COLORADO
Department of Health Care Policy & Financing

MINUTES OF THE QUARTERLY OPEN MEETING
Health First Colorado, Colorado's Medicaid Program
Drug Utilization Review Board
Department of Health Care Policy and Financing

May 11, 2021
Open Session
1:00 pm – 5:00 pm

1. Call to Order

Today's meeting was held virtually via Zoom. The meeting was called to order at 1:02 pm by A Shmerling, Board Vice Chair.

2. Roll Call / Introductions

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.

a. **Members Present:** Allison Shmerling, MD, MPH (Vice Chair); Liza Claus, PharmD; Todd Brubaker, DO; Patricia Lanius, BSPharm, MHA; L Laird, PharmD (Industry Representative); Scott VanEyk, MD; Miroslav Anguelov, PharmD; Brian Jackson, MD, MA; Shilpa Klocke, PharmD
b. **Members Absent:** None
c. **Medicaid Pharmacy Staff:** Jim Leonard, PharmD; Jeffrey Taylor, PharmD
d. **CO-DUR Team**: Robert Page, PharmD, MSPH; Julia Rawlings, PharmD

3. Virtual Meeting Information and General Announcements

J Rawlings shared several announcements:

Today's meeting is being recorded. Board members are encouraged to keep video turned on for all or most of the meeting time. Speakers providing testimony who have signed up in advance will be unmuted by the meeting hosts at the appropriate times during review of the proposed criteria.

Board members are reminded to delete the meeting binder for today after the meeting has been adjourned. Shaded lines on market share tables indicate the current preferred products on the preferred drug list (PDL). Red highlighting indicates proposed deletions and yellow highlighting indicates proposed additions.

J Rasmussen and N Tieu, DUR interns, will be managing many of the technical aspects of today's meeting.

4. Department Updates

J Taylor provided several updates from the Department:

Welcome to new DUR Board members:
Brian Jackson, MD
Shilpa Klocke, PharmD
Lyle Laird, PharmD (industry representative)

Jim Leonard, PharmD, Deputy Director of the Pharmacy Office at HCPF, introduced himself.

The Board will be electing a pharmacist as the new Chair today. Allison Blackmer, pharmacist and Board Chair recently accepted a new job opportunity and she resigned from participating on the Board at the end of her term in March. Thank you to Dr. Blackmer for all of her valuable contributions to the Board and for her service to the State as a Board member.

HCPF has a new mission statement, which Dr. Taylor read aloud:

> *Our mission is to improve health care equity, access and outcomes for the people we serve while saving Coloradans money on health care and driving value for Colorado.*

The Department recently updated the DUR Board Policies & Procedures as well as the Training Packet that is distributed to Board members. Board members were sent a copy of the 2021 revised Training Packet by email earlier this month. If there are any questions from Board members regarding any procedures or anything from either of these documents, please feel free to reach out to Jeff Taylor.

J Taylor announced that, due to time constraints that have historically occurred with DUR Board meetings extended beyond their allotted time, or some cases where very few changes were made to the proposed PDL criteria, the way proposed DUR criteria will be read will be changed as of today's meeting. The Department asks that attendees and board members reference the most current publicly posted Preferred Drug List (PDL) located at www.hcpf.colorado.gov/pharmacy-resources. The Department asks that this resource be referenced in lieu of the DUR team reading aloud all of the criteria that has not undergone any proposed changes for review at this meeting.

The next Board meeting is tentatively scheduled for Tuesday, August 10, 2021, from 1:00 pm to 5:00 pm, to be held virtually on Zoom.

5. Election of Board Chair

For this officer election, the new Board Chair will be a pharmacist. Vice Chair Shmerling verified a quorum.

A Shmerling nominated Liza Claus for Board Chair, seconded by S VanEyk. There were no other nominations.

A Shmerling asked for a show of hands vote to elect L Claus as the new Board Chair. Her election to this officer position was approved unanimously. None opposed.

6. Final Approval of Minutes from March 23, 2021 Meeting (Physician Adminsitered Drugs)

New Board Chair L Claus asked if there were any changes to propose for minutes from the March 23 DUR Board meeting. With no discussion, a motion to approve the minutes as written made by M Anguelov and seconded by T Brubaker. The motion passed.

7. 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 at the time they are speaking.

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, he or she should not participate in the discussion of the agenda item or any vote regarding it.

Dr. Laird disclosed his COIs as the Industry Representative so that he would not need to verbally disclose that information separately for each therapeutic class or product being reviewed during today's meeting.

8. Clinical Updates and General Orders:

Retrospective DUR Reports

R Page presented the RDUR summary. There was a significant drop during 1Q2021 in the number pf members <18 years of age who received two or more antipsychotic medications concomitantly for 45 or days or more. The number of members who had two or more benzodiazepine claims concomitantly for 90 days or more remained fairly constant, with a slight decrease in 1Q2021. The number of members receiving an opioid, a benzodiazepine and a skeletal muscle relaxant concomitantly (excluding individuals with cancer and with sickle cell disease) decreased in number during the most recent quarter. The number of members with claims for opioids exceeding an average of 200 MME in a 30-day period has continued to decline since 1Q2020.

Quarterly Clinical Modules

R Page presented an update on recent Quarterly Clinical Modules

- Characterization of Naloxone Use within Health First Colorado Members Prescribed Opioids *(final module complete)*
- Opioid Utilization Among Health First Colorado Members with Migraine or Episodic Cluster Headaches *(draft module complete)*
- Therapies for Hemophilia Management *(planned for later in 2021)*
- Analysis of the First Health Colorado DUR Pain Management Consultation Service *(planned for later in 2021)*

FDA New Product & Safety Updates

DUR Intern Tracy Bach presented FDA Safety information from 1st quarter 2021.
DUR Intern Nick Tieu presented information about products recently approved by the FDA.

Quarterly Drug Utilization Reports

Board members were referred to these reports in the meeting binder

9. New Business

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

Proposed Criteria

Red indicates proposed deleted text

Yellow indicates proposed new text

1. Non-Opioid Analgesics, oral and topical

Preferred Agents:

Duloxetine capsule (generic CYMBALTA)
Gabapentin capsule, tablet, solution
Lidocaine patch
LIDODERM[BNR] (lidocaine) patch
Pregabalin capsule
SAVELLA (milnacipran) tablet, titration pack

Non-preferred oral non-opioid analgesic agents may be approved if member meets all of the following criteria:

- Member has trialed and failed duloxetine (20mg, 30mg, or 60mg) **AND** has trialed and failed gabapentin **OR** pregabalin capsule (Failure is defined as lack of efficacy with 8-week trial, allergy, intolerable side effects, or significant drug-drug interaction)

Prior authorization will be required for Lyrica (pregabalin) capsule dosages > 600mg per day (maximum of 3 capsules daily) and gabapentin dosages > 3600mg per day

Non-preferred topical products require a trial/failure with an adequate 8-week trial of gabapentin AND pregabalin AND duloxetine AND lidocaine patch. Failure is defined as lack of efficacy with an 8-week trial, allergy, intolerable side effects, or significant drug-drug interaction.

Prior authorization will be required for lidocaine patch quantities exceeding 90 patches per 30 days (maximum of 3 patches daily).

Discussion

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

2. Opioids, Short-Acting

Preferred Agents:

No PA Required*
(if criteria and quantity limit is are met)

*Acetaminophen/codeine tablets
Hydrocodone/acetaminophen solution, tablet
Hydromorphone tablet
Morphine IR solution, tablet
Oxycodone solution, tablet
Oxycodone/acetaminophen tablet
*Tramadol 50mg
*Tramadol/acetaminophen tablet

*Preferred codeine and tramadol products do not require prior authorization for adult members (18 years of age or greater) if meeting all other opioid policy criteria. Preferred codeine or tramadol products prescribed for members < 18 years of age must meet the following criteria:

- **Preferred tramadol and tramadol-containing products** may be approved for members < 18 years of age if meeting the following:
  - Member is ≥ 12 years of age **AND**
  - Tramadol is NOT being prescribed for post-surgical pain following tonsil or adenoid procedure **AND**
  - Member is not obese (BMI greater than 30kg/m^2) and does not have obstructive sleep apnea or severe lung disease
    OR
  - For members < 12 years of age with complex conditions or life-limiting illness who are receiving care under a pediatric specialist, tramadol and tramadol-containing products may be approved on a case-by-case basis

- **Preferred codeine and codeine-containing products** will receive prior authorization approval for members meeting the following criteria may be approved for members <18 years of age if meeting the following:
  - Member is ≥ 12 years of age **AND**
  - Codeine is NOT being prescribed for post-surgical pain following tonsil or adenoid procedure **AND**
  - Member is not obese (BMI greater than 30kg/m^2) and does not have obstructive sleep apnea or severe lung disease **AND**
  - Member is not pregnant or breastfeeding **AND**
  - Renal function is not impaired (GFR > 50 ml/min) **AND**
  - Member is not receiving strong inhibitors of CYP3A4 (e.gfor example erythromycin, clarithromycin, telithromycin, itraconazole, ketoconazole, posaconazole, fluconazole [≥200mg daily], voriconazole, delavirdine, and milk thistle)
    AND
  - Member meets one of the following:
    - Member has trialed codeine or codeine-containing products in the past with no history of allergy or adverse drug reaction to codeine

- Member has not trialed codeine or codeine-containing products in the past and the prescriber acknowledges reading the following statement: "Approximately 1-2% of the population metabolizes codeine in a manner that exposes them to a much higher potential for toxicity. Another notable proportion of the population may not clinically respond to codeine. We ask that you please have close follow-up with members newly starting codeine and codeine-containing products to monitor for safety and efficacy."

****NUCYNTA IR (tapentadol)** may be approved for members who meet the following criteria:

- Member has history of trial/failure of 7-days utilization of preferred product(s) in the last 21 days **OR**
- If member does not meet the above criteria, prior authorization approval for NUCYNTA IR will require trial and failure of three preferred agents. Failure is defined as lack of efficacy, intolerable side effects, significant drug-drug interaction, allergy‡, or significant adverse drug reaction.
- Nucynta IR will have a maximum daily quantity of 6 tablets (180 tabs per 30 days).

Non-preferred tramadol products may be approved following trial and failure of generic tramadol 50mg tablet AND generic tramadol/acetaminophen tablet.

All other non-preferred short-acting opioid products may be approved following trial and failure of three preferred products. Failure is defined as allergy‡, lack of efficacy, intolerable side effects, or significant drug-drug interaction.

‡Allergy: hives, maculopapular rash, erythema multiforme, pustular rash, severe hypotension, bronchospasm, and angioedema

Quantity Limits: Short-acting opioids will be limited to a total of 120 tablets per 30 days (4/day) per member for members who are not included in the opioid treatment naive policy. Exceptions will be made for members with a diagnosis of a terminal illness (hospice or palliative care) or sickle cell anemia. For members who are receiving more than 120 tablets currently and who do not have a qualifying exemption diagnosis, a 6-month prior
authorization can be granted via the prior authorization process for providers to taper members. Please note that if more than one agent is used, the combined total utilization may not exceed 120 units in 30 days. There may be allowed certain exceptions to this limit for acute situations (for example: post-operative surgery, fractures, shingles, car accident).

Maximum Doses:
Tramadol: 400mg/day
Codeine: 360mg/day
Butorphanol intranasal: 10ml per 30 days (four 2.5ml 10mg/ml package units per

Discussion

- No Board members reported a conflict of interest for this therapeutic class.
- B Jackson recommended revising the BMI-related criteria for members <18 years of age in the *Preferred codeine and codeine-containing products* section to align with the CDC-recommended definition for obesity as BMI-for-age >95th percentile. S VanEyk recommended to make an identical revision in the section for *Preferred tramadol and tramadol-containing products.*
- Motion made by A Shmerling to accept criteria for this class as amended above. Seconded by T Brubaker. Motion passed unanimously.

3. Fentanyl Preparations (buccal, intranasal, transmucosal, sublingual)

Preferred Agents:
None

Fentanyl buccal, intranasal, transmucosal, and sublingual products:

Prior authorization approval may be granted for members experiencing breakthrough cancer pain and those that have already received and are tolerant to opioid drugs for the cancer pain **AND** are currently being treated with a long-acting opioid drug. The prior authorization may be granted for up to 4 doses per day. For patients in hospice or palliative care, prior authorization will be automatically granted regardless of the number of doses prescribed.

IONSYS transdermal system requires administration in the hospital setting and is not covered under the pharmacy benefit.

Discussion

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

4. Opioids, Long-Acting

Preferred Agents:

No PA Required (*if dose dosing requirements are met)
BUTRANS^{BNR} (buprenorphine) transdermal patch
*Fentanyl 12mcg, 25mcg, 50mcg, 75mcg, 100mcg transdermal patch
Morphine ER (generic MS CONTIN) tablet
Tramadol ER (generic ULTRAM ER) tablet

***NUCYNTA ER** or **OXYCONTIN** may be approved for members who have trialed and failed‡ treatment with TWO preferred agents.

All other non-preferred products may be approved for members who have trialed and failed‡ three preferred products.

‡Failure is defined as lack of efficacy with 14 day trial due to allergy (hives, maculopapular rash, erythema multiforme, pustular rash, severe hypotension, bronchospasm, and angioedema), intolerable side effects, or significant drug-drug interaction.

Methadone Continuation:
Members who have been receiving methadone for pain indications do not have to meet non-preferred criteria. All new starts for methadone will require prior authorization under the non-preferred criteria listed above.

If a prescriber would like to discuss strategies for tapering off methadone or transitioning to other pain management therapies for a Health First Colorado member, consultation with the Health First Colorado pain management physician is available free of charge by contacting the pharmacy call center helpdesk and requesting an opioid prescriber consult.

Reauthorization:
Reauthorization for a non-preferred agent may be approved if the following criteria are met:

- Provider attests to continued benefit outweighing risk of opioid medication use **AND**
- Member met original prior authorization criteria for this drug class at time of original authorization

* Quantity/Dosing Limits:

- **OXYCONTIN, OPANA ER, NUCYNTA ER**, and **ZOHYDRO ER** will only be approved for twice daily dosing.

- **HYSINGLA ER** will only be approved for once daily dosing.

- **Fentanyl patches** will require a PA for doses of more than 15 patches/30 days (taking if using one strength) or 30 patches for 30 days (taking if using two strengths). For fentanyl patch strengths of 37mcg/hr, 62mcg/hr, and 87mcg/hr. , member must trial and fail two preferred strengths of separate patches summing that will provide the desired dose (i.e. such as 12mcg/hr + 50mcg/hr = 62mcg/hr).

Discussion

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

5. Angiotensin modulators and Angiotensin modulator combinations

5.a ACEIs, ACEI Combinations

Preferred Agents:

Benazepril tablet
Enalapril tablet
Fosinopril tablet
Lisinopril tablet
Quinapril tablet
Ramipril tablet
Enalapril/HCTZ
Lisinopril/HCTZ

Non-preferred ACE inhibitors, ACE inhibitor combinations, ARBs, ARB combinations, renin inhibitors, and renin inhibitor combination products may be approved for members who have trialed and failed treatment with three preferred products. (Failure is defined as lack of efficacy with a 4 week trial, allergy, intolerable side effects, or significant drug-drug interaction).

***EPANED (enalapril) solution** may be approved without trial and failure of three preferred agents for members under the age of 5 years who cannot swallow a whole or crushed tablet.

***QBRELIS (lisinopril) solution** may be approved for members 6 years of age or older who cannot swallow a whole or crushed tablet and have trialed and failed EPANED (enalapril) solution. Failure is defined as lack of efficacy with a 4 week trial, allergy, intolerable side effects, or significant drug-drug interaction.

Non-preferred ACE inhibitors, ACE inhibitor combinations, ARBs, ARB combinations, renin inhibitors, and renin inhibitor combination products may be approved for members who have trialed and failed treatment with three preferred products. (Failure is defined as lack of efficacy with a 4 week trial, allergy, intolerable side effects, or significant drug-drug interaction).

Discussion

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

5.b ARBs, ARB Combinations

Preferred Agents:

Amlodipine/benazepril
Amlodipine/olmesartan
Amlodipine/valsartan
*ENTRESTO (sacubitril/valsartan)
Irbesartan
Irbesartan/HCTZ
Losartan
Losartan/HCTZ
Olmesartan
Olmesartan/HCTZ
Telmisartan
Valsartan
Valsartan/HCTZ

Non-preferred ACE inhibitors, ACE inhibitor combinations, ARBs, ARB combinations, renin inhibitors, and renin inhibitor combination products may be approved for members who have trialed and failed treatment with three preferred products. (Failure is defined as lack of efficacy with a 4 week trial, allergy, intolerable side effects, or significant drug-drug interaction).

***ENTRESTO (sacubitril/valsartan)** may be approved for members if the following criteria are met:

- Member is ≥ 1 year of age and has a diagnosis of symptomatic heart failure with systemic left ventricular systolic dysfunction (LVSD) and/or has chronic heart failure with a below-normal left ventricular ejection fraction (LVEF)
- Diagnosis will be verified through automated verification (AutoPA) of the appropriate corresponding ICD-10 diagnosis codes related to the indicated use of the medication.

Scheduled testimony presentations:

- M Sommers, Novartis, Entresto – speaker relinquished time

Discussion

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

5.c Renin Inhibitors & Combinations

Preferred Agents:

NONE

Non-preferred renin inhibitors and renin inhibitor combination products may be approved for members who have failed treatment with three preferred products from the angiotensin modifier class. (Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction). Renin inhibitors and combinations will not be approved in patients with diabetes. Renin inhibitors are contraindicated when used in combination with an ACE inhibitor, ACE inhibitor combination, ARB, or ARB combination

Discussion

- No Board members reported a conflict of interest for this therapeutic class.
- Motion made by M Anguelov to accept criteria for this class as written. Seconded by B Jackson. Motion passed unanimously.

6. Acne Agents, Topical

Preferred Agents:

No PA Required (if age and diagnosis criteria is are met*)

*ACZONE (dapsone) gel
*Adapalene gel
*Adapalene/benzoyl peroxide (generic EPIDUO)
*Clindamycin phosphate solution, medicated swab
*Clindamycin/benzoyl peroxide gel jar (generic BENZACLIN)
*Clindamycin/benzoyl peroxide (generic DUAC)
*DIFFERIN^{BNR} (adapalene) gel pump
*Erythromycin solution
*Erythromycin/benzoyl peroxide gel
*RETIN-A^{BNR} (tretinoin) cream, gel
*Sulfacetamide sodium suspension
*Tretinoin cream, gel

Authorization for all acne agents prescribed solely for cosmetic purposes will not be approved.

In addition to the above criteria, pPreferred topical clindamycin and erythromycin products may also be approved by AutoPA verification of ICD-10 diagnosis code for acne vulgaris, psoriasis, cystic acne, comedonal acne, disorders of keratinization, neoplasms, folliculitis, hidradenitis suppurativa, or perioral dermatitis (erythromycin only). Approval of preferred topical clindamycin and erythromycin products for other medically accepted indications may be considered following clinical prior authorization review by a call center pharmacist.

All other preferred topical acne agents may be approved if meeting the following criteria:

- For members ≤ 25 years of age, may be approved for a diagnosis of acne vulgaris, psoriasis, cystic acne, disorders of keratinization, neoplasms, or comedonal acne. Diagnosis will be verified through automated verification (AutoPA) of the appropriate corresponding ICD-10 diagnosis code related to the indicated use of the medication.
- For members > 25 years of age, will may be approved following prescriber verification that the medication is not being utilized for cosmetic purposes AND prescriber verification that the indicated use is for acne vulgaris, psoriasis, cystic acne, disorders of keratinization, neoplasms, or comedonal acne. These medications are only eligible for prior authorization approval for the aforementioned diagnoses.

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

- Member has trialed/failed three preferred topical products with different mechanisms (i.e. such as tretinoin, antibiotic). Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction **AND**
- Prescriber verification that the medication is being prescribed for one of the following diagnoses: acne vulgaris, psoriasis, cystic acne, disorders of keratinization, neoplasms, or comedonal acne.

Discussion

- No Board members reported a conflict of interest for this therapeutic class.
- A Shmerling asked how the criteria are administered regarding cosmetic purposes for members over the age of 25. J Taylor explained that Medicaid programs are prohibited from covering cosmetic agents. Providers requesting prior authorizations are asked a “yes” or “no” question regarding cosmetic use.
- Motion made by A Shmerling to accept criteria for this class as written. Seconded by L Claus. Motion passed unanimously.

7. Acne Agents, Oral Isotretinoins

Preferred Agents:
PA Required for all agents
AMNESTEEM capsule
CLARAVIS capsule

Preferred products may be approved for severe, recalcitrant nodulocystic acne for adults and children ≥ 12 years of age that have been unresponsive to conventional therapy.

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

- Member has trialed/failed two preferred agents. (Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction) **AND**
- Member is an adult or child ≥ 12 years of age with severe, recalcitrant nodulocystic acne and has been unresponsive to conventional therapy.

Discussion

- No Board members reported a conflict of interest for this therapeutic class.
- L Claus asked about why a PA is required for all agents in this class. R Page clarified that it is to verify the indication for use.
- Motion made by A Shmerling to accept criteria for this class as written. Seconded by L Claus. Motion passed unanimously.

8. Antineoplastics, Topical

Preferred Agents:

Diclofenac 3% gel
Fluorouracil 5% cream
Fluorouracil 5% solution

SOLARAZE (diclofenac sodium) gel may be approved if the member has a diagnosis of actinic keratosis (AK).

TARGRETIN (bexarotene) gel or **VALCHLOR (mechlorethamine) gel** may be approved for members who meet the following criteria:

- Member is ≥ 18 years of age **AND**
- Member has been diagnosed with Stage IA or IB cutaneous T-cell lymphoma (CTCL) **AND**
- Member has refractory or persistent CTCL disease after other therapies OR has not tolerated other therapies
- Member is not pregnant and is using effective contraception that includes a barrier method

Non-preferred topical neoplastic agents may be approved for members who have failed an adequate trial of all preferred products FDA-approved for that indication. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.

Discussion

- No Board members reported a conflict of interest for this therapeutic class.
- B Jackson asked about the applicability of criteria related to contraception, in general, for members who have previously undergone surgical sterilization procedures (vasectomy, hysterectomy, oophorectomy). A Shmerling added that tubal ligation procedures are often not considered in the DUR criteria.
- S Klocke asked a similar question regarding same-sex couples and pregnancy test requirements in DUR criteria for this and other therapeutic classes on the PDL. Perhaps using the phrase “women or men of childbearing potential” to describe the population would be more inclusive since members

in same-sex relationships or those who have undergone a surgical intervention would not be of childbearing potential.
- S VanEyk suggested that the Board's role and scope is to develop clear and concise language regarding contraception.
- Motion made by L Claus to change bullet 4 for TARGRETIN and VALCHLOR to "For members who are of childbearing potential, member is not pregnant and is using effective contraception that includes a barrier method" and accept the other criteria for this class as written. Seconded by S Klocke. Motion passed unanimously.
- A Shmerling moved to change language about contraception throughout the PDL to "patients who are of childbearing potential" to be more gender inclusive for those who are non-binary. Seconded by S Klocke. Motion passed unanimously.

9. Rosacea Agents, Topical and Oral

Preferred Agents:

Azelaic acid gel
FINACEA[BNR] (azelaic acid) gel
METROGEL[BNR] (metronidazole) gel
Metronidazole cream, gel, lotion

Prior authorization for non-preferred products in this class may be approved if member meets the following criteria:
- Member has a diagnosis of persistent (non-transient) facial erythema with inflammatory papules and pustules due to rosacea **AND**
- Prescriber attests that medication is not being used solely for cosmetic purposes **AND**
- Member has tried and failed two preferred agents of different mechanisms of action (Failure is defined as lack of efficacy with 4 week trial, allergy, intolerable side effects)

***ORACEA (Doxycycline monohydrate DR capsule)** may be approved if the member meets all of the following criteria are met:
- Member is ≥ 18 years of age **AND**
- Member has been diagnosed with rosacea with inflammatory lesions (papules and pustules)
- Member has taken generic doxycycline for a minimum of three months and failed therapy in the last 6 months. Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions **AND**
- Member has history of an adequate trial/failure (8 weeks) of 2 other preferred agents (oral or topical). Failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions **AND**

Discussion
- No Board members reported a conflict of interest for this therapeutic class.
- A Shmerling asked for confirmation that azelaic acid would also be approved for acne for members who are pregnant. J Taylor confirmed that azelaic acid gel, as a preferred agent, would be approved for both rosacea and acne with no prior authorization required.
- Motion made by A Shmerling to accept criteria for this class as written. Seconded by B Jackson. Motion passed unanimously.

10. Phosphate Binders

Preferred Agents:

Calcium acetate capsule
PHOSLYRA (calcium acetate)
RENAGEL[BNR] (sevelamer HCl) tablet
RENVELA[BNR] (sevelamer carbonate) tablet
RENVELA[BNR] (sevelamer carbonate) powder for suspension ~~(~~**6-17 years old)***
Sevelamer carbonate tablet **(6-17 years old)***
Sevelamer HCl authorized *generic - WINTHROP US only -*

Prior authorization for non-preferred products in this class may be approved if member meets all the following criteria:

- Member has diagnosis of end stage renal disease **AND**
- Member has elevated serum phosphorus [>4.5 mg/dL or > 1.46 mmol/L] **AND**
- Provider attests to member avoidance of high phosphate containing foods from diet **AND**
- Member has trialed and failed‡ one preferred agent (Lanthanum products require trial and failure‡ of a preferred sevelamer product).

AURYXIA (ferric citrate) may be approved if the member meets all the following criteria:

- Member is diagnosed with end-stage renal disease, receiving dialysis, and has elevated serum phosphate (> 4.5 mg/dL or > 1.46 mmol/L). AND
- Provider attests to counseling member regarding avoiding high phosphate containing foods from diet **AND**
- Member has trialed and failed‡ three preferred agents with different mechanisms of action prescribed for hyperphosphatemia in end stage renal disease

  OR
- Member is diagnosed with chronic kidney disease with iron deficiency anemia and is not receiving dialysis **AND**
- Member has tried and failed‡ at least two different iron supplement product formulations (OTC or Rx)

VELPHORO (sucroferric oxyhydroxide chewable tablet) may be approved if the member meets all of the following criteria:

- Member is diagnosed with chronic kidney disease and receiving dialysis, and has elevated serum phosphate (> 4.5 mg/dL or > 1.46 mmol/L) **AND**
- Provider attests to counseling member regarding avoiding high phosphate containing foods from diet **AND**
- Member has trialed and failed‡ two preferred agents, one of which must be a preferred sevelamer product

  Maximum Dose: VELPHORO 3,000mg daily

Grandfathering: Members currently stabilized on a non-preferred lanthanum product may receive approval to continue therapy with that product.

‡Failure is defined as lack of efficacy with 6 week trial, allergy, intolerable side effects, or significant drug-drug interaction.

Note: Medications administered in a dialysis unit or clinic are billed through the Health First Colorado medical benefit or Medicare with members with dual eligibility.

Discussion

- No Board members reported a conflict of interest for this therapeutic class.
- J Taylor clarified that the Department is proposing to remove the age limitation for RENVELA.
- Motion made by M Anguelov to accept criteria for this class as written. Seconded by P Lanius. Motion passed unanimously.

11. Respiratory Inhalants

11.a Inhaled Anticholinergics & Anticholinergic Combinations

Preferred Agents:

Solutions
Ipratropium (generic ATROVENT) solution

Short-Acting Inhalers
ATROVENT HFA (ipratropium)

Long-Acting Inhalers
SPIRIVA HANDIHALER (tiotropium)
*SPIRIVA RESPIMAT (tiotropium)

Combination Solutions
Albuterol/ipratropium solution

Combination Short-Acting Inhalers
COMBIVENT RESPIMAT (albuterol/ipratropium)

Combination Long-Acting Inhalers
BEVESPI AEROSPHERE (glycopyrrolate/formoterol fumarate)
ANORO ELLIPTA (umeclidinium/vilanterol)

Non-preferred single agent anticholinergic agents may be approved for members with a diagnosis of COPD including chronic bronchitis and/or emphysema who have trialed and failed‡ treatment with two preferred agents, one of which must be SPIRIVA HANDIHALER.

***SPIRIVA RESPIMAT (tiotropium) for asthma:** SPIRIVA RESPIMAT may be approved for members ≥ 6 years of age with a diagnosis of asthma (qualifying diagnosis verified by AutoPA). SPIRIVA RESPIMAT is intended to be used by members whose asthma is not controlled with regular use of a combination medium-dose inhaled corticosteroid and long-acting beta agonist (LABA). who have trialed and failed‡ treatment with three preferred inhaled corticosteroids, at least two of the trials must be preferred combination inhaled corticosteroid products.

SPIRIVA RESPIMAT (tiotropium) for COPD: Members with a diagnosis of COPD who must meet non-preferred criteria for single agent inhaled anticholinergics listed above for may receive approval of for SPIRIVA RESPIMAT.

BREZTRI AEROSPHERE (budesonide/glycopyrrolate/formoterol) prior authorization may be approved for members ≥ 18 years of age with a diagnosis of COPD who have trialed and failed‡ treatment with two preferred anticholinergic agents.

DUAKLIR PRESSAIR (aclidinium/formoterol) prior authorization may be approved for members ≥ 18 years of age with a diagnosis of COPD who have trialed and failed‡ treatment with two preferred anticholinergic agents.

LONHALA MAGNAIR (glycopyrrolate) may be approved for members ≥ 18 years of age with a diagnosis of COPD including chronic bronchitis and emphysema who have trialed and failed‡ treatment with two preferred anticholinergic agents.

Non-preferred inhaled anticholinergic combination agents may be approved for members with a diagnosis of COPD including chronic bronchitis and/or emphysema who have trialed and failed‡ treatment with two preferred inhaled anticholinergic combination agents. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.

‡Failure is defined as lack of efficacy with 6 week trial, allergy, intolerable side effects, or significant drug-drug interaction or dexterity/coordination limitations (per provider notes) that significantly impact appropriate use of a specific dosage form.

Grandfathering: Members who have been previously stabilized on BEVESPI AEROSPHERE can receive approval to continue therapy with that product.

Discussion

- L Claus asked about the requirement to try and fail two preferred products prior to approval of Breztri Aerosphere and Duaklir Pressair since there is only one preferred anticholingeric combination product. J Taylor suggested a modification to the proposed criteria for those two products to say “two anticholinergic-containing agents” which would include single-agent products and the preferred combination product.
- L Claus raised a concern that upon initial diagnosis of moderate-to-severe COPD providers may want to start with a combination product rather than two single-agent products, although this scenario may not be very common.
- J Taylor clarified that the Department is proposing to remove the age limitation for RENVELA.
- Motion made by L Claus to (1) request that the Department to consider the trial and failure requirements for products in this class and ensure there are appropriate preferred products available for COPD therapies per guideline-directed combination therapy, and (2) approve criteria for this sub-class with that amendment. Seconded by B Jackson. Motion passed unanimously.

11.b Inhaled Beta$_2$ Agonists (short-acting/SABA)

Preferred Agents:

Solutions

Albuterol (generic) solution

Inhalers

PROAIR BNR (albuterol) HFA
VENTOLIN BNR (albuterol) HFA inhaler

Non-preferred, short acting beta$_2$ agonists will may be approved for members who have failed treatment with one preferred agent. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.

MDI formulation quantity limits: 2 inhalers/30 days

Scheduled testimony presentations:

- J Shear, Teva – ProAir Digihaler

Discussion

- J Taylor clarified that the three Digihaler products reviewed in J Shear's testimony today fall within three different subclasses on the PDL (SABA, inhaled corticosteroids and inhaled corticosteroid combinations).
- J Taylor also clarified that the SABA MDI quantity limit of 2 inhalers in 30 days allows for exceptions to made in circumstances when that limit may need to be exceeded, per prescriber request.
- S Klocke asked if the failure definition for this class should also include a provision for dexterity/coordination limitations, similar to the inhaled anticholinergics.
- P Lanius added that spacer devices are available for products in this sub-class, and they are covered under the CO Medicaid DME benefit.
- T Brubaker suggested a clarification that the preferred product, albuterol solution, be further described on the PDL as a solution for nebulizer use and not oral administration.
- Motion made by P Lanius to accept criteria as written. Seconded by T Brubaker. Motion passed unanimously.

11.c Inhaled Beta$_2$ Agonists (long-acting/LABA)

Preferred Agents:
***Must meet eligibility criteria**

Solutions

NONE

Inhalers

*SEREVENT DISKUS (salmeterol) inhaler

*SEREVENT (salmeterol) will may be approved for members with moderate to very severe COPD.

Non-preferred agents will may be approved for members with moderate to severe COPD, **AND** members must have failed a trial of SEREVENT. (Failure is defined as lack of efficacy with a 6-week trial, allergy, intolerable side effects, or significant drug-drug interaction.

Note: **For treatment of members with diagnosis of asthma needing add-on therapy, please refer to
preferred agents in the combination Long-Acting Beta Agonist/Inhaled Corticosteroid therapeutic class.

SEREVENT will not be approved for treatment of asthma in members needing add-on therapy due to safety risks associated with monotherapy.

Discussion

- Motion made by B Jackson to accept criteria as written. Seconded by A Shmerling. Motion passed unanimously.

11.d Inhaled Corticosteroids and Combinations

Preferred Agents:

Solutions
Budesonide nebules 0.25mg, 0.5mg, 1mg

Inhalers
ASMANEX Twisthaler (mometasone)
FLOVENT Diskus (fluticasone)
FLOVENT HFA (fluticasone)
PULMICORT Flexhaler (budesonide)

Combination products
ADVAIR Diskus[BNR] (fluticasone/salmeterol)
ADVAIR HFA (fluticasone/salmeterol)
DULERA (mometasone/formoterol)
SYMBICORT[BNR] (budesonide/formoterol) inhaler

Non-preferred inhaled corticosteroids will may be approved in members with asthma who have failed an adequate trial of two preferred agents. An adequate trial is defined as at least 6 weeks. (Failure is defined as: lack of efficacy with a 6-week trial, allergy, contraindication to, intolerable side effects, or significant drug-drug interactions.)

Maximum Dose:
PULMICORT (budesonide) nebulizer suspension solution: 2mg/day

Non-preferred inhaled corticosteroid combinations will may be approved for members meeting both of the following criteria:

- Member has a qualifying diagnosis of asthma or severe COPD; **AND**
- Member has failed two preferred agents (Failure is defined as lack of efficacy with a 6 week trial, allergy, intolerable side effects, significant drug-drug interactions, or dexterity/coordination limitations (per provider notes) that significantly impact appropriate use of a specific dosage form.)

TRELEGY ELLIPTA prior authorization will may be approved if the member has trialed/failed three preferred inhaled corticosteroid combination products **AND** SPIRIVA HANDIHALER. Failure is defined as lack of efficacy with a 6-week trial, allergy, intolerable side effects, significant drug-drug interactions, or dexterity/coordination limitations (per provider notes) that significantly impact appropriate use of a specific dosage form.

Scheduled testimony presentations:

- J Shear, Teva – ArmonAir Digihaler, AirDuo Digihaler

Discussion

- L Claus asked about any quantity limits that be in place for the inhaled corticosteroid products. J Taylor explained that there are no proposed quantity limits for this sub-class.
- Motion made by L Claus approve these criteria as written. Seconded by T Brubaker. Motion passed unanimously.

11.e Phosphodiesterase Inhibitors (PDEi)

Preferred Agents:
NONE

DALIRESP (roflumilast) tablets may be approved for members when the following criteria are met:

- Member has severe COPD associated with chronic bronchitis and a history of COPD exacerbations (2 or more per year) **AND**
- Member must be ≥ 18 years of age **AND**
- Member must have failed a trial of TWO of the following (Failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interaction):
  - a long-acting beta2 agonist
  - a preferred inhaled anticholinergic or anticholinergic combination

  AND
- Member must not have moderate to severe liver disease (Child Pugh B or C)

Discussion

- S Klocke stated that defining liver disease using the Child Pugh criteria is challenging to quantify in a primary care or non-GI clinical practice and proposed to keep "moderate to severe liver disease" and delete the phrase "Child Pugh B or C" from these criteria. Dr. Claus verified that the Child Pugh phrase is included in the Daliresp product labeling. Dr. Klocke agreed that the phrase be retained but noted that it potentially results in more work for providers to calculate a score.
- Motion made by S Klocke approve these criteria as written. Seconded by M Anguelov. Motion passed unanimously.

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12. Mass review drug classes*

**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 Tetracyclines

Preferred agents
Doxycycline hyclate capsules
Doxycycline hyclate tablets
Doxycycline monohydrate 50mg, 100mg capsule
Doxycycline monohydrate tablets
Minocycline capsules

Prior authorization for non-preferred tetracycline agents may be approved if member has trialed/failed a preferred doxycycline product AND preferred minocycline. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.

Prior authorization for liquid oral tetracycline formulations may be approved if member has difficulty swallowing and cannot take solid oral dosage forms.

NUZYRA (omadacycline) prior authorization may be approved if member meets all of the following criteria: the above "non-preferred" prior authorization criteria and the following:

- Member has trialed and failed† therapy with a preferred doxycycline product and preferred minocycline **OR** clinical rationale is provided describing why these medications cannot be trialed (including resistance and sensitivity) **AND**
- Member has diagnosis of either Community Acquired Bacterial Pneumonia (CABP) or Acute Bacterial Skin and Skin Structure Infection (ABSSSI) or clinical rationale and supporting literature describing/supporting intended use **AND** one of the following:
    - If member diagnosis is ABSSSI, member must have trial and failure‡ of sulfamethoxazole/trimethoprim product in addition to preferred tetracyclines **OR**
    - If member diagnosis is CABP, member must have trial and failure‡ of either a beta-lactam antibiotic (amoxicillin/clavulanic acid) or a macrolide (azithromycin) **AND**
        - Maximum duration of use is 14 days

‡Failure is defined as lack of efficacy with 7 day trial, allergy, intolerable side effects, or significant drug-drug interaction.)

Discussion

- No Board members reported a conflict of interest for this therapeutic class.
- T Brubaker asked about administration of doxycycline to pediatric members since all preferred products are tablet or capsule dosage forms. R Page clarified that doxycycline capsules may be opened and mixed into soft food for administration, and also that the failure definition for this therapeutic class includes a provision for approval of liquid oral tetracycline formulations if a member has difficulty swallowing tablets or capsules.
- Motion made by L Claus approve these criteria as written. Seconded by B Jackson. Motion passed unanimously.

12.b Skeletal Muscle Relaxants

Preferred agents
No PA Required (if under 65 years of age)*
Baclofen (generic LIORESAL)
Cyclobenzaprine (generic FLEXERIL) 5mg and 10mg tablet
Methocarbamol
Tizanidine tablet

All agents in this class will require a PA for members 65 years of age and older. The maximum allowable approval will be for a 7-day supply.

Non-preferred skeletal muscle relaxants will be approved for members who have trialed and failed‡ three preferred agents. (Failure is defined as lack of efficacy, allergy, intolerable side effects, contraindication, or significant drug-drug interactions.)

Authorization for any **carisoprodol** product will be given for a maximum 3-week, one-time authorization for members with acute, painful musculoskeletal conditions who have failed treatment with three preferred products within the last 6 months.

***Dantrolene** will be approved for members 5-17 years of age who have trialed and failed‡ one preferred agent and meet the following criteria:

- Documentation of age-appropriate liver function tests **AND**
- One of following diagnoses: multiple sclerosis, cerebral palsy, stroke, upper motor neuron disorder, or spinal cord injury
- Dantrolene will be approved for the period of one year
- If a member is stabilized on dantrolene at <18 years of age, they may continue to receive approval after turning 18 years of age

‡Failure is defined as: lack of efficacy with 14 day trial, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions.

Discussion

- No Board members reported a conflict of interest for this therapeutic class.
- Motion made by A Shmerling approve these criteria as written. Seconded by S Klocke. Motion passed unanimously.

12.c Topical Immunomodulators

Preferred agents
ELIDEL[BNR] (pimecrolimus) cream
Pimecrolimus cream - *authorized generic only - Oceanside Pharm*
PROTOPIC [BNR] (tacrolimus)

Non-preferred topical immunomodulator products may be approved following adequate trial and failure‡ of one prescription topical corticosteroid **AND** two preferred agents.

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

For members under 18 years of age, must be prescribed by or in conjunction with a dermatologist or allergist/immunologist.

Discussion

- No Board members reported a conflict of interest for this therapeutic class.
- Motion made by M Anguelov approve these criteria as written. Seconded by L Claus. Motion passed unanimously.

12.d Androgenic Agents – Topicals, Injectables, Orals

Preferred agents
PA Required for all agents in this class
*ANDRODERM (testosterone) patch
ANDROGEL(testosterone gel) packet
ANDROGEL (testosterone gel) 1.62% pump
*Testosterone gel 1.62% pump (generic ANDROGEL)
*Testosterone gel packet (generic VOGELXO)
*Testosterone cypionate IM injection

Injectable testosterone cypionate is a pharmacy benefit when self-administered. Administration in an office setting is a medical benefit.

Hypogonadotropic or Primary Hypogonadism (may be secondary to Klinefelter Syndrome):

Preferred products may be approved for members meeting the following:

1. Member is a male patient > 16 years of age with a documented diagnosis of hypogonadotropic or primary hypogonadism **OR** ≥ 12 years of age with a diagnosis of hypogonadotropic or primary hypogonadism secondary to Klinefelter Syndrome (all other diagnoses will require manual review) **AND**
2. Member has two documented low serum testosterone levels below the lower limit of normal range for testing laboratory prior to initiation of therapy **AND**
3. Member does not have a diagnosis of breast or prostate cancer **AND**
4. Member does not have a palpable prostate nodule or prostate-specific antigen (PSA) > 4ng/mL (not required for members < 40 years of age) **AND**
5. Has Baseline hematocrit < 50%

Reauthorization Criteria – Requests for renewal of a currently expiring prior authorization for a preferred product may be approved for members meeting the following criteria:

1. Member is a male patient > 16 years of age with a documented diagnosis of hypogonadotropic or primary hypogonadism **OR** ≥ 12 years of age with a diagnosis of hypogonadotropic or primary hypogonadism secondary to Klinefelter Syndrome **AND**
2. Serum testosterone is being regularly monitored (at least annually) to achieve total testosterone level in the middle tertile of normal reference range **AND**
3. Member does not have a diagnosis of breast or prostate cancer **AND**
4. Has Member's hematocrit < 54%

Gender Transition/Affirming Hormone Therapy:
Preferred androgenic drugs will be approved for members meeting the following:

1. Female sex assigned at birth > 16 years of age **AND**
2. Is undergoing female to male transition **AND**
3. Has a negative pregnancy test prior to initiation **AND**
4. Has baseline hematocrit < 50% or hematocrit < 54% for continuation of therapy

Non-Preferred Products:

Non-preferred **topical** androgenic agents may be approved for patients meeting the above criteria with trial and failed‡ therapy with two preferred topical androgen formulations.

Non-preferred **injectable** androgenic agents may be approved for patients meeting the above criteria with trial and failed‡ therapy with a preferred injectable androgenic drug.

Prior authorization for **oral** androgen agents (tablet, capsule, buccal) may be approved if member has trialed and failed‡ therapy with a preferred topical agent **AND** testosterone cypionate injection.

‡Failure is defined as lack of efficacy with 8 week trial, allergy, intolerable side effects, contraindication to, or significant drug-drug interaction.
For all agents and diagnoses, members < 16 years of age will require a manual prior authorization review by a pharmacist (with exception of members ≥ 12 years of age with a diagnosis of hypogonadotropic or primary hypogonadism secondary to Klinefelter Syndrome).

Discussion

- No Board members reported a conflict of interest for this therapeutic class.
- A Shmerling asked to clarify that the criteria referred to specific PSA levels *or* palpable prostate nodule (bullet point #4 in first set of criteria for this sub-class) and not "*and*" to include both. R Page confirmed that the intent was for the criteria to rule out either a specific PSA level or a prostate nodule prior to approval of androgenic products.
- P Lanius asked about the ability of members to have testosterone levels checked annually, especially during the pandemic, and whether that could possibly affect reauthorization approval. J Taylor clarified that the intent is still for members to have a serum testosterone drawn at least once every 12 months.
- Motion made by B Jackson approve these criteria as written. Seconded by S VanEyk. Motion passed unanimously

12.e Antihistamines, Newer Generation & Combinations

Preferred agents
Cetirizine (generic OTC ZYRTEC) tablet, syrup, solution
Cetirizine (Rx) syrup
Desloratadine (generic CLARINEX) tablet (Rx)
Levocetirizine tablet (Rx/OTC)
Loratadine (generic OTC CLARITIN) 10mg tab and syrup

Combination products
NONE

Non-preferred single-agent antihistamine products may be approved for members who have failed treatment with two preferred products in the last 6 months. For members with respiratory allergies, an additional trial of an intranasal corticosteroid will be required in the last 6 months. Failure is defined as lack of efficacy with a 14 day trial, allergy, intolerable side effects, or significant drug-drug interaction.

Discussion

- Motion made by M Anguelov to approve these criteria as written. Seconded by T Brubaker. Motion passed unanimously.

12.f Benign Prostatic Hypertrophy (BPH) Agents

Preferred agents
Alfuzosin ER tablet
Doxazosin tablet
Dutasteride capsule
Finasteride tablet
Tamsulosin capsule
Terazosin capsule

Prior authorization for non-preferred products in this class may be approved if member meets all of the following criteria:

- Member has tried and failed‡ three preferred agents **AND**
- For combinations agents, member has tried and failed‡ each of the individual agents within the combination agent and one other preferred agent.

‡Failure is defined as lack of efficacy with 8-week trial, allergy, intolerable side effects, contraindication to, or significant drug-drug interaction.

***CIALIS** will be approved for members with a documented diagnosis of BPH who have failed a trial of finasteride (at least 3 months in duration) **AND** either a trial of a nonselective alpha blocker (therapeutic dose for at least two months) **OR** a trial of tamsulosin (therapeutic dose for at least one month). Documentation of BPH diagnosis will require BOTH of the following:

- AUA Prostate Symptom Score ≥ 8 **AND**
- Results of a digital rectal exam.

CIALIS will not be approved for any patient continuing alpha blocker therapy, as this combination is contraindicated in this population.

Maximum dose: Doses exceeding 5mg per day of CIALIS will not be approved.

Discussion

- No Board members reported a conflict of interest for this therapeutic class.
- Motion made by S Klocke to approve these criteria as written. Seconded by M Anguelov. Motion passed unanimously.

Proposed ProDUR and Prior Authorization Criteria for Other Selected Products

- No Board members reported a conflict of interest for the seven products being reviewed in this section of the agenda.

- **UPLIZNA (inebilizumab-cdon) IV injectable solution**

  UPLIZNA (inebilizumab) may be approved for members when the following criteria are met:
  1. Medication is being administered in the member's home or in a long-term care facility by a healthcare professional **AND**
  2. 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**
  3. Member has a past medical history of at least one of the following:
     1. Optic neuritis
     2. Acute myelitis
     3. Area postrema syndrome; episode of otherwise unexplained hiccups or nausea and vomiting
     4. Acute brainstem syndrome
     5. Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions

6. Symptomatic cerebral syndrome with NMOSD-typical brain lesions

4. Member does not have active Hepatitis B infection, as confirmed by negative surface antigen [HBsAg] and anti-HBV tests **AND**
5. 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 UPLIZNA **AND**
6. Member does not have active or untreated latent tuberculosis **AND**
7. Member is not pregnant or breastfeeding and has been counseled to use effective contraception while receiving UPLIZNA and for at least 6 months after the last dose **AND**
8. UPLIZNA is prescribed by, or in consultation with, a neurologist **AND**
9. Member will receive corticosteroid, antihistamine, and antipyretic premedication prior to each infusion

Maximum dose: Initial 300 mg IV infusion followed by 300mg IV infusion 2 weeks later, followed by 300mg IV infusion every 6 months (starting 6 months from the initial infusion)

Stakeholder input:
Letter from D Edberg, Viela Bio, in meeting binder

Scheduled testimony presentations:
D Edberg, Viela Bio – speaker relinquished time

Discussion

- B Jackson proposed that "childbearing potential" language, similar to the contraception verbiage discussed earlier in today's meeting for topical neoplastic agents, also be incorporated into the criteria for Uplizna.
- Motion made by L Claus to approve these criteria as amended. Seconded by B Jackson. Motion passed unanimously.

- **VILTEPSO (viltolarsen) IV injectable solution**

VILTEPSO (viltolarsen) may be approved for members when the following criteria are met:

1. Medication is being administered in the member's home or in a long-term care facility by a healthcare professional **AND**
2. Member must have genetic testing confirming mutation of the Duchenne muscular dystrophy (DMD) gene that is amenable to exon 53 skipping **AND**
3. Serum cystatin C, urine dipstick, and urine protein-to-creatinine ratio should be measured before starting VILTEPSO. Consider measurement of glomerular filtration rate prior to initiation of VILTEPSO.
4. Members with known renal function impairment should be closely monitored during treatment with VILTEPSO, as renal toxicity has occurred with similar drugs **AND**
5. If the member is ambulatory, functional level determination of baseline assessment of ambulatory function is required **OR** if not ambulatory, member must have a Brooke Upper Extremity Function Scale of five or less documented **OR** a Forced Vital Capacity (FVC) of 30% or more.

6. Provider is aware that continued US FDA approval of VILTEPSO (viltolarsen) for Duchenne muscular dystrophy (DMD) may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Maximum dose: 80 mg/kg administered as an IV infusion once weekly

Reauthorization criteria: After 24 weeks of treatment with VILTEPSO (viltolarsen), member may receive approval to continue therapy for one year if the following criteria are met:

1. Member has shown no adverse effects related to VILTEPSO treatment at a dose of 80mg/kg IV once a week **AND**
2. Member has normal renal function or stable renal function if known impairment
3. Member demonstrates response to treatment with VILTEPSO with significant clinical improvement from baseline assessment in ambulatory function **OR** if not ambulatory, member demonstrates improvement from baseline on the Brooke Upper Extremity Function Scale **OR** in Forced Vital Capacity (FVC).

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.

Stakeholder input:

Letter from Parent Project Muscular Dystrophy, in meeting binder

Discussion

- Since the natural state of DMD is degenerative, B Jackson and other Board members discussed editing the reauthorization criteria to reflect either a response to treatment with Viltepso or that the member does now show a trajectory of disease progression. B Jackson suggested for bullet #3 under reauthorization criteria "Member demonstrates response to treatment with VILTEPSO with significant clinical improvement in trajectory from baseline assessment in ambulatory function…etc."
- Due to the current lack of confirmed efficacy for these DMD therapies, along with their high cost, S Klocke advocated for including some level of efficacy criteria, both for initial approval and reauthorization.
- S VanEyk advocated for fewer requirements for approval of initial access to Viltepso.
- B Jackson and other Board members proposed removing the requirements for non-ambulatory members for a specific Brook Upper Extremity Function Scale score range as well as an FVC <30%, while keeping the requirement that one or both of these assessments be evaluated at baseline and prior to authorization of initial therapy.
- Motion made by S VanEyk to approve these criteria as amended with the changes described above to (1) remove specific values for baseline Brooke and FVC baseline assessments from the initial authorization criteria, and (2) to add the phrase "in trajectory" to reauthorization bullet point #3. Seconded by B Jackson. Motion passed unanimously.
- A motion affecting the Viltepso reauthorization and the adverse effects description was made during the criteria review for Amondys 45. (See details under Amondys 45 below)

- **HEMADY (dexamethasone) tablets**

HEMADY (dexamethasone) may be approved when the following criteria are met:

1. Member is an adult (≥18 years of age) **AND**
2. Member has a confirmed diagnosis of multiple myeloma (MM) **AND**
3. HEMADY is being prescribed in combination with other anti-myeloma treatment agents **AND**
4. Member does not have pheochromocytoma **AND**
5. Members of childbearing potential have been advised to use effective contraception during treatment with HEMADY and for at least one month after the last dose **AND**
6. Member has trialed and failed generic dexamethasone tablets. Failure is defined as allergy or intolerable side effects.

Maximum dose: 40 mg/day

Discussion

- Motion made by A Shmerling to approve these criteria as written. Seconded by T Brubaker. Motion passed unanimously.

- **MYCAPSSA (octreotide) delayed-release capsule**

MYCAPSSA (octreotide) may be approved if all of the following criteria are met:

1. Member is an adult (≥ 18 years of age) with a confirmed diagnosis of acromegaly
2. Prior authorization of MYCAPSSA requires trial and failure‡ of bromocriptine mesylate at maximally tolerated doses **AND**
3. The member has responded to and tolerated 3 months of treatment with octreotide acetate injection (vial) OR lanreotide acetate injection
4. The member cannot be treated with surgical resection or pituitary irradiation **AND**
5. Member is not hypersensitive to octreotide of any components of MYCAPSSA (octreotide) capsules, which include but are not limited to gelatin, propylene glycol and povidone **AND**
6. MYCAPSSA (octreotide) is prescribed by, or in consultation with, an endocrinologist **AND**
7. Provider attests that insulin-like growth factor 1 (IGF-1) levels will be monitored every two weeks, along with member's signs and symptoms, during the dose titration period or as indicated, and that the MYCAPSSA dose will be adjusted based on these findings **AND**
8. Provider attests that blood glucose will the monitored during initiation of treatment with MYCAPSSA, and that blood glucose, thyroid function, and vitamin B_{12} levels will be monitored periodically during treatment **AND**
9. Provider confirms awareness of the potential for significant drug interactions between MYCAPSSA (octreotide) and other medications, including (but not limited to) cyclosporine, digoxin, lisinopril, oral contraceptives containing levonorgestrel, bromocriptine, beta blockers, and calcium channel blockers.

Maximum Dose: 80 mg daily

‡Failure is defined as lack of efficacy with a 3-month trial, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction

Discussion

- Motion made by B Jackson to approve these criteria as written. Seconded by A Shmerling. Motion passed unanimously.

- **AMONDYS 45 (casimersen)**

  AMONDYS 45 (casimersen) may be approved if the following criteria are met:

  - Medication is being administered in the member's home or in a long-term care facility by a healthcare professional **AND**
  - Member has a diagnosis of Duchenne Muscular Dystrophy (DMD) **AND**
  - Member must have genetic testing confirming mutation of the DMD gene that is amenable to exon 45 skipping **AND**
  - Medication is prescribed by or in consultation with a neurologist or a provider who specializes in treatment of DMD (such as a pediatric neurologist, cardiologist, or pulmonary specialist) **AND**
  - Provider attests that serum cystatin C, urine dipstick, and urine protein-to-creatinine ratio (UPCR) and glomerular filtration rate (GFR) will be measured prior to initiation of AMONDYS 45 and that member will be monitored periodically for kidney toxicity during treatment.
  - The member must be on corticosteroids at baseline or has a contraindication to corticosteroids **AND**
  - If the member is ambulatory, functional level determination of baseline assessment of ambulatory function is required OR if not ambulatory, member must have a Brooke Upper Extremity Function Scale of five or less documented OR a Forced Vital Capacity of 30% or more.

Reauthorization criteria: After 24 weeks of treatment with AMONDYS 45 (casimersen) member may receive approval to continue therapy for one year if the following criteria are met:

1. Member has shown no adverse effects related to AMONDYS 45 treatment at a dose of 80mg/kg IV once a week **AND**
2. Member has normal renal function or stable renal function if known impairment
3. Member demonstrates response to treatment with AMONDYS 45 with significant clinical improvement from baseline assessment in ambulatory function **OR** if not ambulatory, member demonstrates improvement from baseline on the Brooke Upper Extremity Function Scale **OR** in Forced Vital Capacity (FVC).

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.

Maximum Dose: 30 mg/kg per week

Stakeholder input:
Letter from Parent Project Muscular Dystrophy, in meeting binder

Scheduled testimony presentations:
T Copeland, Sarepta Therapeutics
S Apkon, MD, Dept of Rehabilitation, Children's Hospital Colorado

Discussion

- J Rawlings acknowledged a typo in bullet #1 of the reauthorization criteria. 80 mg/kg IV once a week should read 30 mg/kg IV once a week. This detail will be corrected in the final criteria.
- B Jackson also noted that "no adverse effects" in reauthorization bullet point #1 seems too broad and proposed adding the modifier "serious." L Laird cautioned that the FDA has specific definitions for the term serious adverse event (SAE). After further discussion, the Board decided on "intolerable adverse effects."
- Motion made by L Claus to approve these criteria as amended with the changes described above to:
  (1) Remove specific values for baseline Brooke and FVC baseline assessments from the initial authorization criteria
  (2) Add the phrase "in trajectory" to reauthorization bullet point #3, same as for Viltepso
  (3) Add the word "intolerable" before adverse effects in reauthorization bullet point #3 and also apply this change to the criteria for Viltepso *(above)*
  (4) Change bullet points to numbers throughout this section
  (5) Add a new line, same as for Viltepso, that "provider is aware that continued US FDA approval of AMONDYS 45 (casimersen) for Duchenne muscular dystrophy (DMD) may be contingent upon verification and description of clinical benefit in a confirmatory trial"
  (6) Delete the line "The member must be on corticosteroids at baseline or has a contraindication to corticosteroids **AND**"

  Motion seconded by B Jackson. Motion passed unanimously.

- **BRONCHITOL (mannitol) capsules for oral inhalation**

  BRONCHITOL (mannitol) may be approved as an add-on therapy for cystic fibrosis (CF) if the following criteria are met:

  - Member is an adult (≥ 18 years of age) with a confirmed diagnosis of cystic fibrosis **AND**
  - Member has severe lung disease as documented by bronchoscopy or CT scan **AND**
  - Member has an FEV_1 between 40% and 89% of predicted value **AND**
  - Member is receiving other appropriate therapy for management of cystic fibrosis (such as inhaled antibiotic, airway clearance physiotherapy, inhaled beta2 receptor agonist) **AND**
  - Member has had an adequate trial and failure of nebulized hypertonic saline, or is currently using nebulized hypertonic saline on a regular basis **AND**
  - Member has trialed and failed twice-daily treatment with recombinant human deoxyribonuclease (dornase alfa, rhDNase). Failure is defined as allergy, intolerable side effects or inadequate response. **AND**
  - Member has successfully passed the BRONCHITOL Tolerance Test (BTT) under the supervision of a healthcare practitioner **AND**
  - The member has been prescribed a short-acting bronchodilator to use 5 to 15 minutes before each dose of BRONCHITOL.

  Maximum Dose: 400mg twice a day by oral inhalation

  Quantity Limit: one 4-week Treatment Pack (4 inhalers, 560 capsules) per 30 days

Scheduled testimony presentations:
A Houck, Chiesi USA

Discussion

- Motion made by M Anguelov to approve these criteria as written. Seconded by A Shmerling. Motion passed unanimously.

- **GIMOTI (metoclopramide) nasal spray**

GIMOTI (metoclopramide nasal spray) may be approved if the following criteria are met:

- Member is an adult (≥ 18 years of age) **AND**
- Member has a confirmed diagnosis of acute or recurrent diabetic gastroparesis **AND**
- Member has failed an adequate trial of metoclopramide oral solution. Failure is defined as allergy to inactive ingredients, inability to administer the oral solution through an enteral route (such as nasogastric or percutaneous endoscopic gastrostomy routes), or intolerable side effects.
- Member does not have a history of tardive dyskinesia **AND**
- Member does not have moderate to severe liver disease (Child Pugh B or C) **AND**
- Member does not have moderate or severe renal impairment (creatinine clearance less than 60 mL/min) **AND**
- Member is not a known poor metabolizer of CYP2D6, which may contribute to a higher potential for metoclopramide toxicity, including dystonias.

GIMOTI (metoclopramide nasal spray) will not be approved as initial therapy for diabetic gastroparesis for members ≥ 65 years of age.

Members ≥ 65 years of age who meet the criteria above **AND** have been stabilized on an oral metoclopramide dose of 10mg four times a day for at least the past 30 days may receive approval to switch to GIMOTI nasal spray for up to 12 weeks total of metoclopramide therapy.

Members who are ≥ 65 years of age should avoid metoclopramide use (from all dosage forms and routes of administration) that exceeds 12 weeks.

Maximum Dose: one (15 mg) spray four times daily

Quantity Limit: one 10 mL bottle per 30 days, with lifetime maximum of three 10 mL bottles per member

Discussion

- S Klocke recommended adding “members who do not have Parkinson’s disease” to the criteria. S VanEyk and M Anguelov supported expanding that recommendation to “Member does not have a parkinsonian syndrome.”
- Motion made by A Shmerling to approve these criteria as amended, (1) to include “members who do not have a parkinsonian syndrome” and (2) remove the word “oral” x 2 from the third bullet point. Seconded by T Brubaker. Motion passed unanimously.

- **Pharmacy Claims System Edit for Concomitant Opioid and Oral MAT Buprenorphine-Containing Products**
  - J Taylor described a new proposed opioid policy to align with guidance from the Centers for Medicare and Medicaid Services (CMS) regarding state program monitoring of opioid use disorder drugs such as buprenorphine and naloxone that are dispensed concomitantly with an opioid.
  - A systems edit is being proposed to identify when a member has a current or recent prescription for a buprenorphine-containing product followed by an opioid claim.
  - The opioid claim will initially be denied, then allow pharmacists to place an override in the system that the member has been counseled, or the prescriber has been contacted, or several other possible interventions to allow the claim to be approved if it is appropriate.
  - Opioid pharmacy claims for members receiving an oral buprenorphine-containing medication indicated for the treatment of OUD will require entry of point-of-sale DUR service codes (Reason for Service, Professional Service, Result of Service) for override of a drug-drug interaction pop-up alert.
  - This systems edit is expected to go live in Colorado on 6/1/2021.

Discussion

- P Lanius asked about how pharmacists at the point of service will be educated about this upcoming change in claims adjudication and advocated for getting education out to pharmacies as soon as possible. J Taylor shared that information about this edit will be included in the May 2021 HCPF provider educational bulletin.
- P Lanius asked whether this proposed change was tied to any Colorado Board of Pharmacy requirements. J Taylor clarified that, for the scope of what is being proposed, these changes are based on federal guidance from CMS and not the State Board of Pharmacy.
- S Klocke asked if the Department is aware of how often concomitant use of buprenorphine and opioids occurs among its members, and also if this edit will flag all fills (new and refill) for members who use concomitant buprenorphine and opioid products. J Taylor clarified that the alert will fire each time there is an overlap, and that pharmacists may resolve the alerts at the point of sale rather than needing to make a phone call.
- Although a preliminary analysis was conducted earlier this year, detailed information regarding the specific number of Health First Colorado prescriptions that might be impacted by this change in the system was not readily retrievable during today's discussion.

10. Adjournment

L Claus reminded the Board that the next meeting is scheduled for Tuesday, August 10, from 1:00 to 5:00 pm on Zoom. Dr. Claus also reminded all Board members to delete the meeting binder immediately after adjournment.

R Page thanked all of the Board members for their insightful input during today's meeting.

S VanEyk once again welcomed the new members of the Board and thanked them for their active participation.

S VanEyk moved to adjourn the meeting, seconded by A Shmerling. Motion passed unanimously. The meeting was adjourned at 4:41 pm.

Minutes respectfully submitted by Julia Rawlings, PharmD