this request.

9. Anticoagulants

Preferred:

Oral:
Warfarin
PRADAXA (dabigatran)
XARELTO (rivaroxaban) 10 mg, 15 mg, 20 mg tablet
XARELTO (rivaroxaban) dose pack

Parenteral:
Enoxaparin syringe
LOVENOX[BNR] (enoxaparin) 300mg/3ml vial
Enoxaparin vial *(Amphastar Pharma only)*

Prior Authorization Criteria:

ORAL:

BEVYXXA (betrixaban) may be approved if all the following criteria have been met:

- The member has trialed and failed therapy with two preferred agents. (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction) **AND**
- Member is not on dialysis **AND**
- The member is need of prophylaxis for DVT following hospitalization for an acute medical illness who are at risk for thromboembolic events due to limited mobility **AND**
- The member does not have a mechanical prosthetic heart valve

ELIQUIS (apixaban) may be approved if the following criteria have been met:

- The member is on dialysis or has chronic renal failure **OR**
- The member has failed therapy with ~~two~~ one preferred agent. Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. If the member is on dialysis or has chronic renal failure, trial and failure of preferred agents is not required **AND**
- The member has a diagnosis of deep vein thrombosis (DVT), pulmonary embolism (PE)
  OR
- The member is in need of prophylaxis for DVT following knee or hip replacement surgery
  OR
- The member has a diagnosis of non-valvular atrial fibrillation **AND**
- The member does not have a mechanical prosthetic heart valve

SAVAYSA (edoxaban) may be approved if all the following criteria have been met:

- The member has failed therapy with two preferred agents. (Failure is defined as: lack of

efficacy, allergy, intolerable side effects, or significant drug-drug interaction) **AND**

- Member is not on dialysis **AND**
- Member does not have CrCl > 95 mL/min **AND**
- The member has a diagnosis of deep vein thrombosis (DVT), pulmonary embolism (PE) **OR**
- The member has a diagnosis of non-valvular atrial fibrillation **AND**
- The member does not have a mechanical prosthetic heart valve

XARELTO 2.5mg (rivaroxaban) may be approved for members meeting all of the following criteria:

- XARELTO 2.5mg is being prescribed to reduce major CV events in members diagnosis of chronic coronary artery disease (CAD) or peripheral artery disease **AND**
- XARELTO 2.5mg is being taken twice daily and in combination with aspirin 75-100mg daily

AND

- Member must not be receiving dual antiplatelet therapy, other non-aspirin antiplatelet therapy, or other oral anticoagulant **AND**
- Member must not have had an ischemic, non-lacunar stroke within the past month **AND**
- Member must not have had a hemorrhagic or lacunar stroke at any time

All other non-preferred oral agents require a trial of two or more preferred oral agents**.**

Continuation of Care: Members with current prior authorization approval on file for a non-preferred oral anticoagulant medication may continue to receive approval for that medication.

Non-preferred parenteral anticoagulants may be approved if the member has trialed and failed one preferred parenteral anticoagulant. Failure is defined as lack of efficacy, intolerable side effects, drug-drug interactions or contraindication.

Discussion

- No Board members reported conflicts of interest for this therapeutic class
- A testimony presentation was provided by W Hunter from Bristol Myers Squibb (Eliquis)
- Motion was made by G Thomas to add “for VTE prophylaxis in the setting of malignancy” to criteria for Eliquis (apixiban). Seconded by L Claus. None opposed. Motion passed.
- Motion was made by G Thomas to accept criteria for this class, as amended. Seconded by M Anguelov. Motion passed unanimously.

10. Colony Stimulating Factors

Preferred:

NEUPOGEN (filgrastim) vial, syringe
*UDENYCA (pegfilgrastim-cbqv) syringe

PA Required for all agents in this class

Prior Authorization Criteria:

Prior authorization may be approved if meeting the following criteria:

- Medication is being used for one of the following indications:
  - Cancer patient receiving myelosuppressive chemotherapy –to reduce incidence of infection (febrile neutropenia) (Either the post nadir ANC is less than 10,000 cells/mm3 or the risk of neutropenia for the member is calculated to be greater than 20%)
  - Acute Myeloid Leukemia (AML) patients receiving chemotherapy
  - Bone Marrow Transplant (BMT)
  - Peripheral Blood Progenitor Cell Collection and Therapy
  - Hematopoietic Syndrome of Acute Radiation Syndrome
  - Severe Chronic Neutropenia (Evidence of neutropenia Infection exists or ANC is below 750 cells/mm3)

AND

- *UDENYCA may be approved if the member meets the following criteria:
  - Member has tried and failed NEUPOGEN. Failure is defined as a lack of efficacy, intolerable side effects, drug-drug interaction or contraindication
  - Member will not need to have trialed and failed NEUPOGEN if one of the following is met:
    - Lack of caregiver or support system for assistance with administration **OR**
    - Inadequate access to healthcare facility or home care interventions

- All non-preferred agents will require a documented failure of NEUPOGEN vial or syringe **AND** UDENYCA for approval (Failure is defined as a lack of efficacy with a 3-month trial, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions) **AND**

- For long-acting formulations (such as FULPHILA and NEULASTA), the member has trialed and failed a 3-month trial of UDENYCA. Failure is defined as a lack of efficacy, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions)

Discussion

- No Board members reported conflicts of interest for this therapeutic class
- Motion was made by A Shmerling to modify criteria for UDENYCA to include lack of caregiver or support system or inadequate access to healthcare facility or home care interventions as “bypass criteria” for use of the long-acting agent. Seconded by M Wilkerson. Motion passed unanimously
- Motion was made by G Thomas to accept criteria for this class, as amended. Seconded by A Blackmer. Motion passed unanimously.

11. Newer Hereditary Angioedema (HAE) Agents

Preferred:

Prophylaxis:

HAEGARDA (C1 esterase inhibitor) 2,000 unit and 3,000 unit vial

Treatment:

BERINERT (C1 esterase inhibitor) 500 Unit kit
FIRAZYR^{BNR} (icatibant acetate) 30mg/3 mL syringe

Prior Authorization Criteria:

Medications Indicated for Routine Prophylaxis:
Members are restricted to coverage of one medication for routine prophylaxis at one time. Prior authorization approval will be for one year.

HAEGARDA may be approved for members meeting the following criteria:

- Member has a diagnosis of HAE confirmed by laboratory tests obtained on two separate instances at least one month apart (C4 level, CI-INH level) **AND**
- Member has a documented history of at least one symptom of a moderate to severe HAE attack (moderate to severe abdominal pain, facial swelling, airway swelling) in the absence of hives or a medication known to cause angioedema **AND**
  - Member meets at least one of the following:
    - HAEGARDA is being used for short-term prophylaxis to undergo a surgical procedure or major dental work **OR**
    - HAEGARDA is being used for long-term prophylaxis and member meets one of the following:
      - History of ≥1 attacks per month resulting in documented ED admission or hospitalization **OR**
      - History of laryngeal attacks **OR**
      - History of ≥2 attacks per month involving the face, throat, or abdomen

AND

- Member is not taking medications that may exacerbate HAE including ACE inhibitors and estrogen-containing medications **AND**
- Member has received hepatitis A and hepatitis B vaccination **AND**
- Provider attests to performing annual testing or screening (as appropriate) for HBV, HCV, and HIV

Max Dose: 60 IU/kg
Minimum Age: 10 years

CINRYZE and **TAKHZYRO** may be approved for members meeting the following criteria:

- Member has history of trial and failure of HAEGARDA. Failure is defined as lack of efficacy, allergy, intolerable side effects, or a significant drug-drug interaction **AND**
- Member has a diagnosis of HAE confirmed by laboratory tests obtained on two separate instances at least one month apart (C4 level, CI-INH level) **AND**
- Member has a documented history of at least one symptom of a moderate to severe HAE attack (moderate to severe abdominal pain, facial swelling, airway swelling) in the absence of hives or a medication known to cause angioedema **AND**
- Member meets at least one of the following:
  - CINRYZE is being used for short-term prophylaxis to undergo a surgical procedure or major dental work **OR**
  - CINRYZE is being used for long-term prophylaxis and member meets one of the following:
    - History of ≥1 attacks per month resulting in documented ED admission or hospitalization **OR**
    - History of laryngeal attacks **OR**
    - History of ≥2 attacks per month involving the face, throat, or abdomen

AND

- Member is not taking medications that may exacerbate HAE including ACE inhibitors and estrogen-containing medications **AND**
- Member has received hepatitis A and hepatitis B vaccination **AND**
- Provider attests to performing annual testing or screening (as appropriate) for HBV, HCV and HIV.

Minimum age:

CINRYZE: 6 years

TAKHZYRO: 12 years

Maximum dose:

CINRYZE: 100 Units/kg

TAKHZYRO: The recommended starting dose is 300mg every 2 weeks. A dosing interval of 300 mg every 4 weeks is also effective and may be considered if the patient is well-controlled (attack free) for more than 6 months

Medications Indicated for Treatment of Acute Attacks:

Members are restricted to coverage of one medication for treatment of acute attacks at one time. Prior authorization approval will be for one year.

FIRAZYR may be approved for members meeting the following criteria:

- Member has a diagnosis of HAE confirmed by laboratory tests obtained on two separate instances at least one month apart (C4 level, CI-INH level) **AND**

- Member has a documented history of at least one symptom of a moderate to severe HAE attack (moderate to severe abdominal pain, facial swelling, airway swelling) in the absence of hives or a medication known to cause angioedema **AND**
- Member is not taking medications that may exacerbate HAE including ACE inhibitorsand estrogen-containing medications

Minimum age: 18 years
Maximum dose: 30mg

BERINERT may be approved for members meeting the following criteria:

- Member has a diagnosis of HAE confirmed by laboratory tests obtained on two separate instances at least one month apart (C4 level, CI-INH level) **AND**
- Member has a documented history of at least one symptom of a moderate to severe HAE attack (moderate to severe abdominal pain, facial swelling, airway swelling) in the absence of hives or a medication known to cause angioedema **AND**
- Member is not taking medications that may exacerbate HAE including ACE inhibitors and estrogen-containing medications **AND**
- Member has received hepatitis A and hepatitis B vaccination **AND**
- Provider attests to performing annual testing or screening (as appropriate) for HBV, HCV, and HIV

Minimum age: 6 years
Max dose: 20 IU/kg

RUCONEST may be approved for members meeting the following criteria:

- Member has a history of trial and failure of FIRAZYR **OR** BERINERT. Failure is defined as lack of efficacy, allergy, intolerable side effects, or a significant drug-drug interaction

AND

- Member has a diagnosis of HAE confirmed by laboratory tests obtained on two separate instances at least one month apart (C4 level, CI-INH level) **AND**
- Member has a documented history of at least one symptom of a moderate to severe HAE attack (moderate to severe abdominal pain, facial swelling, airway swelling) in the absence of hives or a medication known to cause angioedema **AND**
- Member is not taking medications that may exacerbate HAE including ACE inhibitors and estrogen-containing medications **AND**
- Member has received hepatitis A and hepatitis B vaccination **AND**
- Provider attests to performing annual testing or screening (as appropriate) for HBV, HCV, and HIV.

Minimum age: 13 years
Max dose: 4200 Units/dose

All other non-preferred agents for either treatment or prophylaxis of HAE may be approved if member has tried and failed at least two other preferred agents for either prophylaxis or treatment of HAE. Failure is defined as lack of efficacy, allergy, intolerable side effects, or a significant drug-drug interaction.

Discussion

- No Board members reported conflicts of interest for this therapeutic class
- Motion was made by M Wilkerson to accept criteria for this class, as written. Seconded by M Anguelov. Motion passed unanimously.

12. Mass Review Drug Classes*

a. Bone Resorption Suppression and Related Agents
b. Diabetes Management Classes – Amylin
c. Diabetes Management Classes – Biguanides
d. Diabetes Management Classes – Meglitinides
e. Diabetes Management Classes – TZDs
f. Erythropoiesis Stimulating Agents
g. Prenatal Vitamins
h. Overactive Bladder Agents
i. Ophthalmic Immunomodulators
j. GI Motility, Chronic

**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.*

12.a Bone Resorption Suppression and Related Agents

Preferred:

Bisphosphonates:

Alendronate (generic) 5mg, 10mg, 35mg, 70mg tablets
Ibandronate tablet

Non-bisphosphonates:

NONE

Prior Authorization Criteria:

Bisphosphonates:
Non-preferred bisphosphonates may be approved for members who have failed treatment with one preferred product at treatment dose. (Failure is defined as lack of efficacy with a 12 month trial, allergy, intolerable side effects, or significant drug-drug interaction.)

Prior authorization for alendronate 70mg/75ml solution may be approved if member cannot swallow solid oral dosage forms or has a feeding tube.

Prior authorization may be approved for **etidronate** in members with heterotopic ossification without treatment failure of a preferred agent.

- For members who have a low risk of fracture, prior authorization will be required for members exceeding 5 years of either a preferred or non-preferred bisphosphonate. Low risk will be defined as having an osteopenic bone mineral density (most recent T-score between -1 and -2.5) **AND** no history of vertebral fracture.

Calcitonin salmon (nasal) may be approved if the member meets the following criteria:

- Member has a diagnosis of post-menopausal osteoporosis (BMD T-scores of –2.5 or less) **AND**
- Has trial and failure of preferred bisphosphonate for one year (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction) **OR**
- Member cannot swallow solid oral dosage forms or has a feeding tube.
    - Quantity limit of one spray per day

Raloxifene may be approved if the member meets the following criteria:

- Diagnosis of postmenopausal osteoporosis (BMD T-scores of –2.5 or less) **AND**
- Has trial and failure of preferred bisphosphonate for one year (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction)
- Maximum Dose of raloxifene is 60mg oral daily

FORTEO (teriparatide) may be approved if the member meets the following criteria:

- Member has one of the following diagnoses:
- Osteoporosis, (BMD T-scores of –2.5 or less) primary or hypogonadal in men
- Osteoporosis due to corticosteroid use
- Postmenopausal osteoporosis **AND**
- Has trial and failure of preferred bisphosphonate for one year (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction)
- Prior authorization will be given for one year and total exposure of parathyroid hormone analogs (FORTEO and TYMLOS) shall not exceed two years
- Maximum dose of FORTEO is 20mcg subcutaneous daily

TYMLOS (abaloparatide) may be approved if the member meets the following criteria:

- Member has a diagnosis of postmenopausal osteoporosis (BMD T-scores of –2.5 or less) **AND**
- Has trial and failure of preferred bisphosphonate for one year (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction)
- Prior authorization will be given for one year and total exposure of parathyroid hormone analogs (FORTEO and TYMLOS) shall not exceed two years.
- Maximum dose of TYMLOS is 80 mcg injection daily

PROLIA (denosumab) is a physician-administered drug and prior authorization criteria may be found on the Appendix P.

12.b Diabetes Management Classes – Amylin

Preferred:
NONE

Prior Authorization Criteria:

SYMLIN will only be approved after a member has failed a three month trial of metformin and a DPP4-inhibitor or a GLP-1 analogue. Failure is defined as: lack of efficacy (e.g., hemoglobin A1C ≥ 7%) **OR** the member cannot tolerate metformin, DPP4-inhibitor and GLP-1 analogue due to allergy, intolerable side effects, or a significant drug-drug interaction. Prior Authorization may be approved for SYMLIN products for members with Diabetes Mellitus Type 1 without failed treatment.

For all products, dosing will be limited to FDA approved dosing. PA will be required for doses in excess of FDA approved dosing

12.c Diabetes Management Classes – Biguanides

Preferred:
Metformin 500mg, 850mg, 1000mg tablets
Metformin ER 500mg tablet (generic GLUCOPHAGE XR)

Prior Authorization Criteria:

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

Liquid metformin may be approved for members who meet one of the following: under the age of 12 years with a feeding tube who have difficulty swallowing

12.d Diabetes Management Classes – Meglitinides

Preferred:
None

Prior Authorization Criteria:

Non-preferred products may be approved for members who have been stable on the two individual ingredients of the requested combination for 3 months

12.e Diabetes Management Classes – TZDs

Preferred:
Pioglitazone

Prior Authorization Criteria:

Non-preferred TZDs may be approved after a member has failed a 3-month trial of metformin and failed a 3-month trial of a preferred product. Failure is defined as lack of efficacy (e.g., hemoglobin A1C ≥ 7%), **OR** the member cannot tolerate pioglitazone and metformin due to allergy, intolerable side effects, or a significant drug-drug interaction.

12.f Erythropoiesis Stimulating Agents

Preferred:
RETACRIT (epoetin alfa-epbx)

PA Required for all agents in this class

Prior Authorization Criteria:
*Prior Authorization is required for all products and may be approved if meeting the following:

- Medication is being administered in the member's home or in a long-term care facility **AND**
- Members meets one of the following:
  - A diagnosis of cancer, currently receiving chemotherapy, with chemotherapy-induced anemia, and hemoglobin† of 10g/dL or lower **OR**
  - A diagnosis of chronic renal failure, and hemoglobin† below 10g/dL **OR**
  - A diagnosis of hepatitis C, currently taking ribavirin and failed response to a reduction of ribavirin dose, and hemoglobin† less than 10g/dL (or less than 11g/dL if symptomatic) **OR**
  - A diagnosis of HIV, currently taking zidovudine, hemoglobin† less than 10g/dL, and serum erythropoietin level of 500mUnits/mL or less **OR**
  - Member is undergoing elective, noncardiac, nonvascular surgery and medication given to reduce receipt of allogenic red blood cell

transfusions, hemoglobin† is greater than 10g/dL, but less than or equal to 13g/dL and high risk for perioperative blood loss. Member is not willing or unable to donate autologous blood preoperatively.

AND

- For any non-preferred product, member has trialed and failed treatment with one preferred product. Failure is defined as lack of efficacy with a 6-week trial, allergy, intolerable side effects, or significant drug-drug interaction.

†Hemoglobin results must be from within the last 30 days.

12. g Prenatal Vitamins

Preferred:
CITRANATAL 90 DHA combo pack
CITRANATAL ASSURE combo pack
CITRANATAL B-CALM
CITRANATAL DHA pack
CITRANATAL HARMONY capsule
CITRANATAL RX tablet
COMPLETE NATAL DHA (PNV2/IRON B-G SUC-P/FA/OMEGA-3)
CONCEPT DHA capsule
CONCEPT OB capsule
M-NATAL PLUS tablet
MACNATAL CN DHA SOFTGEL (PNV69/IRON, CARBONYL/FA/DSS/DHA)
NESTABS tablets
PNV 29-1 tablet
PNV OB+DHA COMBO PACK PNV
PNV PRENATAL PLUS MULTIVIT TAB (PNV with CA, No. 72/IRON/FA)
PNV-FERROUS FUMARATE-DOCU-FA tablet
PR NATAL 400 combo pack
PRENAISSANCE PLUS capsule
PRENATAL LOW IRON tablet
PRENATAL VITAMIN PLUS
PRENATAL VITAMIN PLUS IRON
PRENATAL VITAMIN PLUS LOW IRON
PREPLUS tablet
PREPLUS CA-FE 27MG–FA 1 MG tablet
PROVIDA OB capsule
TRINATAL RX 1 tablet
TRUST NATAL DHA
VIRT-ADVANCE TABLET
VIRT-VITE GT TABLET
VITAFOL gummies
VOL-PLUS tablet (MULTIVIT-MINS60/IRON FUM/FOLIC)

*Preferred and non-preferred prenatal vitamin products are a benefit for members from 11-60 years of age who are pregnant, lactating, or trying to get pregnant.

Prior authorization for non-preferred agents may be approved if member fails 7-day trial with four preferred agents. (Failure is defined as: allergy, intolerable side effects, or significant drug-drug interaction)

12.h Overactive Bladder Agents

Preferred:

GELNIQUE (oxybutynin) gel, pump
Oxybutynin IR, ER tablets, syrup
Oxybutynin ER tablets
Solifenacin tablet
TOVIAZ (fesoterodine ER)

Prior Authorization Criteria:

Non-preferred products may be approved for members who have failed treatment with two preferred products. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.

Members with hepatic failure can receive approval for trospium (SANCTURA) or trospium extended release (SANCTURA XR) products without a trial on a Preferred product.

12.i Ophthalmic Immunomodulators

Preferred:

RESTASIS (cyclosporine 0.05%)

Non-preferred products may be approved for members meeting all of the following criteria:

- Member is 18 years and older **AND**
- Member has a diagnosis of chronic dry eye **AND**
- Member has failed a three month trial of one preferred product (Failure is defined as a lack of efficacy, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions) **AND**
- Prescriber is an ophthalmologist, optometrist or rheumatologist

Maximum Quantity:
60 single use containers for 30 days
5.5 mL/20 days for RESTASIS Multi-Dose

12.j GI Motility , Chronic

Preferred:

AMITIZA (lubiprostone)
LINZESS (linaclotide)
MOVANTIK (naloxegol)

PA Required for all agents in this class

Prior Authorization Criteria:

All GI Motility Agents will only be approved for FDA labeled indications and up to FDA approved maximum doses (listed below):

Preferred agents may be approved if the member meets the following criteria:

- Has diagnosis of Irritable Bowel Syndrome – Constipation (IBS-C), Chronic Idiopathic Constipation (CIC), or Opioid Induced Constipation (OIC) in patients with opioids prescribed for non-cancer pain **AND**
- Member does not have a diagnosis of GI obstruction **AND**
- For indication of OIC, member opioid use must exceed 4 weeks of treatment
- For indications of CIC, OIC, IBS-C; member must have documentation of adequate trial of two or more over-the-counter motility agents (for example; polyethylene glycol, docusate, bisocodyl) (Failure is defined as a lack of efficacy for a 7 day trial, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions)
- If the member cannot take oral medications, then the member must fail a 7-day trial with a nonphosphate enema (docusate or bisocodyl enema)
- For indication of IBS-D; must have documentation of adequate trial with loperamide **AND** dicyclomine **OR** hyoscyamine (Failure is defined as a lack of efficacy for a 7 day trial, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions)

Non-preferred agents may be approved if the member meets the following criteria:

- Member meets all listed criteria for preferred agents **AND**
- Member has trialed and failed two preferred agents
  - If indication OIC caused by methadone, then non-preferred agent may be approved after trial of MOVANTIK (Failure is defined as a lack of efficacy for a 7 day trial, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions) **AND**
  - Member meets additional criteria for the agents listed below

VIBERZI (eluxadoline) may be approved for members who meet the following criteria:

- Has diagnosis of Irritable Bowel Syndrome–Diarrhea (IBS-D) AND

- Member has a gallbladder **AND**
- Member does not have severe hepatic impairment (Child-Pugh C), history of severe constipation, known mechanical gastrointestinal obstruction, biliary duct obstruction, history of pancreatitis or structural disease of the pancreas **AND**
- Member does not drink more than 3 alcoholic drinks per day

LOTRONEX (alesotron) and **ALESOTRON** may be approved for members who meet the following criteria:

- Member is a female with Irritable Bowel Syndrome – Diarrhea (IBS-D) with symptoms lasting 6 months or longer **AND**
- Member does not have severe hepatic impairment (Child-Pugh C), history of severe constipation or ischemic colitis, hypercoagulable state, Crohn's disease or ulcerative colitis,or known mechanical gastrointestinal obstruction

GI Motility Agent	**FDA approved indication(s)**	**FDA Maximum Dose**
AMITIZA (lubiprostone)	IBS-C (females only), CIC, OIC (not caused by methadone)	48mcg/day
LINZESS (linaclotide)	IBS-C, CIC	290mcg/day
MOVANTIK (naloxegol)	OIC	25mg/day
VIBERZI (eluxadoline)	IBS-D	200mg/day
Alosetron	IBS-D (females only)	2mg/day (females only)
RELISTOR syringe (methylnaltrexone)	OIC	12mg subcutaneously/day
RELISTOR oral (methylnaltrexone)	OIC	450mg/day
LOTRONEX (alosetron)	IBS-D (females only)	2mg/day (females only)
SYMPROIC (Naldemedine)	OIC	0.2mg/day
TRULANCE (plecanatide)	CIC, IBS-C	3mg/day
MOTEGRITY (prucalopride)	CIC	2 mg/day
KEY: CIC – chronic idiopathic constipation, **OIC** – opioid induced constipation, **IBS** – irritable bowel syndrome, **D** – diarrhea predominant, **C** – constipation predominant		

Discussion of Mass Review Therapeutic Classes:

- No Board members reported conflicts of interest for the therapeutic classes included in today's Mass Review

- Motion was made by L Claus to change “no history of vertebral fracture” to “no history or low trauma or fragility fracture” in section describing bisphosphonate use after 5 years of therapy. Seconded by M Wilkerson. Motion passed.
- Motion was made by A Shmerling to accept criteria included in this Mass Review, as amended. Seconded by M Wilkerson. Motion passed unanimously.

13. Proposed ProDUR and Prior Authorization Criteria for Other Selected Products **(to be added to Appendix P):**

13.a ORIAHNN (elagolix, estradiol, norethindrone acetate AND elagolix), different AM and PM capsules

ORIAHNN (elagolix, estradiol, norethindrone acetate) prior authorization may be approved for members meeting the following criteria:

- Member is a woman 18 years of age or older **AND**
  - Member has a confirmed diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) **AND**
  - Member has tried and failed treatment with a preferred estrogen-progestin contraceptive (oral tablets, NUVARING, transdermal patch) **OR** a progestin-releasing intrauterine device (IUD). Failure is defined as lack of efficacy, allergy, intolerable side effects, significant drug-drug interaction, or contraindication to therapy **AND**
  - ORIAHNN is prescribed by or in conjunction with an obstetrician/gynecologist
- Member does not have a high risk of arterial, venous thrombotic, or thromboembolic disorder, including:
  - Women over 35 years of age who smoke **OR**
  - Women with a past or current history of the following:
    - DVT, PE, or cebrovascuvascular disease (e.g., cerebrovascular disease, coronary artery disease, peripheral vascular disease) **OR**
    - Thrombogenic valvular or thrombogenic rhythm diseases of the heart (e.g.,, subacute bacterial endocarditis with valvular disease, or atrial fibrillation) **OR**
    - Inherited or acquired hypercoagulopathies **OR**
    - Uncontrolled hypertension **OR**
    - Headaches with focal neurological symptoms, or migraine headaches with aura if over age 35

AND

- Member is not pregnant **AND**
- Member does not have known osteoporosis **AND**
- Member does not have current or history of breast cancer or other hormonally-sensitive malignancies **AND**
- Member does not have known liver impairment or disease **AND**

- Member is not concomitantly taking not an OATP 1B1inhbitor (such as gemfibrozil, ritonavir, rifampin, cyclosporine) **AND**
- Member has been counseled that ORIAHNN does not prevent pregnancy **AND**
- Member has been instructed that only non-hormonal contraceptives should be used during ORIAHNN therapy and for at least 1 week following discontinuation.

Assessment of bone mineral density (BMD) by dual-energy X-ray absorptiometry (DXA) is recommended at baseline and periodically thereafter. Consider discontinuing ORIAHNN if the risk associated with bone loss exceeds the potential benefit of treatment.

Maximum daily dose:
Morning (AM) capsule: elagolix 300 mg, estradiol 1 mg, norethindrone acetate 0.5 mg
Evening (PM) capsule: elagolix 300 mg

Quantity limit: Prior authorization will be given for one year and total exposure to ORIAHNN therapy shall not exceed two years (24 months)

Discussion:
- No Board members reported conflicts of interest for the review of ORIAHNN criteria
- A testimony presentation was provided by L Hill from AbbVie
- Motion was made by A Blackmer to accept criteria for ORIAHNN. Seconded by M Anguelov. Motion passed unanimously.

13.b PALFORZIA (Arachis hypogaea Allergen Powder-dnfp), capsule, sachet

Therapeutic Class: Immunological Agent

PALFORZIA **(**Arachis hypogaea allergen powder**)** prior authorization may be approved for members meeting the following criteria:
- Member is 4 -17 years of age at initiation of therapy **AND**
- Member has a documented diagnosis of peanut allergy within the past 2 years (ICD-10 Z91.010) **AND**
- Diagnosis of peanut allergy is made in conjunction with an allergist or immunologist **AND**
- PALFORZIA will be used in conjunction with a peanut-avoidant diet **AND**
- Member does not have a past or current history of any of the following:
    - severe, unstable or uncontrolled asthma **OR**
    - eosinophilic esophagitis and other eosinophilic gastrointestinal disease **OR**
    - mast cell disorder, including mastocytosis, urticarial pigmentosa, and hereditary or idiopathic angioedema **OR**
    - severe or life-threatening anaphylaxis within the previous 60 days **AND**
- Member (or parent/guardian) has injectable epinephrine available for immediate use at all times and has been instructed on its proper use **AND**

- Member/caregiver will adhere to complex up-dosing schedule that requires frequent visits to the administering healthcare facility
  AND
- Prescriber acknowledges that PALFORZIA doses administered by a healthcare provider in the doctor's office or clinic are to be billed through the Health First Colorado medical benefit.

Maximum daily dose:

- After completing all dose levels of up-dosing, the maintenance dose of PALFORZIA is 300 mg daily

Quantity Limit: 1 year

For continuation of therapy, member must continue to meet the above initial criteria **AND**

- Member must continue to tolerate the prescribed daily doses of PALFORZIA **AND**
- Member has not experienced recurrent asthma exacerbations **AND**
- Member has not experienced any treatment-restricting adverse effects (such as repeated systemic allergic reaction and/or severe anaphylaxis).

Discussion:

- No Board members reported conflicts of interest for the review of PALFORZIA criteria
- A testimony presentation was provided by S Payne from Aimmune
- Motion was made by M Wilkerson to accept criteria for PALFORZIA, as written. Seconded by A Blackmer. Motion passed unanimously.

13.c OXBRYTA (voxelotor) tablet, 500mg

OXBRYTA (voxelotor) prior authorization may be approved for members meeting the following criteria:

- Member is ≥ 12 years of age **AND**
- Member has a confirmed diagnosis of sickle cell disease **AND**
- Member has a hemoglobin ≥ 5.5 g/dL **AND**
- OXBRYTA is prescribed by or in conjunction with a hematologist/oncologist or sickle cell disease specialist **AND**
- Prior to initiation of OXBRYTA therapy, member had at least two episodes of sickle cell related pain crises in the past 12 months; **AND**
- Member has trialed and failed a six-month trial of hydroxyurea (intolerance or contraindication) or is continuing concomitant hydroxyurea therapy following a six-month trial **AND**
- Member is not receiving chronic transfusion therapy **OR**
- Member has severe renal disease (GFR <30 mL/min)

Initial approval: 6 months
Reauthorization duration of approval: 1 year

- Member may have a reduction in vaso-occlusive events, and/or increased hemoglobin response rate defined as a hemoglobin increase of more than 1 g/dL.

Maximum dose: 1,500 mg per day
(2,500 mg per day may be approved for members taking concomitant strong or moderate CYP3A4 inducers (such as carbamazepine, oxycarbazepine, phenytoin, phenobarbital, rifaximin, rifampin or dexamethasone-containing products)

Discussion:

- No Board members reported conflicts of interest for the review of OXBRYTA criteria
- A testimony presentation was provided by Sheritha Lee from Global Blood Therapeutics
- Motion was made by G Thomas to accept criteria for OXBRYTA, as written. Seconded by M Wilkerson. Motion passed unanimously.

13.d OXERVATE (cenegermin-bkbj), ophthalmic solution 0.002%

Therapeutic Class: Ophthalmic Agent –recombinant human nerve growth factor

OXERVATE (cenegermin-bkbi) prior authorization may be approved for members meeting the following criteria:

- Member is 2 years of age or older **AND**
- Member has a confirmed diagnosis of stage 2 neurotrophic keratitis (persistent epithelial defect [PED]) or stage 3 (corneal ulcers) neurotrophic keratitis (NK) **AND**
- Member's PED and/or corneal ulcer have been present for at least two weeks **AND**
- Member has trial or failed one of the following conventional non-surgical treatments: preservative-free lubricant eye drops or ointment, therapeutic soft contact lenses, or topical autologous serum application **AND**
- Prescriber attests to member's discontinued use of preserved topical agents that can decrease corneal sensitivity **AND**
- Member has decreased corneal sensitivity (≤4 cm using the Cochet-Bonnet esthesiometer) within the area of the PED or ulcer and outside the area of defect in at least one corneal quadrant **AND**

- Member does not have any of the following:
  - Active ocular infection or active inflammation not related to NK in the affected eye
  - Schirmer test without anesthesia ≤3 mm/5 min in the affected eye
  - Any ocular surgery in the affected eye within the past 90 days that has not been determined to be the cause of NK
  - Corneal perforation, ulceration involving the posterior third of the corneal stroma, or corneal melting

- OXERVATE is being prescribed in consultation with an ophthalmologist or optometrist

Approval: 8 weeks

Maximum dose is 12 drops daily

Discussion:
- No Board members reported conflicts of interest for the review of OXERVATE criteria
- Motion was made by G Thomas to accept criteria for OXERVATE, as written. Seconded by M Anguelov. Motion passed unanimously.

13.e XERMELO (telotristat ethyl) tablet, 250mg

Therapeutic class: Antidiarrheal

XERMELO (telotristat ethy) prior authorization may be approved for members meeting the following criteria:
- Member is at 18 years of age or older **AND**
- Member has a diagnosis of carcinoid syndrome diarrhea **AND**
- Member has trialed and failed three months of somatostatin analog therapy (such as octreotide) **AND**
- XERMELO is being used in combination with somatostatin analog therapy

Approval: 12 months

Maximum dose: 750 mg per day

Discussion:
- No Board members reported conflicts of interest for the review of OXERVATE criteria
- Motion was made by L Claus to accept criteria for OXERVATE, as written. Seconded by G Thomas. Motion passed unanimously.

13.f PALYNZIQ (pegvaliase-pqpz), injectable solution

Therapeutic class: Endocrine-metabolic agent, Enzyme

PALYNZIQ (pegvaliase-pgpz) prior authorization may be approved for members meeting the following criteria:
- Member is at 18 years of age or older **AND**
- Member has a diagnosis of phenylketonuria (PKU **AND**
- Member has a blood phenylalanine (Phe) concentration > 600 mcmol/L **AND**
- Member is not receiving PALYNZIQ in combination with KUVAN **AND**
- Member is actively on a phenylalanine-restricted diet **AND**

- Member will have a phenylalanine blood level measured at baseline prior to initiation and every four weeks until a maintenance dose is established

Approval: 1 year

Reauthorization may be approved for members showing signs of continuing improvement, as evidenced by blood phenylalanine (Phe) level decrease of at least 20% from pre-treatment baseline or a reduction below 600 micromol/L at current dose **OR** after 16 weeks of treatment as a maximum dose of 40 mg/day

Maximum dose: 40 mg per day

Discussion:

- No Board members reported conflicts of interest for the review of PALYNZIQ criteria
- Motion was made by M Wilkerson to accept criteria for PALYNZIQ, as written. Seconded by M Anguelov. Motion passed unanimously.

13.g QBREXZA (glycopyrronium) pre-moistened cloth 2.4%

Therapeutic class: Anticholinergic

QBREXZA (glycopyrronium) prior authorization may be approved for members meeting the following criteria:

- Member is 9 years of age or older **AND**
- Member has a diagnosis of primary hyperhidrosis occurring more than once weekly and symptoms cease at night **AND**
- Member has a documented sweating scale score (e.g., Hyperhidrosis Disease Severity Scale (HDSS)) of 3 or 4 **AND**
- There is documentation that the axillary hyperhidrosis is severe, intractable and disabling in nature as documented by at least one of the following:
  - Significant disruption of professional and/or social life as a result of excessive sweating
  - The condition is causing persistent or chronic cutaneous conditions (such as skin maceration, dermatitis, fungal infections, secondary microbial infections) **AND**

- Prescriber has considered a trial of OTC topical antiperspirants (such as: 20% aluminum chloride hexahydrate,15% aluminum chloride hexahydrate, 6.25% aluminum chloride hexahydrate)

Approval: 3 months

Maximum dose: 1 cloth per day

Reauthorization may be approved for with an improvement of at least two points in their HDSS score following initiation.

Discussion:

- No Board members reported conflicts of interest for the review of PALYNZIQ criteria
- Motion was made by A Shmerling to accept criteria for PALYNZIQ, as written. Seconded by G Thomas. Motion passed unanimously.

14. Review of Products for Proposed Drug Label Prior Authorization (to be added to Appendix P):

14.a GALAFOLD (migalastat hydrochloride) Oral Capsule, 123 MG

Therapeutic Class: Endocrine-Metabolic Agent

GALAFOLD (migalastat hydrochloride) prior authorization may be approved for members meeting the following criteria:

- Member is ≥ 12 years of age **AND**
- GALAFOLD is being prescribed by or in conjunction with a neurologist
- Member has a confirmed diagnosis of Fabry's disease with an amenable galactose alpha gene (GLA) variant per in vitro assay data. (Amenable GLA variants are those determined by a clinical genetics professional as pathologic or likely pathologic) **AND**
- Member does not have severe renal impairment or end-stage renal disease requiring dialysis
- Maximum dose: 123 mg orally once every other day at the same time of day.

Discussion:

- No Board members reported conflicts of interest for the review of GALAFOLD criteria
- Motion was made by M Wilkerson to accept criteria for GALAFOLD, as written. Seconded by G Thomas. Motion passed unanimously.

14.b Pretomanid Oral Tablet, 200mg

Therapeutic class: Anti-infective Agent, Antitubercular Agent

Pretomanid prior authorization may be approved for members meeting the following criteria:

- Member is an adult (≥ 18 years of age) years of age **AND**
- Member has a confirmed diagnosis of multidrug resistant tuberculosis **AND**
- Pretomanid is prescribed by or in conjunction with an infectious disease specialist
- Pretomanid will be prescribed In combination with bedaquiline and linezolid by directly observed therapy
- Member must comply with directly observed therapy
- Maximum dose: 200 mg orally once daily

Discussion:

- No Board members reported conflicts of interest for the review of Pretomanid criteria
- Motion was made by M Wilkerson to accept criteria for Pretomanid, as written. Seconded by M Anguelov. Motion passed unanimously.

14.c VIMIZIM (elosulfase alfa) Intravenous Solution: 1 mg/1 mL

Therapeutic class: Endocrine-metabolic agent, Enzyme

Medications given in a hospital, doctor's office or clinic, or dialysis unit are only to be billed by those facilities through the Health First Colorado medical benefit.

Physician administered drugs include any medication or medication formulation that is administered intravenously or requires administration by a healthcare professional (including cases where FDA package labeling for a medication specifies that administration should be performed by or under the direct supervision of a healthcare professional) and may only be billed through the pharmacy benefit when given in a long-term care facility or when administered in the member's home by a healthcare professional or home health service.

VIMIZIM (elosulfase alfa) prior authorization may be approved for members meeting the following criteria:

- Member is ≥ 5 years of age **AND**
- Member has a confirmed diagnosis of mucopolysaccharidosis (MPS) Type IV A (Morquio A syndrome)
- VIMIZIM is prescribed by or in conjunction with an endocrinologist
- Due to the risk of life-threatening anaphylactic reactions, VIMIZIM will be administered under close medical observation

Discussion:

- No Board members reported conflicts of interest for the review of VIMIZIM criteria
- Motion was made by G Thomas to accept criteria for VIMIZIM, as written. Seconded by M Wilkerson. Motion passed unanimously.

Adjournment

With no other new business to discuss, the meeting was adjourned by M Noonan at 5:00 PM.