Department of Vermont Health Access
Pharmacy Benefits Management Program
DUR Board Meeting
Draft Minutes

October 24, 2023: 5:00 – 8:30 p.m.

Board Members Present:

	Andy Miller, RPH		**Katharina Cahill, PharmD**		**Margot Kagan, PharmD**
	Bram Starr, MD		**Annie Daly, PharmD**		**Lucy Miller, MD**
	Douglas Franzoni, PharmD		**Mark Pasanen, MD**		

Board Members Absent: N/A

DVHA Staff Present:

	Ashley MacWalters		**Taylor Robichaud, PharmD**		**Michael Rapaport, MD**
	Lisa Hurteau, PharmD		**Stacey Baker**		

Change Healthcare Staff Present:

	Jacqueline Hedlund, MD		**Laurie Brady, RPh**		**Mike Ouellette, RPh**
	Laureen Biczak, DO				

Guests/Members of the Public:

Kristen Heard, PhD, Jenna Bowen, Pharm.D., Andrew Garcia, Pharm.D., Jason Skinner, PhD., Sharon Reizner, Pharm.D., Brian Denger, Christine Dube, Pharm.D., Jai Persico, Adam Denman, Timothy McSherry, Megan Jensen, Beth D'Ambrosio, Richard McCann, Jennifer Tamburo, Melissa Sciulli Greco, Lindsey Walter, Ethan Latour, Kevin Gaffney, Nikhil Kacker, Shelly Nickerson, Steven J Patterson, Nimesh Patel, Dan Basoff, Megan Walsh, Annie Vong, Rodney Francisco, Rob Bigham, Joseph Ward, Laura Goldie, Kelly Maynard, Lisa Dunn, Amy Cunningham

Executive Session:

- An executive session was held from 5:00 p.m. until 6:00 p.m.

Introductions and Approval of DUR Board Minutes:

- Attendance was called and introductions of DVHA and Change Healthcare staff were made.

- The September meeting minutes were accepted as printed.

DVHA Pharmacy Administration Update: Lisa Hurteau, PharmD, DVHA

- COVID Vaccines are now commercially available and are no longer federally funded. Pharmacies are asking patients to make appointments since availability may still be limited through distributors.
- DVHA is working on a research report regarding the feasibility of a Gold Card Program for prescribers of substance use disorder treatment. This was a legislative requirement from last year, and recommendations from the DUR Board are due by 4/1/23.

Chief Medical Officer Update: Michael Rapaport, MD, DVHA

- Positive feedback has been received from several community providers that are thankful for the removal of prior authorization on injectable formulations of Buprenorphine. This alleviates some of the safety concerns with oral formulations.
- There is currently a shortage of the monoclonal antibody, Beyfortus™ (nirsevimab-alip), indicated for the prevention of Respiratory Syncytial Virus (RSV) in children. Use will be reserved only for those at high risk at this time.
- DVHA is participating in a pilot comprehensive pain management program with UVM Medical Center. Up to 100 Medicaid members will be enrolled, and preference will be given to those members with an opioid prescription and who receive home services.

Proposed 2024 DURB Meeting Schedule

- 2024 Meeting dates were presented and accepted by the Board.

Follow-up Items from Previous Meetings: Laurie Brady, RPH Change Healthcare

- None at this time.

Recommendation: None needed.

Board Decision: None needed.

RetroDUR/ProDUR: Jacqueline Hedlund, MD Change Healthcare and Laurie Brady, RPH Change Healthcare

- Introduce: CGRP Antagonist Use in Acute Migraine Headache

Migraine headache management has improved in the last several years. In addition to acetaminophen, NSAIDs and ergotomines to treat acute migraines, there are now a variety of new drugs classified into triptans (serotonin 1b/1d agonists, tryptamine based), CGRP (calcitonin gene-related peptide) receptor antagonists (gepants) and ditans (serotonin 5-HT1F agonists). The triptan class of drugs is contraindicated in patients with cardiovascular disease due to the vasoconstrictive effect; however, the ditans do not cause vasoconstriction as the coronary arteries do not have 5-HT1F receptors. Generally, CGRP antagonists have been reserved for use when patients do

not achieve symptomatic relief with triptans, or in cases where triptans are contraindicated. CGRP antagonists are not FDA approved for use in children. In addition to treating acute migraines some CGRP antagonists can be used to prevent migraines; there are no triptans that have this indication. The safety of using a CGRP medication within 2-4 hours of a triptan is not well-established and it is not recommended to prescribe both for acute management of migraines. Use of ditans with triptans or gepants has not been adequately assessed and is not recommended.

Change Healthcare will use paid, non-reversed Vermont Medicaid pharmacy and medical claims from 2022, excluding members with Part D, VMAP and Healthy Vermonters coverage. They will look for adult members who had at least one prescription for Nurtec® ODT (rimegepant), Ubrelvy® (ubrogepant), or Reyvow® (Lasmiditan) and will then look at prescriptions for triptans with overlapping dates. Use of triptans should be decreased or discontinued after CGRP antagonist or ditan initiation.

Recommendation: None at this time.

Board Decision: None at this time.

Clinical Update: Drug Reviews: Jacqueline Hedlund, MD, Laurie Brady, RPh, Change Healthcare

Biosimilar Drug Reviews (criteria will be discussed with Cytokine Modulator Class):

- Amjevita™ (adalimumab-atto)
- Cyltezo® (adalimumab-adbm)
- Hadlima™ (adalimumab-bwwd)
- Hulio® (adalimumab-fkjp)
- Hyrimoz® (adalimumab-adaz)
- Idacio® (adalimumab-aacf)
- Yuflyma® (adalimumab-aaty)
- Yusimry™ (adalimumab-aqvh)

Full New Drug Reviews:

- None at this time.

New Therapeutic Drug Classes

- None at this time.

Therapeutic Drug Classes- Periodic Review:

- None at this time.

Review of Newly-Developed/Revised Criteria (All changes will be effective 1/1/24 unless otherwise noted):

- There are some differences between the American Academy of Pediatrics (AAP) recommendations for Beyfortus™ (nirsevimab-alip) and Synagis® (palivizumab). Beyfortus™ is indicated in the second year for only those infants aged 8-19 months at increased risk for RSV and entering their second season. However, Synagis® guidance recommends the treatment for infants at high risk up to 24 months. The rationale for this age limit for Beyfortus™ is explained thusly: nirsevimab is not recommended for any child who is age 20 months and older. Children ages 20 months and older have likely already experienced two RSV seasons and been infected with RSV, and thus are less likely to benefit from nirsevimab. Since VFC must follow ACIP guidance, and the guidance does not recommend Beyfortus™ in children older than 19 months, they will not provide coverage for this age range. Of note, the Beyfortus™ label is for children up to 24 months of age. Synagis® requests for infants between 20-24 months of age, still considered to be at high risk, will be evaluated after prior authorization submission.
- Arexvy® is a vaccine indicated for active immunization for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in individuals 60 years of age and older. It is to be administered as a single dose as an IM injection. Arexvy® is an adjuvanted vaccine. The efficacy of Arexvy® against RSV-associated LRTD in adults 60 years of age and older was assessed in an ongoing, phase 3, randomized, placebo-controlled, observer-blind clinical study. The primary objective was to demonstrate the efficacy of Arexvy® in the prevention of a first episode of confirmed RSV-A and/or B-associated LRTD during the first season. Compared with placebo, Arexvy® significantly reduced the risk of developing RSV-associated LRTD by 82.6% in participants 60 years of age and older. The median duration of efficacy follow-up was 6.7 months. In addition, the efficacy was 94.6% in participants 60 years of age and older with at least 1 comorbidity of interest. The Centers for Disease Control and Prevention Advisory Committee on Immunization Practices made recommendations for RSV vaccines in older adults in June 2023. The committee recommended a single dose of RSV vaccine may be received by adults 60 years of age or older, using shared clinical decision-making.
- Abrysvo® is a vaccine indicated for active immunization for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in individuals 60 years of age and older. It is also indicated for active immunization of pregnant individuals at 32 through 36 weeks gestational age for the prevention of LRTD and severe LRTD caused by RSV in infants from birth through 6 months of age. A single dose should be administered intramuscularly. Study 3 is an ongoing Phase 3, multicenter, double-blind, placebo-controlled study assessing the safety and efficacy of Abrysvo® in the prevention of RSV-associated LRTD in individuals 60 years of age and older. Vaccine efficacy was assessed, and the study met the pre-specified success criteria for demonstration of efficacy of Abrysvo® for the primary objectives of prevention of RSV-LRTD with ≥2 symptoms (VE 66.7%) and prevention of RSV-LRTD with ≥3 symptoms

(VE 85.7%). The median duration of follow-up for efficacy was 7 months. Study 1 assessed the efficacy of Abrysvo® in the prevention of RSV-associated LRTD in infants born to individuals vaccinated during pregnancy. The VE results met the statistical criterion for success for reducing severe LRTD due to RSV, at all timepoints to within 180 days. The VE results did not meet the statistical criterion for success for reducing LRTD due to RSV; however, clinically meaningful efficacy was observed after 90 days through 180 days after birth. The Centers for Disease Control and Prevention Advisory Committee on Immunization Practices made recommendations for RSV vaccine use in older adults in June 2023. The committee recommended a single dose of RSV vaccine may be received by adults 60 years of age or older, using shared clinical decision-making.

- The CDC has recommended, for protection of babies from RSV, either the mom can get the Abryvso® vaccine at 32-36 weeks OR the infant can get Beyfortus™ (of if unavailable and indicated, Synagis®), not both.

Recommendation:

Synagis

- Clinical criteria:
  - Add: The prescriber must confirm the member has not already received Beyfortus™ for the current RSV season. Concomitant use with Beyfortus™ will not be approved.
  - Remove limitation statement: This drug must be obtained and billed through a DVHA enrolled specialty pharmacy and processed through the DVHA POS prescription processing system using NDC values. Under no circumstances will claims processed through the medical benefit be accepted.

Vaccines- Other

- Clinical criteria:
  - Add Abrysvo: Covered if ≥ 60 years of age OR the vaccine will be administered during weeks 32 through 36 of pregnancy during September through January.
  - Add Arexvy: Covered if ≥ 60 years of age.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendations.

ADHD Agents Long-Acting Stimulants/Amphetamine Products

Recommendation:

- Move dextroamphetamine SR (compare to Dexedrine CR®) to preferred.
- Add lisdexamfetamine capsule (compare to Vyvanse®) to non-preferred.
  - Clinical criteria:

- Revise Adzenys XR ODT, Adzenys ER suspension, Dyanavel XR chewable tablet, Vyvanse Chew: Patient must have a documented side effect, allergy, or treatment failure to Dyanavel XR suspension.
- Add Dyanavel XR suspension: patient must have medical necessity for a non-solid oral dosage form.
- Add Lisdexamfetamine: patient must have a documented intolerance to Brand Vyvanse.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendations.

ADHD Agents Non-stimulant

Recommendation:

- Clinical criteria:
  - Revise Qelbree: The patient has had a documented side effect, allergy, contraindication, or treatment failure to one preferred stimulant and atomoxetine OR there is a history of substance abuse with the patient or family of the patient and the patient has had a documented side effect, allergy, or treatment failure to atomoxetine.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendations.

Allergen Extract Immunotherapy

Recommendation:

- Add Ragwitek® (Short Ragweed Pollen Allergen Extract), Grastek® (Timothy Grass Pollen Extract), and Odactra® (House Dust Mite Allergen Extract) to non-preferred with QTY LIMIT of 1 tablet/day.
  - Clinical criteria:
    - Revise Grastek, Oralair, Ragwitek: The patient's age is FDA approved for the given indication AND Treatment must start 12 weeks before expected onset of pollen season and only after confirmed by positive skin test or in vitro testing for specific IgE antibodies to the relevant allergen AND Patient must have an auto-injectable epinephrine on-hand.
    - Add Odactra: The patient's age is FDA approved for the given indication AND Diagnosis is confirmed by positive skin test or in vitro testing for IgE antibodies to *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites AND Patient must have an auto-injectable epinephrine on-hand.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendations.

Anticonvulsants

Recommendation:

- Move Lyrica® (pregabalin) oral solution and tablets to preferred.
- Remove Gabitril® (tiagabine) from the PDL. It has been discontinued.
  - Clinical criteria:
    - Revise Fintepla: Diagnosis or indication is treatment of Dravet Syndrome or Lennox-Gastaut Syndrome AND patient has had a documented side effect, allergy, treatment failure/inadequate response or contraindication to at least two preferred anticonvulsants and Epidiolex AND prescriber, pharmacy and patient are registered with the REMS programs AND for reapproval, the patient must have a documented decrease from baseline in seizure frequency per 28 days.
    - Revise Pregabalin oral solution: the patient is unable to use pregabalin capsules (i.e. swallowing disorder) AND has a documented intolerance to brand Lyrica solution.
    - Update Tiagabine: the diagnosis is adjunctive therapy of focal-onset seizures and the patient has had a documented side effect, allergy, treatment failure/inadequate response or a contraindication to at least TWO preferred anticonvulsants.

Public Comments: Kristen Heard, PhD from Neurelis, Inc: yielded the time back to the committee.
Jenna Bowen, PharmD from Marinus Pharmaceuticals: Highlighted the attributes of Ztalmy.

Board Decision: The Board unanimously approved the above recommendations.

Overdose Treatments (effective 11/17/23)

- March 2023 - the FDA approved Narcan®, 4 milligram (mg) naloxone hydrochloride nasal spray for over-the-counter (OTC), nonprescription, use – the first naloxone product approved for use without a prescription.
- September 2023 - Narcan® is no longer available as a prescription product. The manufacturer will only be supplying the Over-the-Counter version.

Recommendation:

- Move Kloxxado™ (naloxone HCl) 8mg Nasal Spray with QTY LIMIT: 4 single-use sprays/28 days to preferred.

- Add Narcan® OTC (naloxone HCl) 4mg Nasal Spray with QTY LIMIT: 4 single-use sprays/28days and NALOXONE HCl OTC 4 mg Nasal Spray with QTY LIMIT: 4 single-use sprays/28days to preferred.

    - Clinical criteria:
        - Update Naloxone Nasal Spray (RX version): Narcan or OTC Naloxone nasal spray must be on a backorder and unavailable from the manufacturer.
        - Remove note regarding Evzio® since it has been discontinued.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendations.

Anti-Parkinson's Agents

Recommendation:

- Add Dhivy® (carbidopa/levodopa) to preferred after clinical criteria are met.
    - Clinical criteria:
        - Add Dhivy: the patient has had a documented side effect, allergy, or treatment failure with a generic formulation of Carbidopa/Levodopa OR the patient has medical necessity for a dose that can only be achieved by splitting tablets.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendations.

Antiretrovirals/Single Product Regimens

Recommendation:

- Move Symfi™ (efavirenz/lamivudine/tenofovir) and Symfi™ LO (efavirenz/lamivudine/tenofovir) to non-preferred with grandfathering of any existing users.
    - Clinical criteria:
        - Add **Symfi, Symfi Lo:** The patient has been started and stabilized on the requested medication. (Note: samples are not considered adequate justification for stabilization.) OR Medical reasoning beyond convenience or enhanced compliance over a preferred single tablet regimen.

Public Comments: Andrew Garcia, PharmD from UVM Medical Center: Highlighted the attributes of Cabenuva®.

Board Decision: The Board unanimously approved the above recommendations but asked that additional details regarding Cabenuva be brought back for discussion at a future meeting.

Antiretrovirals/Protease Inhibitors

Recommendation:

- Move Norvir® (ritonavir) tablets and powder pack to non-preferred.
- Move Brand Kaletra® (lopinavir/ritonavir) to non-preferred. Move lopinavir/ritonavir to preferred.
- Move Prezista® (darunavir ethanolate) to non-preferred with grandfathering of any existing users.
- Add Darunavir (compare to Prezista®) to non-preferred.
    - Clinical criteria:
        - Add Kaletra: patient must have a documented intolerance to generic lopinavir/ritonavir.
        - Add Norvir to Reyataz: patient must have a documented intolerance to the generic equivalent.
        - Add Darunavir, Prezista: The prescriber must provide a clinically compelling reason for the use of the requested medication including reasons why the combination product Prezcobix cannot be used AND for approval of darunavir, the patient must have a documented intolerance to brand Prezista.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendations.

Antiretrovirals/Nucleoside & Nucleotide Analog RTIs

Recommendation:

- Move Cimduo® (lamivudine/tenofovir) to non-preferred with grandfathering of any existing users.
- Move Ziagen® (abacavir sulfate) solution to non-preferred.
    - Clinical criteria:
        - Add Cimduo: The patient has been started and stabilized on the requested medication. (Note: samples are not considered adequate justification for stabilization.) OR The prescriber must provide a clinically compelling reason for the use of the requested medication including reasons why any of the preferred products would not be suitable alternatives.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendations.

Cytokine Modulators

Ankylosing Spondylitis Injectables

Recommendation:

- Add Xeljanz® (tofacitinib) oral solution to non-preferred.
- Add Adalimumab-adaz (compare to Hyrimoz®) biosimilar to Humira®, Adalimumab-adbm (compare to Cyltezo®) biosimilar to Humira®, Adalimumab-fkjp (compare to Hulio®) biosimilar to Humira®, Amjevita™(adalimumab-atto) biosimilar to Humira®, Cyltezo® (adalimumab-adbm) biosimilar to Humira®, Hadlima™ (adalimumab-bwwd) biosimilar to Humira®, Hulio® (adalimumab-fkjp) biosimilar to Humira®, Hyrimoz® (adalimumab-adaz) biosimilar to Humira®, Idacio® (adalimumab-aacf) biosimilar to Humira®, Yuflyma® (adalimumab-aaty) biosimilar to Humira®, and Yusimry™ (adalimumab-aqvh) biosimilar to Humira® to non-preferred.
    - Clinical criteria:
        - Update Additional criteria for Taltz, Xeljanz, Xeljanz XR: the patient had a trial and failure or contraindication to a preferred TNF Inhibitor AND for approval of oral solution, the patient must have medical necessity for a non-solid oral dosage form.
        - Add Additional Criteria for Cosentyx: the patient had a trial and failure or contraindication to a preferred TNF Inhibitor and Taltz.
        - Add Additional Criteria for Humira Biosimilars: the patient must be unable to use Humira.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendations.

Inflammatory Bowel Disease Biologics

Recommendation:

- Add Xeljanz® (tofacitinib) oral solution to non-preferred.
- Add Adalimumab-adaz (compare to Hyrimoz®) biosimilar to Humira®, Adalimumab-adbm (compare to Cyltezo®) biosimilar to Humira®, Adalimumab-fkjp (compare to Hulio®) biosimilar to Humira®, Amjevita™(adalimumab-atto) biosimilar to Humira®, Cyltezo® (adalimumab-adbm) biosimilar to Humira®, Hadlima™ (adalimumab-bwwd) biosimilar to Humira®, Hulio® (adalimumab-fkjp) biosimilar to Humira®, Hyrimoz® (adalimumab-adaz) biosimilar to Humira®, Idacio® (adalimumab-aacf) biosimilar to Humira®, Yuflyma® (adalimumab-aaty)

biosimilar to Humira®, and Yusimry™ (adalimumab-aqvh) biosimilar to Humira® to non-preferred.

- Clinical criteria:
  - Add Skyrizi to Cimzia, Entyvio, Simponi, Stelara, Tysabri criteria.
  - Update **Stelara note:** Initial IV dose for Stelara will be approved through the medical benefit. All subsequent subcutaneous doses may be approved through the pharmacy benefit with quantity limit of 90mg every 8 weeks. For maintenance regimens outside of FDA approved dosing intervals, including monthly dosing intervals, clinical notes must include supporting evidence of drug failure at standard dosing intervals and clinical justification for shortened dosing interval. Approval will be granted for 6 months; for renewal the patient must show increased clinical benefit with shorter dosing interval.
  - Add Humira Biosimilars: The patient must be unable to use Humira.
  - Revise Remicade, Renflexis: The patient must be unable to use Avsola or Inflectra.
  - Add Rinvoq: The patient has had a treatment failure with at least one conventional agent (e.g. 5-ASA, corticosteroids) AND the patient has a documented side effect, allergy, or treatment failure with a preferred TNF inhibitor.
  - Update Xeljanz, Xeljanz XR: The patient has had a treatment failure with at least one conventional agent (e.g. 5-ASA, corticosteroids) AND the patient has a documented side effect, allergy, or treatment failure with at least one preferred TNF Inhibitor AND for approval of oral solution, the patient must have medical necessity for a non-solid oral dosage form.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendations.

Hidradenitis Suppurativa

Recommendation:

- Add Adalimumab-adaz (compare to Hyrimoz®) biosimilar to Humira®, Adalimumab-adbm (compare to Cyltezo®) biosimilar to Humira®, Adalimumab-fkjp (compare to Hulio®) biosimilar to Humira®, Amjevita™(adalimumab-atto) biosimilar to Humira®, Cyltezo® (adalimumab-adbm) biosimilar to Humira®, Hadlima™ (adalimumab-bwwd) biosimilar to Humira®, Hulio® (adalimumab-fkjp) biosimilar to Humira®, Hyrimoz® (adalimumab-adaz) biosimilar to Humira®, Yuflyma®

(adalimumab-aaty) biosimilar to Humira®, and Yusimry™ (adalimumab-aqvh) biosimilar to Humira® to non-preferred. Note that Idacio® (adalimumab-aacf) is not indicated for HS.
    - Clinical criteria:
        - Add Humira Biosimilars: the patient must be unable to use Humira.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendations.

Psoriasis

Recommendation:

- Update quantity limit for Tremfya® (guselkumab) QTY LIMIT: 1 syringe/28 days for the first month, then 1 syringe every 56 days thereafter.
- Add Adalimumab-adaz (compare to Hyrimoz®) biosimilar to Humira®, Adalimumab-adbm (compare to Cyltezo®) biosimilar to Humira®, Adalimumab-fkjp (compare to Hulio®) biosimilar to Humira®, Amjevita™(adalimumab-atto) biosimilar to Humira®, Cyltezo® (adalimumab-adbm) biosimilar to Humira®, Hadlima™ (adalimumab-bwwd) biosimilar to Humira®, Hulio® (adalimumab-fkjp) biosimilar to Humira®, Hyrimoz® (adalimumab-adaz) biosimilar to Humira®, Idacio® (adalimumab-aacf) biosimilar to Humira®, Yuflyma® (adalimumab-aaty) biosimilar to Humira®, and Yusimry™ (adalimumab-aqvh) biosimilar to Humira® to non-preferred.
    - Clinical criteria:
        - Add Additional Criteria for Humira Biosimilars: the patient must be unable to use Humira.
        - Add Additional Criteria for Stelara: The prescriber must provide evidence of a trial and failure or contraindication to a preferred TNF Inhibitor, Taltz, and either Tremfya or Skyrizi.

Public Comments: Jason Skinner, PhD from Amgen: Highlighted the attributes of Otezla.

Board Decision: The Board unanimously approved the above recommendations.

Rheumatoid, Juvenile, & Psoriatic Arthritis Biologics

Recommendation:

- Add Xeljanz® (tofacitinib) oral solution to non-preferred.
- Add Adalimumab-adaz (compare to Hyrimoz®) biosimilar to Humira®, Adalimumab-adbm (compare to Cyltezo®) biosimilar to Humira®, Adalimumab-fkjp (compare to Hulio®) biosimilar to Humira®, Amjevita™(adalimumab-atto) biosimilar to Humira®, Cyltezo®

(adalimumab-adbm) biosimilar to Humira®, Hadlima™ (adalimumab-bwwd) biosimilar to Humira®, Hulio® (adalimumab-fkjp) biosimilar to Humira®, Hyrimoz® (adalimumab-adaz) biosimilar to Humira®, Idacio® (adalimumab-aacf) biosimilar to Humira®, Yuflyma® (adalimumab-aaty) biosimilar to Humira®, and Yusimry™ (adalimumab-aqvh) biosimilar to Humira® to non-preferred.

- Clinical criteria:
  - Update Taltz, Xeljanz, Xeljanz XR additional criteria: patient must be ≥ 18 years of age AND the prescriber must provide evidence of a trial and failure or contraindication to a preferred TNF Inhibitor AND for approval of oral solution, the patient must have medical necessity for a non-solid oral dosage form.
  - Add Cosentyx additional criteria: the prescriber must provide evidence of a trial and failure or contraindication to a preferred TNF Inhibitor and Taltz.
  - Add Humira Biosimilars Additional Criteria: The patient must be unable to use Humira.
  - Add Stelara Additional Criteria: the prescriber must provide evidence of a trial and failure or contraindication to a preferred TNF Inhibitor, Taltz, and either Tremfya or Skyrizi.

Public Comments: Jason Skinner, PhD from Amgen: Highlighted the attributes of Amjevita™.

Board Decision: The Board unanimously approved the above recommendations.

Endometriosis/Uterine Fibroids Agents

Recommendation:

- Move Oriahnn® (elagolix and elagolix/estradiol/norethindrone) capsules with QTY LIMIT: 2 tabs/day and Orilissa® (elagolix) tablets with QTY LIMIT: 200mg dose = 2 tabs/day; maximum of 6 months; 150mg = 1 tab/day to non-preferred. Allow any existing users to continue through therapy through the 2-year mark.
  - Clinical criteria:
    - Add Orilissa, Oriahnn: Patient has a documented side effect, allergy, or treatment failure to at least TWO medications from at least 2 different classes (oral contraceptives, NSAIDs, progestins) AND the patient has a documented side effect, allergy, or treatment failure with Myfembree. Note: Use of GnRH receptor antagonists will be limited to 2 years.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendations.

Gout Agents

Recommendation:

- Move Febuxostat to preferred.
  - Clinical criteria:
    - Add Uloric: The patient has had a documented intolerance to generic febuxostat.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendations.

Hemophilia B Treatments

Recommendation:

- Move Alprolix® and Idelvion® to non-preferred with grandfathering of any existing users.
- Move Rebinyn® to preferred.
  - Clinical criteria:
    - Revise All Non-Preferred Products: The prescriber must provide a clinically compelling reason for the use of the requested medication including reasons why any of the preferred products would not be suitable alternatives. For approval of Alprolix or Idelvion, documentation must include why the member is unable to use the preferred extended half-life concentrate Rebinyn.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendations.

Inhaled Corticosteroids (effective 11/17/23)

Recommendation:

- Remove Flovent® HFA (fluticasone propionate) and Flovent® DISKUS (fluticasone propionate) from the PDL. GSK advised that these will be discontinued effective 12/31/23. Pharmacies may continue to use existing supply.
- Move Arnuity Ellipta 100 or 200mcg/inh (fluticasone furoate) with QTY LIMIT: 90 blisters/90 days, QVAR® Redihaler™ 40mcg/inh with QTY LIMIT: 2 inhalers (21.2 gm)/90 days, and QVAR® Redihaler™ 80mcg/inh with QTY LIMIT: 3 inhalers (31.8 gm)/90 days to preferred.
  - Clinical criteria:

- Revise Pulmicort Respules: medical necessity for the use of a nebulized solution has been provided AND if the dose is 1 mg, the patient must be unable to use two 0.5 mg vials AND the patient has a documented intolerance to the generic.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendations.

Intranasal Antihistamines

Recommendation:

- Move OLOPATADINE 0.6% (compare to Patanase®) Nasal Spray with QTY LIMIT: 1 bottle (31 gm)/30 days to preferred.
  - Clinical criteria:
    - Add Patanase: The patient has a documented side effect, allergy, or treatment failure to Olopatadine 0.6%.
    - Add Ryaltris: The patient has a documented side effect, allergy, or treatment failure to Olopatadine 0.6% AND The patient has a documented side effect, allergy, or treatment failure to a preferred nasal corticosteroid OR the patient has a documented intolerance to Dymista.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendations.

Multiple Sclerosis Agents

Recommendation:

- Move Kesimpta® (ofatumumab) to preferred after clinical criteria are met.
  - Clinical criteria:
    - Add Kesimpta: Patient is ≥18 years AND has a diagnosis of relapsing multiple sclerosis AND has a documented side effect, allergy, treatment failure or contraindication to either Tysabri or rituximab, unless contraindicated.

Public Comments: Sharon Reizner, PhD from Novartis Pharmaceuticals: Highlighted the attributes of Kesimpta.

Board Decision: The Board unanimously approved the above recommendations.

Muscular Dystrophy

Recommendation:

- Move Emflaza™ (deflazacort) to preferred after clinical criteria are met.

Public Comments: Brian Denger from Community Engagement for Parent Project Muscular Dystrophy: Highlighted the attributes of drug class Antisense Oligonucleotides.

Board Decision: The Board unanimously approved the above recommendations.

Ophthalmic Antibiotics and Combinations (effective 11/17/23)

Recommendation:

- Remove Tobradex® (tobramycin/dexamethasone) suspension and ointment from the PDL. Novartis advised distributors that they were removed from the market in September.
- Remove Gentak (gentamicin) ointment, solution, Garamycin (gentimicin) ointment, solution, Pred-G® S.O.P. (gentamicin/prednisolone) ointment, and Pred-G® (gentamicin/prednisolone) ointment, suspension. They are no longer available.
- Move Tobramycin w/dexamethasone suspension to preferred.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendations.

Ophthalmic Immunomodulators/Dry Eye

Recommendation:

- Move Xiidra® (lifitegrast) solution with QTY LIMIT: 180 vials per 90 days to preferred.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendations.

Otic Anti-infectives and Combinations (effective 11/17/23)

Recommendation:

- Remove Ciprodex® (ciprofloxacin 0.3%/dexamethasone 0.1%) otic suspension from the PDL. Novartis advised distributors that they were removed from the market in September.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendations.

Potassium Removing Agents

Recommendation:

- Move SPS® (sodium polystyrene sulfonate) suspension to non-preferred.
  - Clinical criteria:
    - Add SPS: The patient has potentially life-threatening hyperkalemia AND where clinically appropriate, a loop or thiazide diuretic has failed for potassium removal AND newer cation exchangers (i.e. SZC or patiromer) are not available AND the patient is not at high risk for intestinal necrosis as defined by the following: Postoperative patients, Patients with an ileus, Patients with a large or small bowel obstruction, Patients with constipation or at risk of becoming constipated (eg, due to opioid use), Patients with underlying bowel disease, eg, ulcerative colitis or Clostridioides difficile colitis

Public Comments: Christine Dube, PharmD from Astra Zeneca Drug: Highlighted the attributes of Lokelma.

Board Decision: The Board unanimously approved the above recommendations but asked that the contraindications statement be re-worded due to potential confusion with its intent.

Respiratory/Pulmonary Fibrosis Agents

Recommendation:

- Add Pirfenidone with QTY LIMIT:267 mg tablets = 270 tabs/month, 801 mg tablets = 90 tabs/month to non-preferred
  - Clinical criteria:
    - Update Clinical Criteria: Esbriet, Ofev, Pirfenidone:
      - Age ≥ 18
      - Diagnosis of idiopathic pulmonary fibrosis (pirfenidone and Ofev) OR chronic fibrosing interstitial lung disease or systemic sclerosis associated interstitial lung disease (Ofev Only)
      - May not be used in combination
      - The prescriber is a pulmonologist.
      - Clinical documentation that the member is a non-smoker or has not smoked in 6 weeks.
      - FVC≥ 50% of predicted
      - For approval of Esbriet or Ofev (idiopathic pulmonary fibrosis diagnosis only), the patient must have a documented intolerance to generic pirfenidone.

- Update Reauthorization Criteria: Documentation the patient is receiving clinical benefit from pirfenidone or Ofev® therapy as evidenced by < 10% decline in percent predicted FVC or < 200mL decrease in FVC AND There is clinical documentation that the member has remained tobacco-free.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendations.

Sickle Cell Agents

Recommendation:

- Move Endari® (L glutamine powder for oral solution) to preferred after clinical criteria are met.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendations.

Urinary Antispasmodics

Recommendation:

- Move Gelnique® (oxybutynin topical gel) and Oxytrol® (oxybutynin transdermal patch) to preferred.
- Move Trospium, Tolterodine (compare to Detrol®), and Tolterodine SR (compare to Detrol® LA) to preferred.
- Add Fesoterodine ER (compare to Toviaz®) to non-preferred with QTY LIMIT: 1 tab/day.
    - Clinical criteria:
        - Add Fesoterodine ER: the patient has a documented intolerance to brand Toviaz.
        - Revise Gemtesa: The patient has had a documented side effect, allergy, treatment failure, or contraindication with one preferred topical urinary antimuscarinic agent and Myrbetriq.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendations with the revision that Detrol® LA brand be added to non-preferred.

General Announcements:

- None at this time

Adjourn: Meeting adjourned at 8:30 p.m.