MINUTES OF THE QUARTERLY OPEN MEETING OF THE COLORADO MEDICAID DUR BOARD
Held Virtually on May 12, 2020 from 5-9PM

1. Call to Order
The meeting was officially called to order at 5:04 PM by M. Noonan

2. Roll Call
All present board members, HCPF staff, and CO-DUR team introduced themselves. New members (M. Anguelov and W. Lai) were identified. There were sufficient members for a quorum with six voting members participating. Quorum is five members.

a. **Members Present:**, Michael Noonan, MD (Chair); Gosia Thomas, PharmD (Vice-Chair); Scott VanEyk, MD; Allison Blackmer, PharmD; Mary Wilkerson, MD; Miroslav Anguelov, PharmD; William Lai, PharmD (Industry Representative)
b. **Members Absent:** Liza Wilson Clauz, PharmD; Alison Shmerling, MD
c. **Medicaid Pharmacy Staff:** Jeffrey Taylor, PharmD. DeAnn Roecker, PharmD
d. **CO-DUR Team**: Brandon Utter, PharmD. Robert Page, PharmD

3. Final Approval of Minutes from 2/11/20
M. Noonan asked if there were any changes with the minutes from the February 2020 DUR Board meeting. With no discussion, a motion to approve the minutes was made by L. Claus, seconded by M. Noonan. None opposed. Motion passed.

4. Department Updates
J. Taylor read the following rules for Board 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 disclose all relationships to pharmaceutical manufacturers.
DUR Board Conflicts of Interest: DUR Board Members must 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 themselves, they should not participate in the discussion of the agenda item or any vote regarding it.

B. Utter announced that he would accepting a new position but will transitioning/training new CO-DUR faculty liaison. He also the board to let J Taylor or R Page know about any potential Pain Management Specialist physician and highlighted that the next meeting and time.

J Taylor introduced the new personnel for HCPF and HCPF's policies during COVID.

B Utter discussed the policy and discrepancies with mass review topics.

R Page presented RDUR criteria/data and FDA updates.

B Utter presented an update on the Quarterly Module and Summary of PPI module and ongoing Gabapentin module.

J. Taylor reviewed prior authorization criteria implementations that differed from DUR Board recommendations from the November DUR Board Meeting.

B. Utter and R. Page proceeded to new business criteria proposals

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

Proposed Criteria

1. **Non-Opioid Analgesics**
   Preferred: Duloxetine 20mg/30mg/60mg
   Gabapentin
   Lidocaine patch (Rx)
   Pregabalin cap

Prior Authorization Criteria:

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 Lyrica (Failure is defined as lack of efficacy with 8 week trial, allergy, intolerable side effects, or significant drug-drug interaction) AND

Duloxetine (20mg, 30mg, or 60mg) will be approved for members with a diagnosis of fibromyalgia, neuropathic pain, or chronic musculoskeletal pain (e.g. osteoarthritis or chronic lower back pain) through automated verification (AutoPA) upon claim submission of the corresponding ICD-10 diagnosis code related to indicated use of the medication.

Prior authorization will be required for Lyrica 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: B. Boehner (industry representative) acknowledged a conflict of interest and Ryan Flugge, PharmD from Novo-Nordisk provided testimony on behalf of Novo Nordisk. No other Board members made disclosures. Motion was made to accept highlighted changes and consider expanding access to Tresiba for children by A. Blackmer, seconded by G. Thomas, motion passed.

2. Opioids –Long-Acting

Preferred: Butrans *BNR (buprenorphine patch)
Fentanyl 12mcg/25mcg/50mcg/75mcg/100mcg
Morphine ER
Tramadol ER
Embeda (morphine/naltrexone)

Prior Authorization Criteria:

Opioid Utilization Policy (long-acting and short-acting opioids):

It is highly encouraged that the healthcare team utilize the Prescription Drug Monitoring Program (PDMP) to aid in ensuring safe and efficacious therapy for members using controlled substances.

Total Morphine Milligram Equivalent Policy Effective 10/1/17:

- The maximum allowable morphine milligram equivalent (MME) is 200 MME. Prescriptions for short-acting (SA) and long-acting (LA) opioids are cumulatively included in this calculation. The prescription that exceeds the cumulative MME limit of 200 MME for a member will require prior authorization and may require a provider to provider telephone consultation with the pain management physician (free of charge and provided by Health First Colorado).
- Prior authorization will be granted to allow for tapering
- Prior authorization for 1 year will be granted for diagnosis of sickle cell anemia
- Prior authorization for 1 year will be granted for admission to or diagnosis of hospice or end of life care
- Prior authorization for 1 year will be granted for pain associated with cancer

MME calculation is conducted using conversion factors from the following website: http://agencymeddirectors.wa.gov/Calculator/DoseCalculator.htm

Only one long-acting opioid agent (including different strengths) and one short-acting opioid agent (including different strengths) will be considered for a prior authorization.

Medicaid provides guidance on the treatment of pain, including tapering, on our webpage under the heading Pain Management Resources and Opioid Use at:
https://www.colorado.gov/pacific/hcpf/pain-management-resources-and-opioid-use

Opioid Naïve Policy Effective 8/1/17 (Update effective 11/27/19 in Italics):

- Members who have not filled a prescription for an opioid within the past 180 days will be identified as "opioid treatment naïve" and have the following limitations placed on the initial prescription(s):
- The prescription is limited to short-acting opioid agents or Butrans (buprenorphine) 5mcg patch. Use of other long-acting opioid agents will require prior authorization approval for members identified as opioid treatment naïve.
- The days supply of the first, second, and third prescription for an opioid will be limited to 7 days, the quantity will be limited to 8 dosage forms per day (tablets, capsules), maximum #56 tablets/capsules for a 7 day supply
- The fourth prescription for an opioid will require prior authorization, filling further opioid prescriptions may require a clinical pharmacist review or provider to provider telephone consultation with a pain management physician (free of charge and provided by Health First Colorado).
- If a member has had an opioid prescription filled within the past 180 days, then this policy would not apply to that member and other opioid policies would apply as applicable.

Dental Prescriptions Opioid Policy Effective 11/15/18 (implemented in the claims system 01/07/19):

- Members who receive an opioid prescribed by a dental provider will be subject to day supply limits and quantity per day limits for short acting opioids.
- The prescription is limited to short-acting opioid agents only. Use of long-acting opioid agents and short acting fentanyl agents will require prior authorization approval for members' prescriptions written by a dental provider.
- The days supply of the first, second, and third prescription for an opioid will be limited to 4 days, the quantity will be limited to 6 dosage forms per day (tablets, capsules), maximum #24 tablets/capsules for a 4 day supply
- The fourth prescription for an opioid will require prior authorization. A prior authorization for the fourth fill may be approved for up to a 7 day supply and the quantity will be limited to 8 dosage forms per day (#56 tablets/capsules) for members with any of the following diagnoses/undergoing any of the following procedures:
    - Traumatic oro-facial tissue injury with major mandibular/maxillary surgical procedures
    - Severe cellulitis of facial planes
    - Severely impacted teeth with facial space infection necessitating surgical management
- Other potential exemptions that exceed the first 3 fill limits (day supply and quantity) may be evaluated with a provider to provider telephone consult with a pain management specialist (free of charge and provided by Health First Colorado)

If a member has had an opioid prescription prescribed by a non-dental provider, then this policy would not apply to that member and other opioid policies would apply as applicable. Dental prescriptions do not impact the opioid treatment naïve policy, but the prescriptions will be counted towards the Morphine Milligram Equivalent (MME) daily dose.

Opioid and Benzodiazepine Combination Effective 9/15/19:
Prior authorization will be required for members receiving long-term therapy with an opioid medication who are newly started on a benzodiazepine medication OR for members receiving long-term therapy with a benzodiazepine medication who are newly started on an opioid medication. Prior authorization may be approved if meeting the following:

- The member discontinued or is no longer taking either the opioid or benzodiazepine medication and will not be using these in combination OR
- The member will not be taking the prescribed opioid and benzodiazepine medications at the same time based on prescribed dosing interval(such as prn administration) for the regimen AND the prescriber attests that the member has received appropriate counseling* regarding the risks associated with combining opioid and benzodiazepine medications including increased risk for sedation, respiratory depression, overdose, and overdose-related death and counseling regarding the FDA Boxed Warning for combining these medications OR
- The prescriber has evaluated the regimen and attests that it is appropriate for the member to continue use of the concomitant opioid and benzodiazepine medication regimen as prescribed AND the prescriber attests that the member has received appropriate counseling* regarding the risks associated with combining opioid and benzodiazepine medications including increased risk for sedation, respiratory depression, overdose, and overdose-related death and counseling regarding the FDA Boxed Warning for combining these medications OR
- Prior authorization may be approved for members receiving palliative or hospice care OR
- For benzodiazepine prior authorizations, approval may be granted if the benzodiazepine is being prescribed for seizure disorder or convulsions.

*If counseling has not been provided, the prescriber attests that a reasonable effort will be made to contact the member or the member's pharmacy to ensure that counseling is provided.

Opioid and Quetiapine Combination Effective 9/15/19:
Pharmacy claims for members receiving opioid and quetiapine medications in combination will require entry of point-of-sale DUR service codes (Reason for Service, Professional Service, Result of Service) for override of drug-drug interaction (DD) related to risk of increased sedation from concomitant use of this drug combination.

Long-Acting Opioids:
*Nucynta ER or Oxycontin (oxycodone ER) will be approved for members who have trialed and failed‡ treatment with TWO preferred agents in the last 6 months.

Non-Preferred Agents:
All non-preferred abuse-deterrent formulations (OxyContin®, Xtampza®ER, Hysingla®ER, etc) will require trial and failure‡ of three preferred agents within the past year.

All other non-preferred agents may be approved for members who have trialed and failed‡ three preferred products within the past year.

‡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 one strength) or 30 patches for 30 days (taking 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 desired dose (i.e. 12mcg/hr + 50mcg/hr =62mcg/hr)

Discussion: No other Board members made disclosures. Motion was made by M Wilkerson to accept as written, seconded by S. VanEyk, motion passed.

3. **Opioids –Short-Acting**

Preferred: **Codeine/APAP tab
Hydrocodone/APAP soln/tab
Hydromorphone tab
Morphine tab/soln
Oxycodone tab/soln
Oxycodone/APAP tab
*Tramadol 50mg
*Tramadol/APAP tab
Hydrocodone/ibuprofen

Prior Authorization Criteria:

Preferred codeine and tramadol products are available without prior authorization for adult (18 years or greater) members if meeting all other opioid policy.

Members 17 years of age or under being prescribed any tramadol or codeine products must meet the following criteria:

*Tramadol and tramadol-containing products will require prior authorization approval for members < 18 years of age to verify that the following criteria are met:

Non-preferred tramadol products will require trial/failure of generic tramadol 50mg tablet AND generic tramadol/APAP tablet. Failure is defined as allergy‡, lack of efficacy, intolerable side effects, or significant drug-drug interaction.

- Member is ≥ 12 years of age AND
    - If member is less than 18 years of age Tramadol is NOT being prescribed for post-surgical pain following tonsil or adenoid procedure AND
    - If member is ≥ 12 years of age between 12 and 18 years of age Member is not obese (BMI greater than 30kg/m2), does not have obstructive sleep apnea or severe lung disease AND
- For members <12 years of age with complex conditions or life-limiting illness who is receiving care under a pediatric specialist, tramadol and tramadol-containing products may be approved on a case-by-case basis

Rybix® ODT (tramadol hydrochloride) will be approved without trial/failure of three preferred agents for members who meet the tramadol products criteria above AND who are unable to swallow oral tablets or absorb oral medications.

**Codeine and codeine-containing products will require prior authorization approval for members < 18 years of age to verify that the following criteria are met:

- Member is ≥ 12 years of age AND
- If member is less than 18 years of age, codeine is NOT being prescribed for post-surgical pain following tonsil or adenoid procedure AND
- If member is between 12 and 18 years of age, member is not obese (BMI greater than 30kg/m2), does not have obstructive sleep apnea or severe lung disease
- 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.g, erythmromycin, 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 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."

Maximum Doses:
*Tramadol maximum dose is 400mg/day
**Codeine maximum dose is 360mg/day

***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).

Prior authorization for all other non-preferred short-acting opioid products will be approved if the member has trialed/failed three preferred products. Failure is defined as allergy‡, or significant adverse drug reaction.

‡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).

Butorphanol intranasal maximum quantity is 10ml per 30 days (four 2.5ml 10mg/ml package units per 30 days).

Fentanyl buccal, intranasal, transmucosal, and sublingual products:

Prior authorization approval will 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 made disclosures and no testimony was provided for this class. Discussion was had by A Blackmer regarding the age requirement for tramadol and that the drug is highly used particularly in children with complex medical conditions. Additionally, the recommendation was to add "under the supervision of a pediatric specialist." Motion was made to accept highlighted changes by G Thomas, seconded by M Wilkerson, motion passed.

4. Tetracyclines

Preferred: Doxycycline Hyclate cap/tab
Doxycycline Monohydrate 50mg/100mg cap
Doxycycline Monohydrate tab
Minocycline cap

Prior Authorization Criteria (short-acting opioids):

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

Prior authorization for liquid oral tetracycline formulations will 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/failed a preferred doxycycline product AND a preferred minocycline tablet OR clinical rationale 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 made disclosures and no testimony was provided for this class. Motion was made to accept criteria as written by M Wilkerson and seconded by M Anguelov. The motion passed unanimously.

5. Angiotensin Modulators

Preferred: Amlodipine/Olmesartan
Amlodipine/Valsartan
Benazepril
Benicar (olmesartan)
Enalapril
Enalapril/HCTZ
Fosinopril
Irbesartan
Irbesartan/HCTZ
Lisinopril

Lisinopril/HCTZ
Losartan
Losartan/HCTZ
Olmesartan
Olmesartan/HCTZ
Quinapril
Ramipril
Telmisartan
Valsartan
Valsartan/HCTZ

Prior Authorization Criteria:

Angiotensin-converting enzyme inhibitors (ACE Inh):
Non-preferred ACE inhibitors, ACE inhibitor combinations, ARBs, ARB combinations, renin inhibitors, and renin inhibitor combination products will be approved for members who have trialed and failed treatment with three preferred products in the last 12 months (Failure is defined as lack of efficacy with a 4 week trial, allergy, intolerable side effects, or significant drug-drug interaction).

*Epaned (enalapril) powder will be approved without trial/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/or failed Epaned. (Failure is defined as lack of efficacy with a 4 week trial, allergy, intolerable side effects, or significant drug-drug interaction).

ACE Inh Combinations:
Non-preferred ACE inhibitors, ACE inhibitor combinations, ARBs, ARB combinations, renin inhibitors, and renin inhibitor combination products will be approved for members who have trialed and failed treatment with three preferred products in the last 12 months (Failure is defined as lack of efficacy with a 4 week trial, allergy, intolerable side effects, or significant drug-drug interaction).

Angiotensin II Receptor Blockers (ARBs):
Non-preferred ACE inhibitors, ACE inhibitor combinations, ARBs, ARB combinations, renin inhibitors, and renin inhibitor combination products will be approved for members who have trialed and failed treatment with three preferred products in the last 12 months (Failure is defined as lack of efficacy with a 4 week trial, allergy, intolerable side effects, or significant drug-drug interaction).

ARB Combinations:
Non-preferred ACE inhibitors, ACE inhibitor combinations, ARBs, ARB combinations, renin inhibitors, and renin inhibitor combination products will be approved for members who have trialed and failed treatment with three preferred products in the last 12 months (Failure is defined as lack of efficacy with a 4-week trial, allergy, intolerable side effects, or significant drug-drug interactions).

Renin Inhibitors and Renin Inhibitor Combinations:
Non-preferred renin inhibitors and renin inhibitor combination products will be approved for members who have failed treatment with three preferred products from angiotensin modulator class in the last 12 months (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 made disclosures and no testimony was provided for this class. M Thomas highlighted to add angiotensin modulator class to make the criteria more understandable. Motion was made to accept criteria with changes by M Anguelov and seconded by G. Thomas. The motion passed unanimously.

6. Acne Agents

Preferred:

Topical:
- Adapalene gel
- Adapalene/Benzoyl Peroxide gel
- Clindamycin Phosphate swab/soln
- Clindamycin/Benzoyl Peroxide gel (generic Duac)
- Clindamycin/Benzoyl Peroxide jar (generic Benzaclin)
- Differin pump (Rx)
- Erythromycin soln
- Sodium sulfacetamide/sulfur cleanser, wash
- Sulfacetamide susp
- Tretinoin cream/gel
- Retin-A cream *BNR

Oral:
- Amnesteem
- Claravis

Prior Authorization Criteria:

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

Preferred topical acne agents prescribed for members > 25 years of age will require prior authorization and 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.

Preferred topical acne agents prescribed for members ≤ 25 years of age will may only be approved for members with 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.

In addition to the above criteria, preferred topical clindamycin and erythromycin products prescribed for members ≤ 25 may also be approved for a diagnosis of folliculitis, hidradenitis suppurativa, or perioral dermatitis (erythromycin only). Approval of preferred topical clindamycin and erythromycin products for other medically accepted indications for members ≤ 25 may be considered following clinical prior authorization review by a call center pharmacist.

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

- Member has trialed/failed three preferred topical products with different mechanisms (i.e. 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.

All preferred and non-preferred oral isotretinoin agents will require prior authorization and will may be approved for severe, recalcitrant nodulocystic acne for adults and children ≥ 12 years of age and has been unresponsive to conventional therapy AND

Non-preferred oral isotretinoin agents will may be approved if member has trialed/failed two preferred agents. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.

Discussion: No Board members made disclosures and no testimony was provided for this class. Motion was made to accept criteria as written by M Anguelov and seconded by M Wilkerson. The motion passed unanimously.

7. Androgenic Agents

Preferred: Androderm patch
Testosterone 1% pump (generic Androgel)
Testosterone 1.62% packet (generic Androgel)
Testosterone gel pump (generic Axiron)
Testosterone gel (generic Fortesta)
Testosterone gel (generic Testim)
Testosterone 50mg/5g tube (generic Vogelxo)
Testosterone Cypionate vial

Prior Authorization Criteria:

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

Preferred androgenic drugs will be approved for members meeting the following:

1. Male patient > 16 years of age, or if onset of primary hypogonadism is prior to this age, 12 years of age and older AND
2. Has a documented diagnosis of hypogonadotropic or primary hypogonadism (Patients with other diagnoses will require a manual review) AND

3. Has two documented low serum testosterone levels below the lower limit of normal range for testing laboratory prior to initiation of therapy AND
4. Does not have a diagnosis of breast or prostate cancer AND
5. Does not have a palpable prostate nodule or prostate-specific antigen (PSA) > 4ng/mL (not required for members less than 18 years of age) AND
6. Has normal liver function tests prior to initiation of therapy, or documentation that benefit outweighs risk if member has elevated LFTs

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 normal liver function tests prior to initiation of therapy

*Testosterone 1.62% packet (generic Androgel®) is a preferred agent for gender transition/affirmation and is non-preferred for all other indications.

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.

Reauthorization Criteria (for Hypogonadism diagnoses):

Members may continue to receive preferred agents without requirement of updated low serum testosterone laboratory testing that meet the following criteria:

- Male patient > 16 years of age , or if onset of primary hypogonadism is prior to this age, 12 years of age and older AND
- Has at least one past documented low serum testosterone levels below the lower limit of normal range for testing laboratory prior to initiation of therapy AND
- Has documented diagnosis of hypogonadotropic or primary hypogonadism AND
- Does not have a diagnosis of breast or prostate cancer AND
- Does not have a palpable prostate nodule or prostate-specific antigen (PSA) > 4ng/mL (not required for members less than 18 years of age)AND
- Has normal liver function tests prior to initiation of therapy or documentation that benefit outweighs risk if member has elevated LFTs

Discussion: No Board members made disclosures and no testimony was provided for this class. A Blackmer provided feedback from the pediatricians at Children's that there is no need for breast exam and PSA when used in children. Also, she recommended adding "onset of primary hypogonadism is prior to this age, 12 years of age and older" to the criteria. Motion was made to accept criteria with changes by A Blackmer and seconded by M Wilkerson. The motion passed unanimously.

8. Respiratory Inhalants

Preferred:

Inhaled Anticholinergics:
- Atrovent HFA
- Ipratropium soln (generic Atrovent)
- Spiriva Handihaler

Inhaled Anticholinergic Combinations:
- Albuterol/Ipratropium soln
- Bevespi Aerosphere (glycopyrrolate/formoterol)
- Combivent Respimat (ipratropium/albuterol)

Inhaled Beta Agonists – Short-Acting
- Albuterol soln
- ProAir HFA *BNR
- Proventil *BNR
- Ventolin *BNR

Inhaled Beta Agonists – Long-Acting
- Serevent Diskus

Inhaled Corticosteroids
- Asmanex (mometasone)
- Budesonide respules
- Flovent Diskus (fluticasone propionate)
- Flovent HFA (fluticasone propionate)
- Pulmicort Flexhaler (budesonide)

Inhaled Corticosteroid Combinations
- Adviar Diskus *BNR (fluticasone/salmeterol)
- Advair HFA *BNR (fluticasone/salmeterol)
- Dulera (mometasone/formoterol)
- Symbicort (budesonide/formoterol)

Prior Authorization Criteria:

Inhaled Anticholinergics:

Non-preferred single agent anticholinergic agents will 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® will be approved for members with a diagnosis of asthma who have trialed and failed‡ treatment with three preferred inhaled corticosteroids, at least two of the trials must be preferred combination inhaled corticosteroid products. Members with a diagnosis of COPD must meet non-preferred criteria for single agent inhaled anticholinergics listed above for approval of Spiriva Respimat®.

Lonhala Magnair® will receive prior authorization approval 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.

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

Inhaled Anticholinergic Combinations:
Bevespi aerospere (glycopyrrolate/formoterol) will be available for members with a diagnosis of COPD including chronic bronchitis and/or emphysema.

Non-preferred combination anticholinergic agents will be approved for members with a diagnosis of COPD including chronic bronchitis and/or emphysema who have trialed and failed‡ treatment with two preferred anticholinergic combination agents respiratory agents, one of which must be Spiriva Handihaler®. 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.

Inhaled Beta2 Agonists (short-acting):
Non-preferred, short acting beta2 agonists will 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.

Proair HFA, Proventil HFA, Ventolin HFA: Quantity limits: 2 inhalers / 30 days

Inhaled Beta2 Agonists (Long-acting):
SEREVENT ® will be approved for members with moderate to very severe COPD.

Non-preferred agents will 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.

**For treatment of members with diagnosis of asthma needing add-on therapy, please refer to preferred agents in combination Long-Acting Beta Agonist/Inhaled Corticosteroid. SEREVENT will not be approved for treatment of asthma in members needing add-on therapy due to safety risks associated with monotherapy.

Inhaled Corticosteroids:
Pulmicort (Budesonide) nebulizer solution will only be approved for a maximal dose of 2mg/day.

Pulmicort Flexhaler will only be approved for female members with asthma who have a new diagnosis of pregnancy.

Non-preferred inhaled corticosteroids will 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.)

Inhaled Corticosteroid Combination:
Non-preferred inhaled corticosteroid combinations will 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 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.

Discussion: No Board members made disclosures and no testimony was provided for this class. M Wilkerson stated that the number of Proair inhalers per month was high. She made the recommendation that quanity limits should change to 2 inhalers per 30 days. Motion was made to accept criteria with changes by M Wilkerson and seconded by S VanEyk. The motion passed unanimously.

9. Skeletal Muscle Relaxants –mass reviewed

Preferred: Baclofen
Cyclobenzaprine 5mg/10mg tab
Methocarbamol
Tizanidine 2mg/4mg tab

Prior Authorization Criteria:

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 to, 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, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions.)

‡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 made disclosures and no testimony was provided for this class. Motion was made to accept criteria as written by M Wilkerson and seconded by G Thomas. The motion passed unanimously.

10. Rosacea Agents, Topical – mass reviewed

Preferred: Azelaic Acid gel
Metronidazole cream/gel/lotion

Prior Authorization Criteria:

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) may be approved if the member meets all of the following criteria:

- 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
- Member is ≥ 18 years of age and has been diagnosed with rosacea with inflammatory lesions

Discussion: No Board members made disclosures. Motion was made to accept criteria as written by M Wilkerson and seconded by G Thomas. The motion passed unanimously.

11. Antihistamines, Newer Generation and Combinations – mass reviewed

Preferred: Cetirizine 5mg/10mg tab (OTC)
Cetirizine soln (OTC, Rx)
Levocetirizine tab (OTC, Rx)
Loratadine tab/soln (OTC)

Prior Authorization Criteria:
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.

Non-preferred antihistamines and antihistamine/decongestant combinations will 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, allergy, intolerable side effects, or significant drug-drug interaction.

Discussion: No Board members made disclosures and no testimony was provided for this class. Motion was made to accept criteria as written by M Wilkerson and seconded by S VanEyk. The motion passed unanimously.

12. Topical Immunomodulators

Preferred: Pimecrolimus (authorized generic Elidel)
Protopic *BNR
Elidel cream (tacrolimus)

Prior Authorization Criteria:

Manual prior authorization review for preferred and non-preferred agents will be required for members exceeding >6 weeks of continuous therapy.

Preferred topical immunomodulator products may be approved following adequate trial and failure‡ of a prescription topical corticosteroid (verified in claims history).

Non-preferred topical immunomodulator products may be approved following adequate trial and failure‡ of one prescription topical corticosteroid AND one 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 made disclosures. Motion was made to accept criteria as written by M Wilkerson and seconded by S VanEyk. The motion passed unanimously.

Discussion: No Board members made disclosures and no testimony was provided for this class. Motion was made to accept criteria as written by S. VanEyk and seconded by A Blackmer. The motion passed unanimously.

13. Phosphate Binders

Preferred: Calcium acetate cap
Phoslyra (calcium acetate)
Fosrenal chew (lanthanum)
Sevelamer HCL tab (authorized generic Renagel)
Renagel (savelamer) BNR
*Sevelamer carbonate

Prior Authorization Criteria:
*Sevelamer carbonate tablet may be approved as a preferred agent for children and adolescents 6-17 years of age. For adults ≥ 18 years of age, sevelamer carbonate tablet may be approved if member meets criteria for non-preferred products listed below.

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

Prior authorization for non-preferred products in this class may be approved if member meets all of 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‡ two one preferred agent.
- Lanthanum products require trial and failure‡ of a preferred savelamer product. s. One trial must be from the same pharmacologic class as the non-preferred agent being requested, if applicable (for example; member is requesting Phoslo® must have trial with Phoslyra® or generic calcium acetate).

Auryxia®(ferric citrate) may be approved if the member meets all of 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 tablet, chewable) 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 3000mg daily

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

Discussion: No Board members made disclosures and no testimony was provided for this class. Motion was made to accept criteria as written by M Anguelov and seconded by M Wilkerson. The motion passed unanimously.

14. Benign Prostatic Hypertrophy (BPH) Agents – mass reviewed

Preferred: Alfuzosin
Doxazosin
Dutasteride
Finasteride
Tamsulosin
Terazosin

Prior Authorization Criteria:

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. Doses exceeding 5mg per day of Cialis will not be approved.

Discussion: No Board members made disclosures and no testimony was provided for this class. Motion was made to accept criteria as written by M Wilkerson and seconded by G Thomas. The motion passed unanimously.

15. Nayzilam (midazolam)

Nayzilam (midazolam) may be approved if member meets all of the following criteria:

- Member is 12 years of age or older AND
- Nayzilam is being prescribed for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern and medical records are provided supporting this diagnosis AND
- Member is stable on regimen of antiepileptic medications AND
- Medication is being prescribed by or in conjunction with the same provider/provider team who manages the member's anti-epileptic regimen AND
- Has trial and/or failure of midazolam vial for emergency use (Failure is defined as:, allergy to formulation, intolerable side effects or significant drug-drug interactions)
- Member is educated on appropriate identification of seizure cluster and Nayzilam administration, member should not exceed 2 doses per seizure cluster AND
- Members who are confined to wheelchairs or experiencing severe mobility issues may receive Nayzilam without previous midazolam formulation trial

  Maximum dose: Nayzilam 4 nasal spray units per year unless used / damaged / lost

Grandfathering: if member is receiving Nayzilam, they may continue to receive authorization.

Discussion: No Board members made disclosures. Presentations were provided by S Klein with Epilepsy Foundation regarding the need for open access for both Nayzilam/Valtoco due to the need for a nasal preparation due to issues with atomizer availability and rectal administration. B Yeager from UCB pharmaceuticals also provided testimony. Discussion was had by the board regarding the need for these products and to minimize access. S VanEyk recommended to remove the need for a trial and failure of midazolam vial first. Motion was made to accept criteria with amended changes by M Wilkerson and seconded by S VanEyk. The motion passed unanimously.

16. Valtoco (diazepam)

Valtoco (diazepam) may be approved if member meets all of the following criteria:

- Member is 6 years of age or older AND
- Valtoco is being prescribed for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern and medical records are provided supporting this diagnosis AND
- Member is stable on regimen of antiepileptic medications AND
- Medication is being prescribed by or in conjunction with the same provider/provider team who manages the member's anti-epileptic regimen AND
- Has trial and/or failure of diazepam or midazolam vial for emergency use (Failure is defined as:, allergy to formulation, intolerable side effects or significant drug-drug interactions) AND
- Member is educated on appropriate identification of seizure cluster and Valtoco administration, member should not exceed 2 doses per seizure cluster AND
- Members who are confined to wheelchairs or experiencing severe mobility issues may receive Valtoco without previous diazepam or midazolam formulation trial

Maximum dose: Valtoco 4 nasal spray units per year unless used / damaged / lost

Grandfathering: if member is receiving Valtoco, they may continue to receive authorization.

Discussion: No Board members made disclosures. Presentations were provided by C Hartsfield from Neuralis. M Noonan made a motion to change the criteria to reflect that of Nayzilam. Motion was seconded by S VanEyk. The motion passed unanimously.

17. Dupixent (dupilumab) (to be updated on Appendix P)

Dupixent® (dupilumab) maybe approved if the following criteria are met:

Atopic Dermatitis:

- Member is 12 years of age or older AND
- Member has a diagnosis of moderate to severe chronic atopic dermatitis AND
- Member has been educated by provider regarding the elimination of exacerbating factors including aeroallergens, food allergens, and contact allergens AND
- Member has been educated by provider regarding the appropriate use of emollients and moisturizers for promotion of skin hydration AND
- Member has baseline Investigator Global Assessment (IGA) score for atopic dermatitis severity of at least 3 (Scored 0-4, 4 being most severe) OR moderate erythema and moderate papulation/infiltration AND
- Member has trialed and failed‡ the following agents:
    - Two one medium potency to very-high potency topical corticosteroid [such as mometasone furoate, betamethasone dipropionate, or fluocinonide (see PDL for list of preferred products)] AND
    - Two one preferred topical calcineurin inhibitors, such as pimecrolimus AND tacrolimus (see PDL for list of preferred products)

  AND
- Must be prescribed by or in conjunction with a dermatologist, allergist/immunologist, or rheumatologist AND
- Initial authorization will be for 18 weeks. Continuation will be authorized for 12 months with prescriber attestation to 16-week IGA score showing improvement by at least 2 points OR clinically significant improvement with Dupixent® regimen.

Asthma:

- Member is 12 years of age or older AND
- Member has a diagnosis of moderate to severe asthma (on medium to high dose inhaled corticosteroid and a long-acting beta agonist) with eosinophilic phenotype OR oral corticosteroid dependent asthma AND
- Member has had at least one asthma exacerbation in the past year requiring systemic corticosteroids or emergency department visit or hospitalization OR dependence on daily oral corticosteroid therapy PLUS regular use of high dose inhaled corticosteroid PLUS an additional controller medication AND
- Medication is being prescribed as add-on therapy to existing regimen AND
- Medication is being prescribed by or in conjunction with a rheumatologist, allergist, or pulmonologist AND
- For indication of moderate to severe asthma with eosinophilic phenotype:
    - baseline lung function (FEV1) is provided and baseline eosinophils are greater than 300 cells/mcL AND
    - Initial authorization will be for 12 weeks. Continued authorization will require prescriber attestation of improvement in FEV1of 25% from baseline and will be for 12 months
- For indication of oral corticosteroid dependent asthma:
    - Dosing of the oral corticosteroid is provided AND

  - Initial authorization will be 24 weeks. Continued authorization will require prescriber attestation of a reduction of oral corticosteroid by at least 50% and will be for 12 months

Chronic rhinosinusitis with nasal polyposis:

- If member has diagnosis of asthma or atopic dermatitis, they must meet listed criteria for that indication
- Member is 18 years of age or older AND
- Medication is being prescribed as an add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP) AND
- Member must have a baseline bilateral endoscopic nasal polyps score (NPS; scale 0-8) AND nasal congestion/obstruction score (NC; scale 0-3) averaged over 28-day period AND
- Member must have trial and failure‡ of three intranasal corticosteroids (see PDL Class) AND
- Medication is being prescribed by or in conjunction with a rheumatologist, allergist, ear/nose/throat specialist or pulmonologist AND
- Dose of Dupixent 300mg every 2 weeks is used AND
- Initial authorization will be for 24 weeks, for additional approval member must meet the following criteria:
  - NC and NPS scores are provided and show a 20% reduction in symptoms AND
  - Member continues to use primary therapies such as intranasal corticosteroids

Dupixent® quantity limit: 2 syringes every 28 days after initial 14 days of therapy (first dose is twice the regular scheduled dose)

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

Discussion: No Board members made disclosures and no testimony was provided for this medication. Motion was made to accept criteria with as written M Wilkerson and seconded by M Anguelov. The motion passed unanimously.

18. Soliris (eculizumab) (to be added to Appendix P)

Soliris (ecluizumab) will be approved if member meets all of the following criteria:

- Medication is being administered in the member's home or in a long-term care facility by a healthcare professional AND
- Member is diagnosed with either Paroxysmal Nocturnal Hemoglobinuria (PNH), Atypical Hemolytic Uremic Syndrome (aHUS), Generalized Mysthenia Gravis (gMG), or Neuromyleitis Optica Spectrum Disorder (NMOSD) AND
- Member does not have a systemic infection AND
- Member must be administered a meningococcal vaccine at least two weeks prior to initiation of Soliris therapy and revaccinated according to current medical guidelines for vaccine use AND
- Prescriber is enrolled in the Soliris Risk Evaluation and Mitigation Strategy (REMS) program AND
- Medication is prescribed by or in conjunction with a hematologist for PNH and by or in conjunction with a hematologist or nephrologist for aHUS and by or in conjunction with a neurologist for gMG or NMOSD
- And member meets all of the specific criteria below based on diagnosis

Paroxysmal Nocturnal Hemoglobinuria

- Member is 18 years of age or older AND
- Diagnosis of PHN must be accompanied by detection of PNH clones by flow cytometry diagnostic testing AND
- Member demonstrate the presence of at least 2 different glycosylphosphatidylinositol (GPI) protein deficiencies (e.g. CD55, CD59, etc.) within at least 2 different cell lines (granulocytes, monocytes, erythrocytes); AND
- Member has one of the following indications for therapy:
    - Presence of a thrombotic event
    - Presence of organ damage secondary to chronic hemolysis
    - Patient is pregnant and potential benefit outweighs potential fetal risk
    - Patient is transfusion dependent
    - Patient has high LDH activity (defined as ≥1.5 x ULN) with clinical symptoms AND
- Member has documented baseline values for one or more of the following:
    - Serum lactate dehydrogenase (LDH)
    - Hemoglobin level
    - Packed RBC transfusion requirement

Atypical Hemolytic Uremic Syndrome

- Member is 2 months or older AND
- Thrombotic Thrombocytopenic Purpura (TTP) has been ruled out by evaluating ADAMTS13 level (ADAMTS-13 activity level > 10%); AND

- Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS) has been ruled out; AND
- Other causes have been ruled out such as coexisting diseases or conditions (e.g. bone marrow transplantation, solid organ transplantation, malignancy, autoimmune disorder, drug-induced, malignant hypertension, HIV infection, etc.), Streptococcus pneumonia or Influenza A (H1N1) infection, or cobalamin deficiency AND
- Documented baseline values for one or more of the following:
  - Serum lactate dehydrogenase (LDH)
  - Serum creatinine/eGFR
  - Platelet count
  - Plasma exchange/infusion requirement

Generalized Myasthenia Gravis

- Member is 18 years or older AND
- Patient has Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of Class II to IV disease; AND
- Patient has a positive serologic test for anti-acetylcholine receptor (AchR) antibodies; AND
- Physician has assessed the baseline Quantitative Myasthenia Gravis (QMG) score; AND
- Patient has a MG-Activities of Daily Living (MG-ADL) total score of ≥6; AND
- Patient has failed treatment over at least 1 year with at least 2 immunosuppressive therapies (e.g. azathioprine, cyclosporine, mycophenolate, etc), or has failed at least 1 immunosuppressive therapy and required chronic plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIG)

Neuromyelitis Optica Spectrum Disorder

- Member is 18 years or older AND
- Member has a past medical history of one of the following:
  - Optic neuritis
  - Acute myelitis
  - Area postrema syndrome; episode of otherwise unexplained hiccups or nausea and vomiting
  - Acute brainstem syndrome
  - Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions
  - Symptomatic cerebral syndrome with NMOSD-typical brain lesions; AND
- Member has a positive serologic test for anti-aquaporin-4 immunoglobulin G (AQP4-IgG)/NMP-IgG antibodies; AND
- Diagnosis of multiple sclerosis or other diagnoses have been ruled out AND
- Member has not failed a previous course of Soliris therapy AND
- Member has a history of failure, contraindication, or intolerance to rituximab therapy AND
- Member has at least one of the following:

  - History of at least two relapses during the previous 12 months prior to initiating Soliris
  - History of at least three relapses during the previous 24 months, at least one relapse occurring within the past 12 months prior to initiating Soliris AND
- Member is not receiving Soliris in combination with any of the following:
  - Disease modifying therapies for the treatment of multiple sclerosis (e.g. Gilenya (fingolimod), Tecfidera (dimethyl fumarate), Ocrevus (ocrelizumab), etc.)
  - Anti-IL6 therapy

Maximum dose: Soliris 900mg weekly for 4 weeks induction, followed by 1200mg every 2 weeks maintenance dose

Discussion: No Board members made disclosures and no testimony was provided for this medication. Motion was made to accept criteria with as written M Wilkerson and seconded by A Blackmer. The motion passed unanimously.

19. Ergomar (ergotamine) (to be added to Appendix P)

Ergomar may be approved if member meets all of the following criteria:

- Ergomar is being prescribed to prevent or treat vascular headache (migraine, migraine variants or so-called "histaminic cephalalgia") AND
- Member has a negative pregnancy test within 30 days of receipt of Ergomar AND
- Member is not taking a potent CYP 3A4 inhibitor (ritonavir, nelfinavir, indinavir, erythromycin, clarithromycin and troleandomycin) AND
- Member has adequate trial and/or failure of 2 triptan agents (see PDL class) AND
- Member has adequate trial and/or failure of 2 NSAIDs (see PDL class) AND
- Member has adequate trial and/or failure of dihydroergotamine vial
  (Failure is defined as lack of efficacy with 10 day trial, allergy, intolerable side effects or significant drug-drug interactions)
  AND
  Maximum quantity: Ergomar #20 tablets per 28 days (40mg per 28 days)

Discussion: No Board members made disclosures and no testimony was provided for this medication. Motion was made to accept criteria with as written M Anguelov and seconded by S VanEyk. The motion passed unanimously.

20. Migergot (ergotamine/caffeine) suppository (to be added to Appendix P)

Migergot may be approved if member meets the following criteria:

- Migergot is being prescribed to prevent or treat vascular headache (migraine, migraine variants or so-called "histaminic cephalalgia") AND
- Member has a negative pregnancy test within 30 days of receipt of Ergomar AND
- Member is not taking a potent CYP 3A4 inhibitor (ritonavir, nelfinavir, indinavir, erythromycin, clarithromycin and troleandomycin) AND

- Member has adequate trial and/or failure of 2 triptan agents (see PDL class) AND
- Member has adequate trial and/or failure of 2 NSAIDs (see PDL class) AND
- Member has adequate trial and/or failure of dihydroergotamine vial
  (Failure is defined as lack of efficacy with 10 day trial, allergy, intolerable side effects or significant drug-drug interactions)
  AND
  Maximum quantity: Migergot #20 suppositories per 28 days

Discussion: No Board members made disclosures and no testimony was provided for this medication. Motion was made to accept criteria with as written by M Wilkerson and seconded by S VanEyk. The motion passed unanimously.

21. Thiola EC (tiopronin) (to be added to Appendix P)

Thiola EC may be approved if member meets all of the following criteria:

- Member is an adult or pediatric weighing 20kg or more AND
- Member has severe homozygous cystinuria AND
- Member has increased fluid intake and diet modifications have been implemented for the prevention of cysteine stone formation AND
- Member has trial and failure of urinary alkalization agent (such as potassium citrate or potassium bicarbonate) AND
- Member has trial and failure of Thiola IR (tiopronin) AND
  (Failure is defined as lack of efficacy with 14 day trial, allergy, intolerable side effects or significant drug-drug interactions)

Maximum dose: Thiola EC 1500mg per day

Discussion: No Board members made disclosures and no testimony was provided for this medication. Motion was made to accept criteria with as written by M Wilkerson and seconded by G Thomas. The motion passed unanimously.

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

22. Ultomiris (ravulizumab)

Ultomiris may be approved if member meets all of the following criteria:

- 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 either paroxysmal nocturnal hemoglobinuria (PNH) OR atypical hemolytic uremic syndrome (aHUS)

Maximum dose: Ultomiris 3.6g every 8 weeks (IV infusion)

23. Revcovi (elapegademase-lvlr)

Revcovi may be approved if member meets all of the following criteria:

- Member has diagnosis of adenosine deaminase severe combined immune deficiency (ADA-SCID)

Maximum dose: Revcovi 0.4mg/kg per week (based on ideal body weight, IM administration)

24. Lumizyme (alglucosidase alfa)

Lumizyme may be approved if member meets all of the following criteria:

- Medication is being administered in the member's home or in a long-term care facility by a healthcare professional AND
- Member has diagnosis of Pompe disease (acid α-glucosidase [GAA] deficiency)

Maximum dose: Lumizyme 20mg/kg every 2 weeks (IV Infusion)

25. Adakveo (crizanlizumab-tmca)

Adakveo may be approved if member meets all of the following criteria:

- Medication is being administered in the member's home or in a long-term care facility by a healthcare professional AND
- Medication is being used to reduce the frequency of vasoocclusive crises (VOCs) in adults and pediatric patients aged 16 years and older with sickle cell disease.

Maximum dose: Adakveo 5mg/kg every 2 weeks (IV Infusion)

Discussion: No Board members made disclosures. Testimony was provided by J Hardisty from Novartis. Motion was made to accept criteria for Adakveo, Revocoi, Lumizyme, and Ultomiris as written by M Wilkerson and seconded by G Thomas. The motion passed unanimously.

With no other new business to discussion, the meeting ended at 9:02 PM. The motion was made by M Noonan and seconded by G Thomas.