

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

October 22, 2024: 5:00 - 8:00 p.m.

Board Members Present:

Andy Miller, RPH	Anne Daly, PharmD	Douglas Franzoni, PharmD
Katharina Cahill, PharmD	Bram Starr, MD	Louise Rosales, APRN
Rima Carlson, MD	Julie MacDougall, PharmD	

Board Members Absent: None

DVHA Staff Present:

Carrie Germaine	Lisa Hurteau, PharmD	Ashley MacWalters
Taylor Robichaud, PharmD	Michael Rapaport, MD	

Change Healthcare Staff Present:

Upasana Bhatnagar, MD Mike Ouellette, RPh Molly Trayah, PharmD

Guests/Members of the Public: Angela Hathaway, Adam Ferguson, Jigna Bhalla, Chad Bohigian, Cole Wyrough, Corey O'Brien, Dennis Sholler, Kristin DiDesidero, Bryan Dillon, Susan Donnelly, Scott Ebersol, Elena Fernandez, Jai Persico, Jalal Nait Hammoud, James Sharp, Jennifer Golwyn, Richard Junk, Kevin Gaffney, Kim Ahearn, Kristen Chopas, Vincent Lawler, Mark Golick, Timothy McSherry, Nick Boyer, Nicole Pinkerton, Nikhil Kacker, Amy Cunningham, Omer Oziz, Paul Isikwe, Ryan Miller, Matt Sankey, Daniel Shan, Sharmi Patel, Timothy Birner, Tina Hartmann, Nicole Trask, Annie Vong, Megan Walsh, Lindsey Walter, Joseph Ward

Executive Session

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

Introductions

o Attendance was called and introductions to DVHA and Optum staff were made

• Julie MacDougall, PharmD was introduced as a new member to the board. She is the Coordinator of Specialty Pharmacy Quality and Outcomes and Resident Program Coordinator of the PGY1 Ambulatory Pharmacy Residency Program at UVM Medical Center. Additionally, she has extensive experience as an inpatient pharmacy and transplant clinician.

DVHA Pharmacy Administration Updates: Lisa Hurteau, PharmD

 Status of the annual best practice/cost control report, due to the state by October 30, 2024. Final report will be sent to DURB members and posted on the DVHA



website. This report outlines pharmacy spending over the previous year and includes gross spending reports on top 10 drugs and therapeutic classes.

- Reminder of public speaker time limits given the full agenda and number of speakers
- Shared proposed dates of 2025 DURB meetings and discussed potential to change to Thursday meeting date. Will update once a final schedule has been agreed upon.

DVHA Chief Medical Officer Update: Michael Rapaport, MD

- Additional announcement of the new DVHA Commissioner, DaShawn Groves. Unfortunately, he was unable to attend the meeting.
- Update provided on Comprehensive Chronic Pain Pilot:
 - Integrates alternative therapies with traditional treatments
 - Aims to evaluate its impact on opioid prescriptions, pain medication usage, emergency department visits, and inpatient admissions
 - Goal from a pharmacy standpoint is to see a reduction in costs and appropriate care
 - Ex: Patient with Ankylosing Spondylitis has an increase in cost because of Humira treatment, however, now has appropriate disease treatment
 - Received funding through next year, and are hopeful the program will be able to enroll the target of 100 members
 - In November Dr. Rapaport will be collaborating with folks from the pain clinic on speakers panel at the NIH on integrative and complementary health.

Follow-up Items from Previous Meetings

• Approval of September DUR Board minutes

Board Decision: The Board unanimously approved the above recommendations.

<u>RetroDUR/ProDUR</u> <u>Consent Agenda Items</u> <u>Clinical Update</u> Therapeutic Drug Classes- Periodic Review

• None at this time

Review of Newly Developed/Revised Criteria

• ADHD Agents

- Move Methylin to non-preferred
 - Clinical Criteria:
 - Update **Adderall, Focalin, Methylin, Ritalin**: the patient must have had a documented intolerance to the preferred generic equivalent.



- o Move Adderall XR to non-preferred
 - Clinical Criteria:
 - Update: Adderall XR: Patient must have a documented intolerance to generic product
- o Move Qelbree to preferred, after clinical criteria are met
 - Clinical Criteria:
 - Update **Qelbree:** The patient has had a documented side effect, allergy, contraindication, or treatment failure to two preferred stimulants OR atomoxetine.

Board Discussion: A board member inquired about the process for forcing a switch in members from generic to brand Adderall XR. They expressed concern about pharmacies being left with excessive stock of brand product. DVHA staff explained that a notification would go out ahead of the January 1, 2025, changes so that pharmacies and providers will be informed of the upcoming changes.

Board Decision: The Board unanimously approved the above recommendations.

• Anticonvulsants

Recommendation:

 Remove Diastat from PDL as product has been discontinued by the manufacturer

Board Decision: No vote required

• Pulmonary Agents

Recommendation:

- Add tiotropium bromide to non-preferred
 - Clinical Criteria
 - Add Tiotropium Bromide: The patient has had a documented intolerance to brand Spiriva
- Add Sandoz labeler to preferred albuterol HFA inhalers
 - Update Albuterol HFA (Preferred products are Teva labeler code 00093 and Sandoz labeler code 00781)
- Remove ProAir Digihaler from PDL, as product removed from market by manufacturer
- Remove age criteria from Asmanex HFA and make preferred for all ages

Public Comment: Jigna Bhalla, PharmD from AstraZeneca highlighted the attributes of Airsupra (albuterol/budesonide)



Board Decision: The Board unanimously approved the above recommendations.

• Anti-Diabetic Agents

Recommendation:

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- Move Fiasp (insulin aspart to preferred)
- Move Humalog (insulin lispro) Kwikpen U-200 and Novolog (insulin aspart to non-preferred
 - O Clinical Criteria
 - Update Non-preferred rapid-acting insulin: Patient has been started and stabilized on the requested medication. (Note: samples are not considered adequate justification for stabilization) OR patient has had a documented side effect, allergy OR treatment failure to two preferred formulations of rapid-acting insulin.
 - Update: Additional criteria for Lyumjev: Patient has had a documented side effect, allergy, or treatment failure to Fiasp.
- Update Intermediate-acting insulin criteria
 - o Clinical Criteria
 - Update criteria to include Humulin R and Novolin R
 - Move Tresiba (insulin degludec) to non-preferred
 - o Clinical Criteria
 - Update Non-preferred long-acting insulin products: Patient has had a documented side effect, allergy or treatment failure to two preferred long-acting insulin products.
 - Update Insulin Degludec: Patient has had a documented side effect, allergy or treatment failure to Tresiba
- Move Humulin 70/30 (NPH/Regular) insulin to preferred
- o Move Rybelsus (semaglutide) to preferred, after clinical criteria are met
- Move Ozempic (semaglutide) to non-preferred
 - Clinical Criteria
 - Add criteria for Ozempic: patient has a documented side effect, allergy, contraindication, or treatment failure with Trulicity. Treatment failure is defined as <1% reduction in HbA1c after 12 weeks at the maximally tolerated dose.
 - Existing patients will be grandfathered for continued approval.
 - Update Additional criteria for Adlyxin, Byetta, Bydureon BCise, Mounjaro: patient has a documented side effect, allergy, contraindication, or treatment failure with one preferred GLP-1 Receptor Agonist AND Ozempic. Treatment failure is defined as <1% reduction in HbA1c after 12 weeks at the maximally tolerated dose.
- \circ Move dapagliflozin and Invokana (canagliflozin) to non-preferred
 - Clinical Criteria



- Update Dapagliflozin, Steglatro: Patient has a documented side effect, allergy, or contraindication to two preferred SGLT2 inhibitors.
- Move Synjardy XR (empagliflozin/metformin ER) to preferred
- Move Invokamet (canagliflozin/metformin) to non-preferred
 - Clinical Criteria
 - Update Invokamet, Invokamet XR, Segluromet, Xigduo XR: The patient has documentation of a failure of therapy with a preferred SGLT2 inhibitor used in combination with metformin/metformin XR.

Board Discussion: A board member requested consideration of grandfathering in members who are stable on long-acting insulins instead of forcing a switch, as they have historically seen breakthroughs when patients are switched between products. Additional discussion explained that the ultra-long acting can be interchangeable and are not reached for first by providers, but instead provide more options for patients when a large dose is needed, and this can be delivered in a smaller volume. DVHA and Optum staff proposed rolling start to the change to allow members time to make the switch to the preferred product. The original board member felt comfortable with the proposed change after discussion.

Board Decision: The Board unanimously approved the above recommendations.

Antipsychotics
 Children < 18 years old

Recommendation:

- Move olanzapine orally disintegrating tablets (ODT) to preferred
 - Clinical Criteria
 - Update Asenapine, Saphris: patient has had a documented side effect, allergy or treatment failure with at least two preferred products (typical or atypical antipsychotics) one of which is risperidone or olanzapine ODT. For approval of Saphris, patient must have a documented intolerance to asenapine.
- Antipsychotics Adults

- \circ Move olanzapine orally disintegrating tablets (ODT) to preferred
 - Clinical Criteria
 - Update Asenapine, Saphris: The indication for use is the treatment of schizophrenia/schizoaffective disorder or bipolar



disorder AND the patient has had a documented side effect, allergy or treatment failure with at least two preferred products (typical or atypical antipsychotics) one of which is risperidone or olanzapine ODT. For approval of Saphris, patient must have a documented intolerance to asenapine.

- Add indication to Rexulti (brexipiprazole) for treatment of agitation associated with dementia due to Alzheimer disease
 - o Clinical Criteria
 - Update Rexulti: Indication for use is schizophrenia or agitation associated with dementia due to Alzheimer disease: the patient has had a documented side effect, allergy or treatment failure with at least three preferred products (typical or atypical antipsychotics), one of which must be aripiprazole
- Move Rykindo (risperidone injection, extended release) to preferred
- Move risperidone ER suspension and Zyprexa Relprevv (olanzapine pamoate) to non-preferred
 - Clinical Criteria
 - Update Risperidone ER Injection: The patient has had a documented side effect, allergy, or treatment failure with Risperdal Consta
 - Update Zyprexa Relprevv: The indication for use is the treatment of schizophrenia/schizoaffective disorder AND The patient has had a documented side effect, allergy or treatment failure with a preferred product

Public Comment: Joe Ward from Abbvie highlighted the attributes of Vraylar; Omer Aziz from Teva highlighted the attributes of Uzedy, in addition he asked for board to consider requirement of step-through of Perseris for use of Uzedy when the manufacturer has halted sales; Timothy Birner from Alkermes yielded his time back to the board. Dennis Sholler of Intra-Cellular Therapies highlighted the attributes of Caplyta.

Board Discussion: DVHA informed Dr. Aziz that they would investigate the availability of Perseris further and update criteria if needed.

Board Decision: The Board unanimously approved the above recommendations.

Cardiovascular

- o Move Hemangeol (propranolol) oral solution to non-preferred
 - Clinical Criteria
 - Update **Hemangeol:** Indication for use is the treatment of proliferating infantile hemangioma and the patient is initiating treatment at ages 5 weeks to 5 months AND patient has had a documented side effect, allergy, or treatment failure with



propranolol generic solution.

- Add new subcategory: Major Adverse Cardiovascular Events (MACE) Reduction.
 - Add Wegovy (semaglutide) to non-preferred
 - Clinical Criteria
 - Add Wegovy:
 - Patient has BMI > 27 kg/m², and is not being used for weight loss only
 - Patient has history of at least one of the following:
 - Stroke
 - Myocardial Infarction
 - Symptomatic peripheral arterial disease
 - Patient does not have diagnosis of diabetes, end stage renal disease/dialysis, or NYHA class IV heart failure
 - Patient has received counseling on chronic weight management (increased physical activity and a reduce calorie diet) and will continue to follow a treatment plan
 - Initial approval will be for 6 months, for reapproval: Patient must continue to follow a reduced calorie diet and increased physical activity plan AND patient has shown a documented weight loss of > 5% of baseline body weight OR continued to maintain initial 5% weight loss

Public Comment: Corey O'Brien from Novo Nordisk yielded time back to the board on discussion of Wegovy. Mr. O'Brien updated the board on potential updates to Ozempic FDA labeling for patients with type 2 diabetes and chronic kidney disease.

Board Discussion: A board member asked about the exercise and nutrition requirements under the proposed criteria. DVHA and Optum staff explained that a plan, not a formal program, would be preferred on prior authorizations.

Board Decision: The Board unanimously approved the above recommendations.

Cytokines

- Move adalimumab-adbm to preferred for all categories
 Ankylosing Spondylitis
 - Add Simponi (golimumab) Aria vial to non-preferred (age > 18)
 - Clinical Criteria:
 - Update Additional criteria for Cimzia, Simponi, Taltz, Xeljanz, Xeljanz XR: the patient had a trial and failure or



contraindication to a preferred TNF Inhibitor.

- Add Additional criteria for Simponi Aria: The patient has not responded adequately to Simponi subcutaneous AND The prescriber must provide a clinically valid reason why at least 2 preferred agents cannot be used
- Gastrointestinal agents (IBD/Crohns)
 - Move Skyrizi (risankizumab-rzaa) to preferred, after clinical criteria are met
 - Clinical Criteria
 - Update Avsola, Humira, Inflectra, Skyrizi: The patient has had a treatment failure with at least one conventional agent (e.g. methotrexate, corticosteroids) OR there is evidence of severely active disease and early introduction of a biologic without prior medication trials is medically necessary.
 - Add Entyvio (vedolizumab) subcutaneous to non-preferred with quantity limit 216mg (2 Pens) per 28 days)
 - Add Tremfya (guselkumab) to non-preferred
 - Clinical Criteria
 - Update Entyvio, Omvoh, Simponi, Stelara, Tremfya, Velsipity, Zeposia: 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 biologic.
 - Update Remicade criteria for biosimilars
 - Update Remicade, Renflexis, Zymfentra: The patient must be unable to use Avsola or Inflectra. For approval of Zymfentra, the patient must have had a documented side effect, allergy, or treatment failure with a Humira
- -Hidradenitis Suppurativa
 - No additional changes
- -Psoriasis
 - Move Skyrizi (risankizumab-rzaa) to preferred, after clinical criteria are met
 - Clinical Criteria: Follow general criteria for all drugs
 - Move Cimzia and Sotyktu into new criteria section
 - Update Additional Criteria for Taltz, Cimzia, Sotyktu: The prescriber must provide evidence of a trial and failure or contraindication to a preferred TNF Inhibitor.
 - Move Bimzelx and Illumya into new criteria section
 - Update Additional Criteria for Bimzelx, Illumya, Stelara: The prescriber must provide evidence of a trial and failure or contraindication to a preferred TNF Inhibitor, Taltz, and either Tremfya or Skyrizi.
 - Move tazarotene cream and gel and Vtama (tapinarof) cream to



preferred

-Rheumatoid, Juvenile, and Psoriatic Arthritis

- Move Skyrizi (risankizumba-rzaa) to preferred, after clinical criteria are met
 - Clinical Criteria: Follow general criteria for all drugs
- Move Tyenne (toclizuman-aazg) to preferred
- Update Actemra, Kevzara, Orencia, and Tremfya additional criteria: The prescriber must provide clinically valid reason why at least 2 preferred agents cannot be used. For approval of Actemra, patient has had a documented side effect, allergy, or treatment failure Tyenne.
- Update Stelara Criteria: the prescriber must provide evidence of a trial and failure or contraindication to a preferred TNF Inhibitor, Taltz, and Tremfya

Public Comment: Nicole Trask of Johnson & Johnson highlighted the attributes of Tremfya for moderately to severely active ulcerative colitis; Daniel Shen of UCB highlighted the attributes of Bimzelx.

Board Decision: The Board unanimously approved the above recommendations.

• Endometriosis/Uterine Fibroids Agents

Recommendation:

- Move Orilissa (elagolix) to preferred, after clinical criteria are met
 - Clinical Criteria
 - Update Myfembree, Orilissa: 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). Note: Use of GnRH receptor antagonists will be limited to 2 years.

Public Comment. None at this time.

Board Decision: The Board unanimously approved the above recommendations.

• Gastrointestinal Agents: Bowel Prep/Laxatives

- Move Docusate enema and Enemeez enema to non-preferred
 - Clinical Criteria
 - Add Docusate enema, Enemeez enema: Patient had a trial and failure or contraindication to a preferred generic.
- Move Gavilyte-C and Golytely to preferred



Board Decision: The Board unanimously approved the above recommendations.

• Hemophilia A Treatments

Recommendation:

- Move Altuviiio (antihemophilic factor (recombinant), Fc-VWF-XTEN fusion protein-ehtl) to preferred
 - Clinical Criteria
 - Update Adynovate, Elocate, Esperoct: Documentation must include why the member is unable to use the preferred extended half-life concentrate Jivi or Altuviiio.
- o Move Advate, Afstyla, Kogenate, and Recombinate to non-preferred
 - o Clinical Criteria
 - Existing patients receiving Advate will be grandfathered for continued approval.
 - Add Afstyla, Kogenate, Recombinate, Advate: Documentation must be provided why member is unable to use each of the preferred non-extended concentrates.

Public Comment: Nikhil Kacker of Genentech yielded his time back to the board.

Board Decision: The Board unanimously approved the above recommendations.

• Hyperammonia Treatments

Recommendation:

- Move Carbaglu (carglumic acid) to preferred, after clinical criteria are met
- Move Carglumic acid to non-preferred
 - o Clinical Criteria
 - Update Carbaglu, Carglumic Acid: The diagnosis or indication for the requested medication is hyperammonemia due to N-acetylglutamate synthetase (NAGS) deficiency, propionic acidemia, or methylmalonic acidemia AND The prescriber is a specialist in metabolic disorders (e.g., medical geneticist) or prescriber is in consultation with a specialist AND for approval of generic product, the patient has had a documented intolerance to the brand equivalent of the requested product.

Public Comment: None at this time.

Board Decision: The Board unanimously approved the above recommendations.



• Immunologic Therapies for Asthma

Recommendation:

- Add criteria for diagnosis of IgE mediated food allergy to Xolair
 - Clinical Criteria
 - The patient must be 1 year of age or older AND, the patient has a diagnosis of IgE-mediated food allergy to at least one of the following: cashew, egg, hazelnut, milk, peanut, walnut, wheat AND
 - Patient has an IgE level ≥ 30 and ≤ 1850 IU/mI AND
 - Prescriber is an allergist or immunologist AND
 - The patient has history of significant symptomatic allergic reaction that was demonstrated through signs and symptoms (hives, swelling, wheezing, hypotension, or gastrointestinal symptoms)
 - For continuation of therapy after the initial 6 month authorization, the patient must have clinical documentation of food avoidance, a positive clinical response to therapy, and confirmed adherence to treatment.
- Add criteria for diagnosis of COPD to Dupixent
 - Clinical Criteria
 - The patient must have a diagnosis of COPD
 - The patient must have an eosinophilic count of \geq 300 cells per mcL within 12 months prior to initiation of therapy
 - The patient must have post-bronchodilator FEV1/FVC < 0.7 and FEV1 30-70% of predicted
 - The patient has a history of uncontrolled disease, as indicated by ≥ 2 moderate of ≥ 1 severe exacerbation despite being on standard of care defined as triple therapy (LAMA+LABA+ICS) for at least 3 months prior to request, and at a stable dose for at least 1 month

prior. Note: LAMA+LABA allowed if ICS is contraindicated. Pharmacy claims will be evaluated to assess compliance with therapy. AND

- The prescriber is a pulmonologist
- If the member is a current tobacco user, they must receive tobacco cessation counseling
- Update age limits for use of Dupixent in Chronic Rhinosinusitis with Nasal Polyps
 - \circ Clinical Criteria
 - Patient is 12 years of age or older
- Update age limits for use of Dupixent in Eosinophilic Esophagitis
 - o Clinical Criteria
 - Patient is 1 year of age or older, weight at least 15 kg

Public Comment: Nikhil Kacker of Genentech highlighted the attributes of Xolair;



Jigna Bhalla, PharmD from AstraZeneca highlighted the attributes of Fasenra, updating the board on the expanded labeling of Fasenra for the use in patients with a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA)

Board Decision: The Board unanimously approved the above recommendations.

• Dermatological Agents

Recommendation:

- Move Opzelura (ruxolitinib) to preferred, after clinical criteria are met
 - Clinical Criteria
 - Update quantity limit to not exceed 4 tubes per year
- Move criteria for Dupixent in the treatment of Prurigo Nodularis to Dermatological Agents of the PDL

Public Comment: None at this time.

Board Decision: The Board unanimously approved the above recommendations.

• Movement Disorders

Recommendation:

- Move tetrabenazine to preferred
- Update criteria for Austedo, Austedo XR, and Ingrezza to highlight requirement of step through of tetrabenazine for the treatment of Huntington's Disease
 - Update Austedo, Austedo XR, Ingrezza: The diagnosis or indication for the requested medication is Huntington's Disease (HD) with chorea or Tardive Dyskinesia (TD) AND the results of an Abnormal Involuntary Movement Scale (AIMS) exam have been submitted AND the patient is ≥18 years of age. If the request is for Huntington's Disease (HD) with chorea, patient has documented side effect, allergy, or treatment failure with tetrabenazine. For re-approval, there must be documented clinical improvement.

Public Comment: Omer Aziz from Teva yielded his time back to the board; Mark Golick from Neurocrine Biosciences highlighted the attributes of Ingrezza and asked for clarification with the step through requirement of tetrabenazine.

Board Discussion: Optum staff clarified the step through requirement of tetrabenazine is only for the diagnosis of Huntington's Chorea.

Board Decision: The Board unanimously approved the above recommendations.

• Multiple Sclerosis Medications



Recommendation:

- Update Glatiramer and Glatopa criteria
 - o Clinical Criteria
 - Update Glatiramer, Glatopa: Patient is ≥ 18 years AND diagnosis of relapsing forms of Multiple Sclerosis AND the provider provides a clinical reason why Copaxone cannot be prescribed. For Glatopa: Clinical reason why Glatiramer cannot be used.

Public Comment: Paul Isikwe from Biogen highlighted the attributes of Vumerity.

Board Decision: The Board unanimously approved the above recommendations.

Botulinum Toxins

Recommendation:

- Move Botox (onabotulinumtoxinA) and Dysport (abobotulinumtoxinA) to preferred, after clinical criteria are met
 - o Clinical Criteria
 - No changes to criteria for approval of all drugs

Public Comment: None at this time

Board Decision: The Board unanimously approved the above recommendations.

• Ophthalmic Agents

Recommendation:

- Move Flarex (fluorometholone acetate) to non-preferred
 - o Clinical Criteria
 - No changes to criteria for non-preferred agents
- Move Eysuvis (loteprednol etabonate ophthalmic suspension) to preferred
- Move Acular LS (ketorolac), flurbiprofen 0.03% ophthalmic solution, and Nevanac (nepafenac) to preferred

Public Comment. None at this time

Board Decision: The Board unanimously approved the above recommendations.

• Pulmonary Arterial Hypertension Agents

- o Move sildenafil suspension to preferred, after clinical criteria are met
 - o Clinical Criteria
 - No changes to criteria



Board Decision: The Board unanimously approved the above recommendations.

• Sickle Cell Agents

Recommendation:

- Remove Oxbryta tablet and oral suspension from PDL as product as been removed from the market
 - Clinical Criteria Remove requirement to step-through Oxbryta for approval of Adakveo

Public Comment. Jalal Nait Hammoud from Medunik USA highlighted the attributes of Siklos.

Board Decision: No vote required

• Thyroid Agents

Recommendation:

- Move Ermeza (levothyroxine) to preferred, after clinical criteria are met
 Clinical Criteria
 - Update Ermeza: The patient has a medical necessity for a nonsolid oral dosage form (dysphagia)
 - Update Thyquidity, Tirosint-Sol: The patient has a medical necessity for a non-solid oral dosage form and the medication cannot be administered by crushing oral tablets AND the patient must have documented intolerance to Ermeza.

Public Comment: None at this time

Board Decision: The Board unanimously approved the above recommendations.

• Urinary Antispasmodics

- Move Toviaz (fesoterodine) to non-preferred
 - o Clinical Criteria
 - Update Darifenacin ER, Detrol, Detrol LA, Ditropan XL, Flavoxate, Toviaz, trospium ER (generic), Vesicare: The patient has had a documented side effect, allergy, or treatment failure with two preferred long-acting agents. If a medication has an AB rated generic, there must have also been a trial of the generic formulation.



Board Decision: The Board unanimously approved the above recommendations.

• Vaginal Anti-infectives

Recommendation:

- Move Cleocin (clindamycin) vaginal cream 2% to preferred
- Move Xaciato (clindamycin) to preferred
- Move Clindamycin vaginal cream 2% to non-preferred
 - Clinical Criteria
 - Update Clindesse, Clindamycin: The patient has had a documented side effect, allergy, or treatment failure to a preferred Cleocin vaginal cream.

Public Comment: None at this time

Board Decision: The Board unanimously approved the above recommendations.

General Announcements

- FDA safety communications shared
 - FDA adds warning about rare occurrence of serious liver injury with use of Veozah (fezolinetant) for hot flashes due to menopause
 - FDA is alerting patients and health care professionals about the voluntary withdrawal of Oxbryta from the market due to safety concerns

Board Discussion: Group shared in open discussion regarding the accelerated approval of medications and safety impacts on the population.

Adjourn

8:02 pm

