Department of Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes
October 22, 2019

Board Members:

Present:

Clayton English, PharmD	Jocelyn Van Opdorp, PharmD	Renee Mosier, PharmD
Zail Berry, MD	Bill Breen, RPh	Louise Rosales, NP
Joseph Nasca, MD	Claudia Berger, MD	Patricia King, MD

Absent: Marc Pasanen, MD, Margot Kagan, PharmD

Staff:

Laurie Brady, RPh, Change HealthCare	Mary Pion, RPh, Change HealthCare	Jeffrey Barkin, MD, Change Healthcare
Carrie Germaine, DVHA	Mike Ouellette, RPh, Change Healthcare	Lisa Hurteau, PharmD, DVHA
Jason Pope, DVHA	Nancy Hogue, PharmD, DVHA	Scott Strenio, MD, DVHA

Guests:

Franco Casagrande, Abbvie	Jessica Kritzman, Amgen	Jai Persico, Neurocrine
Megan Walsh, Abbvie	Adan Sosa, Sunovin	Michael Armlin, Johnson &Johnson
John Meyer, Avexis	Bryan Dillon, Otsuka	Laura Sedita, Novo Nordisk
Jane Guo, Otsuka	Ahmad Nessar, Amgen	Chadwick Larson, BMS
John Ryan, Pfizer	Paul Isikwe, Teva	Janice Waterman, The Health Ctr

1. Executive Session:

- An executive session was held from 5:00 p.m. until 6:05 p.m.

2. Introductions and Approval of DUR Board Minutes:

- Introductions were made around the table.
- The September meeting minutes were accepted as printed.

3. DVHA Pharmacy Administration Updates: Nancy Hogue, PharmD DVHA

- Annual Best Practices Cost Control report is currently being worked on and will be final by Nov 1st. The full report is public and will be posted on both DVHA and legislative site.

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

- There is a new Secretary of the agency, Mike Smith.

5. Follow-up Items from Previous Meetings: Laurie Brady, RPh, Change Healthcare

- None at this time.

Recommendation:

Public Comment: No public comment.

Board Decision: None needed.

6. RetroDUR/DUR: Laurie Brady, RPh, Change Healthcare,

- None at this time

Recommendation:

Public Comment: No public comment.

Board Decision: None needed.

7. Clinical Update: Drug Reviews: Jeffrey Barkin, MD, Change Healthcare and Laurie Brady RPh, Change Healthcare

Biosimilar Drug Reviews:

- None at this time

Full New Drug Reviews:

- None at this time.

8. New Therapeutic Drug Classes

- None at this time.

9. Therapeutic Drug Classes- Periodic Review: Jeffrey Barkin, MD, Change Healthcare and Laurie Brady, RPh, Change Healthcare

- None at this time.

Recommendation:

- No changes at this time.

Public Comment: No public comment

Board Decision: None needed.

10. Review of Newly-Developed/Revised Criteria – All changes will take effect 1/1/2020

- **ADHD**

Recommendation:

- Remove METADATE ER® (compare to Ritalin® SR) and KAPVAY® (clonidine extended release) Tablet from the PDL.
- Move Methylphenidate (compare to Ritalin ®) chewable tablets, Daytrana® (methylphenidate) patch Quantity Limit = 1 patch/day and Clonidine ER

(compare to Kapvay®) Quantity Limit = 4 tablets/day to non-preferred. Grandfather existing users.

- Move Methylphenidate SA OSM to preferred (authorized generic, Patriot labeler code 10147 is the only preferred generic).
- Add Amphetamine Sulfate (compare to Evekeo) and Evekeo® ODT (amphetamine sulfate) to non-preferred.
    - Clinical criteria
        - Add Methylphenidate chewable tablets: patient has a documented intolerance to methylphenidate tablets and Methylin solution.
        - Update Evekeo ODT, Procentra, Dextroamphetamine oral solution: patient has a medical necessity for a non-solid oral dosage form. (eg. Swallowing disorder). AND if the request is for Evekeo ODT or Procentra, the patient has a documented intolerance to generic dextroamphetamine oral solution.
        - Add Amphetamine Sulfate, Dextroamphetamine IR, Zenzedi, Evekeo: the patient has had a documented side-effect, allergy, or treatment failure of at least 2 preferred agents (If a product has an AB rated generic, there must have been a trial of the generic.)
        - Update Methylphenidate SA OSM (non-authorized generic forms): the patient must have a documented intolerance to brand Concerta or the authorized generic (labeler 10147) methylphenidate SA OSM.
        - Add Daytrana patch: patient has a documented medical necessity for a specialty non-oral dosage form.
        - Add Clonidine ER: patient has had a documented side effect, allergy, or treatment failure to 2 preferred agents (may be stimulant or non-stimulant) OR patient has not been able to be adherent to the dosing schedule of clonidine immediate release resulting in significant clinical impact.
        - Add Xyrem: indication for use is the treatment of cataplexy or excessive daytime sleepiness in narcolepsy AND patient has had a documented side effect, allergy, or treatment failure to 2 preferred agents (may be stimulant or non-stimulant) AND patient has been enrolled in the REMS program.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendations with the change to criteria for Clonidine ER: the patient had a documented side effect, allergy, or treatment failure to Guanfacine ER.

- **AHF/Factor IX**

Recommendation:

- Move Ixinity®, Profiline® and Rixubis® to preferred.

Public Comments: Laura Sedita from Novo Nordisk: Highlighted the attributes of Rebinyn.

Board Decision: The Board unanimously approved the above recommendation

- **AHF/Factor VIII**

Recommendation:

- Move Afstyla® to preferred.
- Remove HELIXATE FS® and MONOCLATE-P ® from the PDL.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendation

- **Alzheimer's Medications**

Recommendation:

- Remove Aricept® ODT (donepezil), NAMENDA® (memantine) Oral Solution and EXELON® (rivastigmine) Oral Solution from the PDL.
- Move Donepezil (compare to Aricept ®) Tablet 23 mg, Donepezil ODT (compare to Aricept® ODT) Quantity Limit = 1 tablet/day, Galantamine tablet (compare to Razadyne® Tablet), Galantamine ER capsule (compare to Razadyne® ER), Rivastigmine (compare to Exelon®) capsule Quantity Limit = 2 capsules/day and Exelon® (rivastigmine transdermal) Patch Quantity Limit= 1 patch/day to non-preferred. Grandfather existing users.
- Add Memantine Oral Solution and Memantine XR (compare to Namenda® XR) Oral Capsule Quantity Limit = 1 capsule/day to non-preferred.
    - Clinical criteria
        - Update Donepezil Tablet 23mg, Galantamine Tablet, Galantamine ER Capsule, Razadyne Tablet, Razadyne ER Capsule, Rivastigmine capsule: diagnosis or indication for the requested medication is Alzheimer's disease. AND patient has been started and stabilized on the requested medication (Note: samples are not considered adequate justification for stabilization) OR patient had a documented side effect, allergy or treatment failure to donepezil. AND if the product has an AB rated generic, the patient has a documented intolerance to the generic.
        - Update Exelon patch, Donepezil ODT, Galantamine Oral Solution, Rivastigmine patch: diagnosis or indication for the requested medication is Alzheimer's disease. AND medical necessity for a specialty dosage form has been provided AND for approval of

Exelon patch the patient has a documented intolerance to the generic formulation.
- Add Memantine Oral Solution: medical necessity for a specialty dosage form has been provided.
- Add memantine XR to the Namenda XR criteria.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendation

- **Analgesics/NSAIDS Naproxen**

Recommendation:

- Move Naproxen Sodium 275 mg and 550 mg (compare to Anaprox, Anaprox DS®) to non-preferred.
- Add NAPROXEN SODIUM OTC 220mg to preferred.
- Add Naproxen oral suspension to non-preferred.
    - Clinical criteria
        - Remove the requirement for a trial of a generic naproxen suspension for Cambia.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendation

- **Analgesics/Long-acting Opioids**

Recommendation:

- Remove EMBEDA® (morphine sulfate/naltrexone is hydrochloride) Capsules from the PDL.
- Move XTAMPZA ER® (oxycodone ER) (QTY LIMIT = 60 tabs/strength/30days) to preferred.
    - Clinical criteria
        - Update Oral Non-Preferred (except methadone & tramadol containing products): the patient has had a documented side effect, allergy, or treatment failure to morphine sulfate CR 12hr tablet (generic) AND generic fentanyl patch. (If a product has an AB rated generic, there must have been a trial of the generic). AND the patient must have a documented side effect, allergy, or treatment failure to the preferred abuse deterrent formulation (Xtampza ER) before Arymo ER, Morphabond ER, or OxyContin or will be approved.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendation

- **Anticoagulants/NOAC's**

Recommendation:

- Add Xarelto® (rivaroxaban) 2.5 mg (Quantity Limit = 2 tablets/day) to preferred after criteria are met.
  - Clinical criteria
    - Add Xarelto 2.5 mg: Patient has a diagnosis of chronic coronary artery disease (CAD) or peripheral artery disease (PAD) AND medication is being used concurrently with aspirin.

Public Comments: Chadwick Larson from BMS: Highlighted the attributes of Eliquis.

Board Decision: The Board unanimously approved the above recommendation

- **Antidiabetics/Insulin**

Recommendation:

- Move Humulin R® (Regular) U-100, Novolin R® (Regular) U-100, Humulin N® (NPH), Novolin N® (NPH), Humulin 70/30® (NPH/Regular) and Novolin 70/30® (NPH/Regular) to non-preferred. Humulin R U-500 will remain preferred.
  - Clinical criteria
    - Update Apidra, Humulin R, Novolin R, Humulin N, Novolin N: 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 Novolog or Humalog.
    - Add Humulin 70/30, Novolin 70/30: 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 Novolog Mix or Humalog Mix.

Public Comments: Janice Waterman a diabetes educator from the Health Center: Highlighted that size of devices of the GLP-1 devices is a factor in patient use.

Board Decision: The Board unanimously approved the above recommendation with a change to Humulin N and Novolin N criteria: The patient has had a documented treatment failure of at least one preferred long-acting agent (Lantus or Levemir).

- **Antihypertensives/Beta Blockers**

Recommendation:

- Move Hemangeol® oral solution (propranolol) to preferred after clinical criteria are met.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendation

- **Antipsychotics/LAIs**

Recommendation:

- Move PERSERIS® (risperidone) and ZYPREXA RELPREVV® (olanzapine pamoate) to preferred.
- Move Abilify Maintena® (aripiprazole monohydrate) to non-preferred.
    - Clinical criteria
        - Add Abilify Maintena: patient has been started and stabilized on the requested medication. (Note: samples are not considered adequate justification OR the patient is unable to tolerate Aristada.
        - Remove Perseris and Zyprexa Relprevv criteria

Public Comments: Jane Guo from Otsuka: Highlighted that attributes of Abilify Maintena.
Adan Sosa from Sunovion: Highlighted the attributes of Latuda.

Board Decision: The Board unanimously approved the above recommendation

- **Botulinum Toxins**

Recommendation:

- Move Dysport® (abobotulinumtoxinA) to preferred are clinical criteria are met.
    - Clinical criteria
        - Update Dysport (abobotulinumtoxinA): The patient has a diagnosis of cervical dystonia AND The patient is ≥18 years of age OR the patient has a diagnosis of upper or lower limb spasticity and is 2 years of age or older.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendation

- **Derm-Atopic Dermatitis**

Recommendation:

- Move Elidel®(pimecrolimus) to non-preferred.

- Add PIMECROLIMUS cream (compare to Elidel®) to preferred (authorized generic, labeler code 68682 is the only preferred form).
    - Clinical criteria
        - Revise Elidel, Pimecrolimus additional criteria: The quantity requested does not exceed 30 grams/fill and 90 grams/6 months. AND If the request is for non-authorized generic forms of pimecrolimus or Elidel, the patient has a documented intolerance to the authorized generic.

Public Comments: John Ryan from Abbvie: Highlighted the attributes of Eucrisa.

Board Decision: The Board unanimously approved the above recommendation

- **Derm-Lidocaine Patches**

Recommendation:

- Defer recommendation at this time so that more research on availability can be done.

Public Comments: None at this time.

Board Decision: None needed.

- **Derm-Scabicides**

Recommendation:

- Move Sklice® (Ivermectin 0.5 %) L to non-preferred.
    - Clinical criteria
        - Remove trial of Sklice from non-preferred pediculicides criteria.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendation

- **Endometriosis**

Recommendation:

- Move Lupaneta Pack™ (leuprolide acetate for depot suspension and norethindrone acetate tablets) Quantity Limit = 3.75 mg kit/month or 11.25 mg kit/3 months to non-preferred.
    - Clinical criteria
        - Add Lupaneta Pack: patient has a documented intolerance to Lupron Depot and norethindrone tablets used in combination.

Public Comments: Franco Casagrande from Abbvie: Deferred time back to committee.

Board Decision: The Board unanimously approved the above recommendation

- **GI-Mesalamine (Oral and Rectal)**

Recommendation:

- Move Asacol HD® (mesalamine tablet delayed release) and Pentasa ER ® (mesalamine cap CR) 500mg to preferred.
- Move Delzicol® (mesalamine capsule delayed-release) Quantity Limit = 6 capsules/day and Canasa® suppository (mesalamine) to non-preferred.
- Add Mesalamine capsule delayed release (compare to Delzicol®) Quantity Limit = 6 capsules/day and Mesalamine tablet delayed release (compare to Asacol® HD) to non-preferred.
- Add MESALAMINE SUPPOSITORY (compare to Canasa®) to preferred.
    - Clinical criteria
        - Update Delzicol, mesalamine capsule DR, mesalamine tablet DR: The patient has had a documented side effect, allergy, or treatment failure to 2 preferred oral mesalamine products.
        - Update Canasa, Sfrowasa: The patient has had a documented intolerance to mesalamine enema and suppositories.
        - Remove Pentasa 500mg criteria.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendation

- **Hematopoietics-ESA**

Recommendation:

- Move Procrit® (epoetin alpha) to non-preferred.
    - Clinical criteria
        - Update last sentence of Aranesp, Procrit, Epogen and Retacrit criteria to say: for approval of Aranesp or Procrit, the patient has had a documented side effect, allergy, or treatment failure to the preferred agents.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendation

- Platelet Stimulating

Recommendation:

- Move Promacta® (eltrombopag) to preferred after clinical criteria is met.
    - Clinical criteria
        - Update Doptelet: *Indication for use is chronic immune (idiopathic) thrombocytopenic purpura (ITP):* The patient's platelet count is less than 30,000/µL (< 30 x 10^9/L) or the patient is actively bleeding AND The patient has an insufficient response or documented intolerance to corticosteroids, immunoglobulins, or splenectomy AND Promacta. OR *Indication for use is thrombocytopenia in a patient with chronic liver disease scheduled to undergo an elective surgical or dental procedure:* The patient is at least 18 years of age AND the patient's platelet count is less than 50,000/µL (< 50 x 10^9/L) AND approval will be limited to a maximum of 5 days' supply per procedure.
        - 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 10^9/L) AND approval will be limited to a maximum of 7 days' supply per procedure.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendation

- **Hereditary Angioedema**

<u>Recommendation</u>:

- Move Cinryze® (human C1 inhibitor) (Quantity Limit =20 vials/30days), Firazyr® (icatibant) (Quantity Limit = 3 syringes (9 ml)/fill), Ruconest® (recombinant C1 esterase inhibitor) (Quantity Limit = 4 vials/fill), Takhzyro™ (lanadelumab-flyo) (Quantity Limit = 2 vials/28 days) to preferred after clinical criteria are met.
    - Clinical criteria
        - Update Berinert, Firazyr, Ruconest: The diagnosis or indication is treatment of an acute Hereditary Angioedema (HAE) attack. (Approval may be granted so that 2 doses may be kept on hand for Berinert or Ruconest and 3 doses for Firazyr).
        - Update Kalbitor: The diagnosis or indication is treatment of an acute Hereditary Angioedema (HAE) attack AND the patient has a documented side effect, allergy, treatment failure or contraindication to a preferred agent (Approval may be granted so that 2 doses may be kept on hand.
        - Update Cinryze, Haegarda, Takhzyro: The diagnosis or indication is prophylaxis of Hereditary Angioedema (HAE) attacks.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendation

- Migraine Products- CGRP Inhibitors

Recommendation:

- Move Aimovig™ (erenumab-aooe) (Quantity Limit = 1 injection (1mL) per 30 days) to preferred. Add strength clarification of 120mg/mL to the preferred formulation of Emgality® (galcanezumab-gnlm).
- Add Emgality ® galcanezumab-gnlm) 100mg/mL (Quantity limit = 300mg (3 injections) per 30 days, maximum of 6 months per year approved to non-preferred.
    - Clinical criteria
        - Update Aimovig, Ajovy, Emgality 120mg/mL : The patient is 18 years of age or older AND patient has a diagnosis of episodic migraine (4-14 headache days per month with migraine lasting 4 hours or more) or chronic migraine (≥ 15 headache days per month, of which ≥ 8 are migraine days, for at least 3 months) AND patient has failed or has a contraindication to an adequate trial (≥ 60 days) of at least TWO medications for migraine prophylaxis from at least 2 different classes (tricyclic antidepressants, SNRI's, beta-blockers, or anticonvulsants). Initial approval will be granted for 6 months. For re-approval after 6 months, the patient must have documentation of a decrease in the number of headache days per month or decreased use of acute migraine medications such as triptans. Pharmacy claims will also be evaluated to assess compliance with the medication.
        - Update Ajovy additional criteria: The patient must have a documented side effect, allergy, or treatment failure to Emgality and Aimovig.
        - Add Emgality 100mg/mL: Patient is 18 years of age or older AND Patient has a diagnosis of episodic cluster headache as defined by the following: Severe to very severe unilateral pain felt in the orbital, supraorbital, and/or temporal regions lasting 15-180 minutes (when untreated); Pain is accompanied by a sense of restlessness or agitation OR at least one of the following signs or symptoms, ipsilateral to the headache: Conjunctival injection and/or lacrimation, Eyelid edema, Miosis and/or ptosis, Nasal congestion and/or rhinorrhea, Forehead and facial sweating, Forehead and facial swelling,; Patient has ≥ 2 active cluster periods lasting 7 days to 1 year, separated by remission for periods lasting ≥ 3 months AND Patient has not achieved satisfactory response to adequate doses of corticosteroids (≥

30mg prednisone or ≥ 16mg dexamethasone daily) started promptly at the start of the cluster period (Failure is defined as the need to use acute/abortive medications (oxygen, triptans, ergotamines, lidocaine) at least once daily for at least 2 days/week after the first full week of steroid therapy) AND Patient has not achieved satisfactory response to adequate doses of verapamil (480mg/day, titrated up as needed to a max of 960mg/day) given for at least 3 weeks (Failure is defined as the need to use acute/abortive medications (oxygen, triptans, ergotamines, lidocaine) at least once daily for at least 2 days/week after 3 weeks of adequately dosed verapamil) **Note:** this requirement will be waived if the patient's 2 most recent active cluster periods were less than 3 weeks in duration.

Public Comments: Paul Isikwe from Teva: Highlighted the attributes of Ajovy.
Ahmad Nessar from Amgen: Highlighted the attributes of Aimovig.

Board Decision: The Board unanimously approved the above recommendation

- **Ophthalmics/NSAIDS**

Recommendation:

- Move Diclofenac 0.1% ophthalmic solution and Nevanac® ophthalmic suspension (nepafenac 0.1%) to preferred.
- Move Flurbiprofen 0.03% ophthalmic solution and Ilvero® ophthalmic suspension (nepafenac 0.3%) to non-preferred.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendation

- **Ophthalmics/Corticosteroids**

Recommendation:

- Move Dexamethasone sodium phosphate 0.1% solution and FML Forte® (fluorometholone) 0.25% suspension to preferred.
- Add Lotemax SM (loteprednol) 0.038% gel drops and Loteprednol suspension to non-preferred.
- Remove Omnipred® from the PDL.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendation

- **Ophthalmics/Antibiotics**

Recommendation:
Move Pred-G® (gentamicin/prednisolone) ointment, suspension to non-preferred.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendation

- **Ophthalmics/Carbonic Anhydrase Inhibitors**

Recommendation: Defer to the December meeting

Public Comments: None at this time.

Board Decision: None needed

- **Phosphate Binders**

Recommendation:
- Move Renagel® (sevelamer) and Fosrenol® (lanthanum carbonate) to non-preferred.
- Move Sevelamer carbonate tablets (compare to Renvela®) to preferred.
- Add Sevelamer hydrochloride (compare to Renagel®) to non-preferred.
    - Clinical criteria
        - Update Auryxia, lanthanum carbonate, Renagel, Renvela tablets, sevelamer hydrochloride tablets, Velphoro Chew Tablet: The patient must have a documented side effect, allergy, or inadequate response to one preferred phosphate binder.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendation

- **Resp-Inhaled Anticholinergics**

Recommendation:
- Move Combivent® Respimat (ipratropium/albuterol) Quantity Limit = 3 inhalers (12 grams)/90 days and Utibron™ Neohaler® (indaceterol/glycopyrrolate) Quantity Limit = 3 inhalers (180 blisters)/ 90 days to preferred.
- Move Tudorza® Pressair® (aclidinium bromide) Quantity Limit = 3 inhalers/90 days to non-preferred.
    - Clinical criteria

- Update Incruse Ellipta/Seebri Neohaler/Tudorza: The patient has had a documented side effect, allergy or treatment failure to Spiriva®.
- Update Stiolto Respimat: The patient has a documented side effect, allergy, or treatment failure to TWO preferred LAMA/LABA combinations.
- Remove Combivent clinical criteria.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendation

- **Urinary Antispasmodics**

Recommendation:

- Add SOLIFENACIN (compare to Vesicare®) to preferred.
- Add Darifenacin ER (compare to Enablex®) to non-preferred.
  - Clinical criteria
    - Update Darifenacin, Detrol, Detrol LA, Ditropan XL, Enablex, Tolterodine (generic), Tolterodine SR (generic), Trospium (generic), 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.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendation

- **Vaginal Anti-infectives**

Recommendation:

- Add CLOTRIMAZOLE Vaginal cream, MICONAZOLE Nitrate Vaginal cream, suppositories, MICONAZOLE 1 Vaginal Kit, MICONAZOLE 3 Vaginal Kit, cream, MICONAZOLE 7 Vaginal cream, suppositories to preferred.
- Add Gynazole-1® (butoconazole vaginal cream 2%) and Terconazole (compare to Terazol®) vaginal cream 0.4%, 0.8%, vaginal suppositories 80mg to non-preferred.
- Move VANDAZOLE (metronidazole vaginal 0.75%) to non-preferred.
  - Clinical criteria
    - Add Gynazole, Terconazole: The patient has a documented side effect, allergy, or treatment failure to a preferred miconazole or clotrimazole formulation.

- Update Metrogel Vaginal, Nuvessa Vaginal, Vandazole: The patient has had a documented side effect, allergy, or treatment failure to generic metronidazole vaginal gel 0.75 %

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendation

11. General Announcements: Michael Ouellette, RPh, Change Healthcare

Selected FDA Safety Alerts

FDA review finds no increased risk of prostate cancer with Parkinson's disease medicines containing entacapone (Comtan, Stalevo)
https://www.fda.gov/drugs/drug-safety-and-availability/fda-review-finds-no-increased-risk-prostate-cancer-parkinsons-disease-medicines-containing?utm_campaign=New%20FDA%20Drug%20Safety%20Communication%20on%20medicines%20containing%20entacapone&utm_medium=email&utm_source=Eloqua

FDA warns about rare occurrence of serious liver injury with use of hepatitis C medicines Mavyret, Zepatier, and Vosevi in some patients with advanced liver disease
https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-about-rare-occurrence-serious-liver-injury-use-hepatitis-c-medicines-mavyret-zepatier-and?utm_campaign=Hep%20C%20DSC%20liver%20injury&utm_medium=email&utm_source=Eloqua

SOVALDI and HARVONI: New dosage forms and use in pediatric patients 3 years of age to less than 12 years of age
http://s2027422842.t.en25.com/e/es?s=2027422842&e=250032&elqTrackId=376c7bc788024cd5a73d955f2e3dcbdc&elq=794ae4ee00af4d12be56b65e3ee2ce12&elqaid=9298&elqat=1

FDA warns about rare but severe lung inflammation with Ibrance, Kisqali, and Verzenio for breast cancer
https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-about-rare-severe-lung-inflammation-ibrance-kisqali-and-verzenio-breast-cancer?utm_campaign=New%20FDA%20Drug%20Safety%20Communication%20on%20Ibrance%20%28palbociclib%29%2C%20Kisqali%20%28ribociclib%29%2C%20and%20Verzenio&utm_medium=email&utm_source=Eloqua

Public Comment: No public comment.

Board Decision: No action is needed.

12. Adjourn: Meeting adjourned at 7:40 p.m.