Department of Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes
October 20, 2020

NOTE: The Meeting was held via Skype due to the Governor's "Stay Home Stay Safe" order related to the COVID-19 Emergency Declaration, and as authorized by recent modifications to Vermont's Public Meeting Law.

Board Members Present:

Zail Berry, MD	Margot Kagan, PharmD	Patricia King, MD
Andy Miller, RPh	Bill Breen, RPh	Renee Mosier, PharmD
Marc Pasanen, MD	Claudia Berger, MD	Joseph Nasca, MD
Doug Franzoni, PharmD		

Absent:

Staff:

Laurie Brady, RPh, Change HealthCare	Stacey Baker, DVHA	Laureen Biczak, DO, Change Healthcare
Jason Pope, DVHA	Mike Ouellette, RPh, Change Healthcare	Scott Strenio, MD, DVHA
Lisa Hurteau, PharmD, DVHA	Jacquelyn Hedlund, MD, Change Healthcare	Marietta Scholten, MD, DVHA
Nancy Hogue, Pharm D, DVHA		

Guests:

Adam Denman, Global Blood Therapeutics	Beth D'Ambrosio, Novartis	Mark Leyden
Angela Hathaway, Lilly	Christine Dube, AstraZeneca	Nikhil Kacker, Genetech
Ryan Gregg, Ironshore	Eric Sherr, Viiv	Niki Patel, Novo Nordisk
Nicole Trask, Janssen	Franco Casagrande, Abbvie	Hannah Parker
Bryan Dillon, Otsuka	Gene Muise, Amgen	Paul Isikwe, Teva
Patty Arcese	Jeffrey Olson, Gilead	Roy Riddhi
Robert Jason Arcott	Lisa Libera, Teva	Steve McRae
Linda Burns, Abbott	Margaret Glassman	Wing Yeung
Megan Walsh, Abbvie	Melissa Porricelli	Kristin Kollecas, Sanofi Genzyme
	Jane Guo, Otsuka	Kristen Chopas

1. Executive Session:

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

2. 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.

3. DVHA Pharmacy Administration Update: Lisa Hurteau, Pharm.D., DVHA:

- Emergency guidance was issued allowing pediatric immunizations to be given in the pharmacy. The vaccine must be FDA approved. The pharmacist or pharmacy intern must undergo training, notify the PCP of the vaccination, send a record of the administration to the vaccine registry, and council on the importance of a well-child visit with the pediatrician.
- DVHA participates in the federal Vaccines for Children Program (VFC) which supplies vaccine directly to providers. For Medicaid reimbursement, the pharmacy would have to enroll with VFC. They would not be reimbursed for the cost of the vaccine but would be paid an administration fee.

4. Medical Director Update: Scott Strenio, MD, DVHA

- None at this time.

5. Proposed 2021 DURB Meeting Schedule

- **2021 DUR Board Meeting Dates**

  February 16, 2021
  April 6, 2021
  May 11, 2021
  June 22, 2021
  September 14, 2021
  October 19, 2021
  December 7, 2021

Recommendation: None needed.

Public Comment: No public comment.

Board Decision: None needed.

6. Follow-up Items from Previous Meetings

- None at this time.

7. RetroDUR/ProDUR: Jacquelyn Hedlund, MD, Change Healthcare

- Introduction of RetroDUR: Chantix Use

The benefits of smoking cessation are obvious. While some people quit on their own, either by tapering or going "cold turkey", many will require the aid of counseling, medications or both. It has been demonstrated that of those who use medication, long-term abstinence often requires counseling in addition to medication. Luckily, several medications have been used successfully, including nicotine replacement products (short and long acting), bupropion and varenicline (Chantix). While initially there was concern that Chantix was associated with neuropsychiatric side effects, including risk of suicide, a recent, large study (EAGLES trial of 8000 smokers randomized to NRT, bupropion or varenicline or placebo) showed that the risk was equal

among treatments and a black box warning was removed. Many who take Chantix have already tried nicotine replacement products unsuccessfully. While Chantix is meant to be used alone, there has been some success in adding short-acting NRTs in those who continue to experience withdrawal symptoms. In those who have successfully quit at 12 weeks, some may benefit from an additional 12 weeks of therapy to prevent relapse. 2020 guidelines for tobacco cessation issued by the American Thoracic Society recommend Chantix as first line therapy over nicotine replacement products and bupropion and state that for many patients, longer duration of treatment (greater than 12 weeks) is necessary to ensure success with quitting.
Change Healthcare will use paid, non-reversed Medicaid pharmacy and medical claims from SFY 2020, excluding members with Part D, VMAP and Healthy Vermonters coverage. They will look at all members who were prescribed Chantix and evaluate the number of monthly prescriptions dispensed per member. Additionally, they will see which members were also simultaneously prescribed a short acting nicotine replacement product (gum, lozenges, inhaler, nasal spray). They will look to see if there were any members taking either bupropion or the long acting nicotine patches, which is not common practice or recommended.

Recommendation: None needed.

Public Comment: No public comment.

Board Decision: None needed.

8. Clinical Update: Drug Reviews

Biosimilar Drug Reviews:

- None at this time.

Full New Drug Reviews:

- None at this time

9. New Managed Therapeutic Drug Classes: Nancy Hogue, PharmD, DVHA, Laureen Biczak, DO, Change Healthcare and Laurie Brady, RPh, Change Healthcare

- Antiretrovirals

- Act 178 was signed by the governor on October 2, 2020. This is a change to previous legislation enacted in 2000 which prohibited DVHA from managing HIV medications any more strictly than the VMAP (Ryan White) Program. DVHA has been working with the Department of Health, prescribers, and advocacy groups for more than 3 years on this change in legislation.

- Antiretroviral therapy is guided by several key principles that are well-accepted and outlined in the NIH Guidelines that are frequently updated. Three active drugs are generally recommended to be part of every regimen for new starts
    - Two-drug regimens can be used in certain clinical situations.

- Low dose ritonavir and cobicistat are not considered active drugs.

- Genotype testing should be performed prior to new therapy and therapy changes if possible.
  - Results of this testing are used to craft the regimens.
- Fail first or "step therapy" strategies are NOT appropriate for antiretroviral medications due to the likelihood of resistance to entire classes of drugs if a wrong medication is used
- Use of low pill burden regimens may improve compliance.
- Current users should be grandfathered when instituting an antiretroviral PDL.
- Some therapies are non-preferred due to concerns re: toxicities or not favored for use in most circumstances.
- A few therapies are non-preferred because the same or similar drugs are available less expensively as generics or with similar pill burdens (may be 1 pill once daily vs two pills once daily).
- All therapies are available with prior authorization if medically necessary.

Recommendation:

- Move Combivir (lamivudine/zidovudine), Epivir (lamivudine), Epzicom (abacavir/lamivudine), lopinavir/ritonavir solution, ritonavir, Retrovir (zidovudine), Reyataz (atazanavir), Sustiva (efavirenz), Viread 300mg (tenofovir disoproxil fumarate), Ziagen (abacavir) Aptivus (tipranavir), Crixivan (indinavir), Fuzeon (enfuviritide), Invirase (saquinavir), Lexiva and fosamprenavir, Selzentry (maraviroc), Trizivir (abacavir/lamivudine/zidovudine), Tybost (cobicistat), Videx and didanosine, Viracept, Viramune and nevirapine, stavudine, Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir), and Symtuza (darunavir/cobicistat/emtricitabine/tenofovir AF) to non-preferred.
- Add Rukobia and Trogarzo to preferred at clinical criteria are met.
  - Clinical criteria:
    - Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir):
      - The patient has been started and stabilized on the requested medication. (Note: samples are not considered adequate justification for stabilization.) OR
      - Genotype testing supporting resistance to other regimens OR
      - Intolerance or contraindication to preferred combination of drugs AND
      - Medical reasoning beyond convenience or enhanced compliance over preferred agents AND
      - CrCl > 70mL/min to initiate therapy OR CrCl >50mL/min to continue therapy
    - Symtuza (darunavir/cobicistat/emtricitabine/tenofovir AF):

- 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 preferred agents (Prezcobix & Descovy)

- Combivir, Epivir, Epzicom, Retrovir, Reyataz, Sustiva, Viread 300mg, Ziagen: patient must have a documented intolerance to the generic equivalent
- Lopinavir/ritonavir: patient must have a documented intolerance to brand Kaletra
- Ritonavir: patient must have a documented intolerance to brand Norvir.
- Aptivus, Crixivan, Fosamprenavir, Fuzeon, Invirase, Lexiva, Nevirapine, Nevirapine ER, Selzentry, Stavudine, Trizivir, Viracept, Viramune ER, Videx and Didanosine: 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.
- Rukobia, Trogarzo:
  - The patient must meet ALL of the following criteria:
  - ≥ 18 years of age
  - Prescription is written by or in consultation with an infectious disease specialist
  - Viral Load is ≥ 1,000 copies/mL (results must be submitted)
  - Patient has been compliant but has had an inadequate response to at least 6 months of treatment with anti-retroviral therapy (ART), including recent failure within the last 8 weeks
  - Patient has multi-drug resistant HIV-1 infection including documented resistance to at least one medication from each of the following classes: Protease Inhibitor (PI), Nucleoside Reverse Transcriptase Inhibitor (NRTI, Non-nucleoside Reverse Transcriptase Inhibitor (NNRTI)
  - Medication will be used in combination with ART that includes at least one drug to which the individual's virus is susceptible
  - Initial approval will be granted for 6 months. For continuation of therapy, there must be a decrease in viral load from baseline AND the patient must continue to be compliant with the optimized background regimen of ART.

- Tybost: The patient has been started and stabilized on the requested medication. (Note: samples are not considered adequate justification for stabilization.) OR a clinically valid reason beyond compliance or convenience is given for not using a preferred combination drug or a ritonavir- based regimen with similar components

Public Comment: Nicole Trask from Janssen: yielded time back to committee.

Board Decision: The Board unanimously approved the above recommendation.

10. Therapeutic Drug Classes- Periodic Review

- None at this time.

11. Review of Newly Developed/Revised Criteria: All changes effective 1/1/2021

ADHD and Narcolepsy Cataplexy Medications: Long Acting Stimulants

- Move Adderall XR to preferred.
- Move Methylphenidate SA OSM IR/ER to non-preferred.
    - Clinical criteria:
        - Update Ritalin LA, Methylphenidate CR, Methylphenidate SR 24 HR: patient has had a documented side effect, allergy, or treatment failure on one preferred long acting Methylphenidate products AND for approval of Ritalin LA, the patient must have a documented intolerance to the generic equivalent.
        - Methylphenidate SA OSM: the patient must have a documented intolerance to brand Concerta.

Public Comment: Ryan Gregg with Ironshore Pharmaceuticals: highlighted the attributes of Jornay PM.

Board Decision: The Board unanimously approved the above recommendation.

ADHD and Narcolepsy Cataplexy Medications: Short/ Intermediate acting stimulants

- Move Methylphenidate SR to preferred.
- Remove clinical criteria for Methylphenidate SR.

Public Comment: No comment.

Board Decision: The Board unanimously approved the above recommendation.

Anti-Diabetics: GLP-1 Receptor Antagonists

- Move Bydureon® (exenatide extended-release) QTY LIMIT: 12 vials/84 days and Byetta® (exenatide) QTY LIMIT: 3 pen/90 days to non-preferred. Existing users will be grandfathered.
    - Clinical criteria:
        - Remove clinical criteria for Victoza and Trulicity.
        - Adlyxin/Bydureon/Byetta/Bydureon BCise/Ozempic: patient has a documented side effect, allergy, contraindication, or treatment failure with at least one preferred GLP-1 Receptor Agonist.

Public Comment: Niki Patel from Novo Nordisk: Highlighted the attributes of Rybelsus.

Board Decision: The Board unanimously approved the above recommendation.

Anti-Diabetics: SGLT-2 Inhibitors

- AstraZeneca's Farxiga (dapagliflozin) Phase III DAPA-CKD trial was stopped early due to overwhelming efficacy in patients with chronic kidney disease. This is the first SGLT2 Inhibitor to show clinically meaningful benefit in patients with CKD, both with and without Type II Diabetes.

    - Move INVOKAMET® (canagliflozin/metformin) QTY LIMIT: 1 tab/day, SYNJARDY® (empagliflozin/metformin) QTY LIMIT: 2 tabs/day, XIGDUO XR® (dapagliflozin & metformin ER) QTY LIMIT: 5/1000 mg = 2/day, all other strengths = 1/day to preferred.
        - Clinical criteria:
            - Remove clinical criteria for Farxiga, Invokana, Jardiance, Invokamet, Synjardy, and Xigduo XR

Public Comment: No comment

Board Decision: The Board unanimously approved the above recommendation.

Antivirals: Influenza Medications

- Move Tamiflu® (oseltamivir)QTY LIMIT: 45 and 75 mg caps = 10 caps/30 days, 30 mg caps = 20 capsule /30 days, 6 mg/ml suspension = 180 ml/30 days to non-preferred.
    - Clinical criteria:
        - Tamiflu: Patient has a documented intolerance to generic Oseltamivir

Public Comment: Nikhil Kacher from Genentech: Highlighted the attributes of Xofluza.

Board Decision: The Board unanimously approved the above recommendation.

Anti- Psychotics: Long-Acting Injectables

- Move ABILIFY MAINTENA® (aripiprazole monohydrate) FDA maximum recommended dose = 400 mg/month QTY LIMIT: 1 vial/28 days to preferred.
  - Clinical criteria:
    - Remove Abilify Maintena clinical criteria.

Public Comment: Jane Guo from Otsuka: yielded time back to committee.

Board Decision: The Board unanimously approved the above recommendation.

Antihyperlipidemics: PCSK9 Inhibitors

- Note that Sanofi US labeler 72733 is the only preferred form of Praluent (after clinical criteria are met).
  - Clinical criteria:
    - Add: Approval of Praluent NDC's with labeler code 00024 will be considered only if labeler code 72733 NDC's are on a long-term backorder and unavailable from the manufacturer.

Public Comment: No comment.

Board Decision: The Board unanimously approved the above recommendation.

Cardiovascular: Heart Failure

- The FDA approved Farxiga (dapagliflozin) for the treatment of heart failure with reduced ejection fraction (HFrEF) in adults with and without Type II Diabetes. It is the first SGLT2 inhibitor to gain this approval.

  - Add Heart Failure as a new category
  - Move Entresto out of the antihypertensives section of the PDL. It will remain preferred after clinical criteria are met.
  - Add Farxiga (dapagliflozin) QTY LIMIT: 1 tab/day to preferred.

Public Comment: Beth D' Ambrosio from Novartis Pharmaceutical: yielded time back to committee.

Board Decision: The Board unanimously approved the above recommendation.

Endometriosis Agents

- Move Orilissa® (elagolix) tablets to preferred after clinical criteria are met.
  - Clinical criteria:
    - Orilissa: Patient has a diagnosis of moderate-severe endometriosis pain and has a documented side effect, allergy, or treatment failure to at least TWO medications from at least 2 different classes (oral contraceptives, NSAIDs, progestins).

Note: Approval for 200mg dose will be limited to 2 tablets/day for a maximum of 6 months. Approval for 150mg dose will be limited to 1 tablet/day. Maximum length of therapy 2 years.

Public Comment: Franco Casagrande from Abbvie: yielded time back to committee.

Board Decision: The Board unanimously approved the above recommendation.

Hereditary Angioedema Medications

- Move Ruconest® (recombinant C1 esterase inhibitor) QTY LIMIT: 4 vials/fill and Firazyr® (icatibant) QTY LIMIT: 3 syringes (9 ml)/fill to non-preferred.
- Add ICATIBANT (compare to Firazyr®) QTY LIMIT: 3 syringes (9 ml)/fill to preferred after clinical criteria are met.
    - Clinical criteria:
        - Berinert, Firazyr, Icatibant: The diagnosis or indication is treatment of an acute Hereditary Angioedema (HAE) attack AND for approval of Firazyr, the patient must have a documented intolerance to generic Icatibant. (Approval may be granted so that 2 doses may be kept on hand or Berinert and 3 doses for Icatibant/Firazyr).
        - Add Ruconest to the Kalbitor criteria.

Public Comment: No comment.

Board Decision: The Board unanimously approved the above recommendation.

Hematopoeitics: ITP (Platelet Stimulating Agents)

- Clinical criteria:
    - Update Mulpleta: The patient is at least 18 years of age AND the diagnosis is thrombocytopenia in a patient with chronic liver disease scheduled to undergo an elective surgical or dental procedure AND the patient's platelet count is less than 50,000/µL (< 50 x 109/L) AND approval will be limited to a maximum of 7 days' supply per procedure. AND patient has had a documented side effect, allergy, contraindication or treatment failure to Doptelet.

Public Comment: No comment.

Board Decision: The Board unanimously approved the above recommendation.

Hypoglycemia Treatments

- Note that Lilly labeler code 00002 is the only preferred form of Glucagon Emergency Kit (glucagon for injection) 1mg

Public Comment: No comment.

Board Decision: The Board unanimously approved the above recommendation.

Monoclonal Antibodies: Anti-IL and Anti-IgE (Immunologic Therapies for Asthma)

- Move Cinqair® (reslizumab) Intravenous injection and FASENRA® (benralizumab) subcutaneous Injection, pre-filled syringe and auto-injector pen QTY LIMIT: 1 mL every 28 days for 3 doses then 1 mL every 56 days to preferred after clinical criteria are met.
- Update Dupixent non-preferred formulations to include pre-filled syringe and auto injector pen.
- Update Nucala non-preferred formulations to include vial, pre-filled syringe and auto-injector pen.
- Add Xolair non-preferred formulations to include vial, pre- filled syringe
    - Clinical criteria:
        - Update Xolair criteria to add: The patient has a history of uncontrolled asthma symptoms (symptoms occurring almost daily or waking at night with asthma at least once a week) or 2 or more exacerbations in the previous year despite regular use of medium-high dose ICS/LABA given in combination with a leukotriene receptor antagonist or long-acting bronchodilator (e.g. tiotropium) for a minimum of 3 consecutive months, with or without oral corticosteroids. Pharmacy claims will be evaluated to assess compliance with therapy.
        - Remove requirement that the patient has a pre-treatment FEV1 < 80% predicted from Fasenra, Nucala, Cinqair, and Dupixent.
        - Updated Fasenra, Nucala, Cinqair, and Dupixent:
            - The patient must be 6 years of age or older for Nucala, 12 years of age or older for Fasenra/Dupixent, or 18 years of age or older for Cinqair AND
            - The patient must have a diagnosis of severe persistent asthma with an eosinophilic phenotype as defined by pre-treatment blood eosinophil count of ≥ 150 cells per mcL within the previous 6 weeks or ≥ 300 cells per mcL within 12 months prior to initiation of therapy AND
            - The patient has a history of uncontrolled asthma symptoms (symptoms occurring almost daily or waking

at night with asthma at least one a week) or 2 or more exacerbations in the previous year despite regular use of medium-high dose ICS/LABA given in combination with a leukotriene receptor antagonist or long-acting bronchodilator (e.g. tiotropium for a minimum of 3 consecutive months, with or without oral corticosteroids. Pharmacy claims will be evaluated to assess compliance with therapy. AND

- The prescriber is an allergist, immunologist, or pulmonologist. AND
- For approval of Dupixent or Nucala, the patient must have a documented side effect, allergy, or treatment failure with Cinqair or Fasenra.
- For continuation of therapy after the initial 3 month authorization, the patient must continue to receive therapy with an ICS/LABA AND have either a decreased frequency of exacerbations, decreased use of maintenance oral corticosteroids, reduction in the signs and symptoms of asthma, or an increase in predicted FEV1 from baseline.

Public Comment: Letter to the board from The American Academy of Allergy Asthma & Immunology.
Nikhil Kacker from Genentech: yielded time back to committee.

Board Decision: The Board unanimously approved the above recommendation.

Migraine Therapy: Preventative Treatments

- Move Aimovig™ (erenumab-aooe) QTY LIMIT: 1 injection (1mL) per 30 days to non-preferred.
- Move Ajovy® (fremanezumab-vfrm) QTY LIMIT: 225 mg (1 injection) per 30 days or 675 mg (3 injections) every 90 days to preferred after clinical criteria are met.
    - Clinical Criteria:
        - Remove Ajovy additional criteria.
        - Update Aimovig, Vyepti additional criteria: The patient must have a documented side effect, allergy, or treatment failure to Emgality and Ajovy.

Public Comment: Gene Muise from Amgen: Highlighted the attributes of Aimovig. Paul Isikwe from Teva: yielded time back to committee.

Board Decision: The Board unanimously approved the above recommendation.

Narcolepsy Cataplexy Medications: Miscellaneous

- Clinical criteria:
    - Revise Wakix and Xyrem to indicate that one of the drugs tried and failed must be Sunosi.

Public Comment: no comment

Board Decision: The Board unanimously approved the above recommendation.

Neurotoxins

- Move Dysport® (abobotulinumtoxinA) to non-preferred.
- Remove Calcium Channel Blockers (CCB) from permitted migraine prophylaxis trials for Botox approval.

Public Comment: No comment.

Board Decision: The Board unanimously approved the above recommendation.

Progestational Agents

- Remove MAKENA® (hydroxyprogesterone caproate) 250 mg/ml vial intramuscular injection from the PDL. It has been discontinued. Subcutaneous injection is still available and will remain preferred after clinical criteria are met.

Public Comment: No comment.

Board Decision: The Board unanimously approved the above recommendation.

Pulmonary Arterial Hypertension Medications

- Move Ambrisentan (compare to Letairis®) QTY LIMIT: 1 tablet/day to non-preferred.
- Move Letairis® (ambrisentan) Tablet QTY LIMIT: 1 tablet/day to preferred.
    - Clinical criteria:
        - Update Ambrisentan, Bosentan: patient has a documented intolerance to the brand name equivalent.
        - Remove Letairis clinical criteria.

Public Comment: No comment.

Board Decision: The Board unanimously approved the above recommendation.

Pulmonary Agents: Beta Agonists

- All albuterol HFA formulations have been preferred during the COVID19 public health emergency due to initial shortages and backorders. Vermont Medicaid will resume management of this class since the shortages are now resolved.
- Move Ventolin® HFA (albuterol) to preferred.
- Move Proventil® HFA (albuterol) to non-preferred.
    - Clinical criteria:
        - Remove Ventolin HFA clinical criteria
        - Albuterol HFA, Levalbuterol (aerosol), Proventil HFA, Xopenex HFA: patient has a documented side effect, allergy, or treatment failure to two preferred short acting metered dose inhalers. AND for approval of levalbuterol aerosol, the patient must have a documented intolerance to brand Xopenex HFA

Public Comment: No comment.

Board Decision: The Board unanimously approved the above recommendation.

Pulmonary Agents: Corticosteroids and Combinations

- Global Initiative for Asthma (GINA) guidelines updated April 3, 2020. For safety, GINA no longer recommends starting with SABA-only treatment. GINA recommends that all adults with asthma should receive ICS-containing controller treatment to reduce their risk of serious exacerbations and to control symptoms.
- Options now include:
    - For mild asthma, as needed low dose ICS-formoterol or, if not available, low dose ICS taken whenever SABA is taken OR
    - Regular ICS or ICS-LABA every day, plus as needed SABA OR
    - Maintenance and reliever treatment with ICS-formoterol
- Single Maintenance and Reliever Therapy is often referred to as "SMART" and evidence is only with budesonide-formoterol. Maintenance dose is adjustable but should be a minimum of 2 doses per day. This can be given as 2 doses once daily or 1 dose twice daily.
    - Move Advair® Diskus (fluticasone/salmeterol) QTY LIMIT: 3 inhalers/90 days to preferred.
    - Move Fluticasone/salmeterol inhalation Powder (compare to Advair® Diskus) QTY LIMIT: 3 inhalers/90 days to non-preferred.
    - Add Budesonide/formoterol (compare to Symbicort®) QTY LIMIT: 9 inhalers (91.8gm)/90 days to non-preferred.
    - Update Symbicort quantity limit to 9 inhalers/90 days
        - Clinical criteria:
            - Fluticasone/salmeterol powder (authorized generic), Wixela Inhub: A clinically compelling reason must be provided detailing why the patient is unable to use Advair HFA or Adviar Diskus.

- AirDuo Respiclick, Breo Ellipta, Fluticasone/Salmeterol (non-authorized generics): The patient has had a documented side effect, allergy, or treatment failure to any 2 of the following: Advair HFA, Advair Diskus, Dulera, or Symbicort.
- Budesonide/formoterol: the patient has a documented intolerance to brand Symbicort

Public Comment: No comment.

Board Decision: The Board unanimously approved the above recommendation.

Sickle Cell Disease Therapies

- Remove Nutrestore (L-glutamine powder or oral solution) from the PDL. It has been discontinued.
  - Clinical criteria:
    - Update Endari: Indication for use is to reduce the acute complications of Sickle Cell Anemia AND medication will be approved with quantity limits based on patient weight (< 30kg = 2 packets/day, 30-65 kg = 4 packets/day, > 65kg = 6 packets/day
    - Remove Nutrestore clinical criteria.

Public Comment: No comment.

Board Decision: The Board unanimously approved the above recommendation.

Vaginal Anti-infectives

- Move Nuvessa Vaginal® (metronidazole vaginal gel 1.3%) to preferred.
- Update Vandazole: The patient has had a documented side effect, allergy, or treatment failure to a preferred metronidazole vaginal gel.

Public Comment: No public comment

Board Decision: The Board unanimously approved the above recommendation.

12. General Announcements:

- Benadryl (diphenhydramine): Drug Safety Communication - Serious Problems with High Doses of the Allergy Medicine https://www.fda.gov/safety/medical-product-safety-information/benadryl-diphenhydramine-drug-safety-communication-serious-problems-high-doses-allergy-medicine?utm_medium=email&utm_source=govdelivery

- Invokana, Invokamet, Invokamet XR (canagliflozin): MedWatch Safety Alert - Boxed Warning about Risk of Leg and Foot Amputations Removed

https://www.fda.gov/safety/medical-product-safety-information/invokana-invokamet-invokamet-xr-canagliflozin-medwatch-safety-alert-boxed-warning-about-risk-leg-and?utm_campaign=FDA%20MedWatch%20-%20Invokana%2C%20Invokamet%2C%20Invokamet%20XR%20%28canagliflozin%29%3A%20MedWatch%20Safety%20Alert&utm_medium=email&utm_source=Eloqua

Public Comment: No public comment.

Board Decision: No action needed.

13. Adjourn: Meeting adjourned at 8:05 p.m.