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

May 14, 2024: 6:00 – 8:30 p.m.

Board Members Present:

	Andy Miller, RPH		**Lucy Miller, MD**		**Douglas Franzoni, PharmD**
	Margot Kagan, Pharm D		**Bram Starr, MD**		**Louise Rosales, APRN**
	Rima Carlson, MD		**Katharina Cahill, PharmD**		

Board Members Absent:

	Anne Daly, PharmD		**Mark Pasanen, MD**		

DVHA Staff Present:

	Carrie Germaine		**Lisa Hurteau, PharmD**		**Sandi Hoffman**
	Taylor Robichaud, PharmD		**Michael Rapaport, MD**		

Change Healthcare/Optum Staff Present:

	Jacquelyn Hedlund, MD		**Mike Ouellette, RPh**		

Guests/Members of the Public:
Michelle Zellner, Phong Pham, Jon Ciruso, Tina McCann, Kristen Chopas, Anita Gulmiri, Nikhil Kacker, Annie Vong, Ryan Miller, Joseph Ward, Tina Hartmann, Omer Aziz, Mark Golick, Jai Persico, Nick Boyer, Adam Denman, Kevin Gaffrey, Jessica Katzman, Tim McSherry, Nicole Pinkerton

Executive Session:

- An executive session was held from 6:00 p.m. until 6:30 p.m.

Introductions and Approval of DUR Board Minutes

- Attendance was called and introductions to DVHA and Change Healthcare/Optum staff were made.
- The February meeting minutes were accepted as printed.

DVHA Pharmacy Administration Updates: Lisa Hurteau, PharmD

- "Gold Carding" Feasibility study has been sent to the legislature and Governor Scott.
- The process to register for DURB public comment has been updated. Submission of a Public Comment Registration Form will now be necessary prior to providing comments at a DURB meeting. The form can be found on DVHA's DURB website.

DVHA Chief Medical Officer Update

- DVHA has not noted any Protected Health Information (PHI) breach from Change Healthcare cyber-security incident on February 21, 2024.
- Change Healthcare/Optum is still working to implement full prescription adjudication procedures, including prior authorizations in select areas.
- During the Change Healthcare system outage, DVHA incorporated a payment system to pharmacies based on their previous weekly averages.
  For legislative updates, a bill referred to as S.98-PDAB bill, was passed by the legislature and is currently with the governor. Another bill, H.766, requires health insurance providers to follow Medicaid's procedures for select prior authorization services and may lead to an increase in premiums.

Follow-up Items from Previous Meetings

- None at this time.

RetroDUR/Pro DUR

- None at this time.

Clinical Update: Drug Reviews: Jacqueline Hedlund, MD and Mike Ouellette, RPh Change Healthcare/Optum

Biosimilar Drug Reviews

- None at this time.

Full New Drug Reviews

- Airsupra® (albuterol/budesonide)

Airsupra® is a pressurized metered dose inhaler containing a combination of albuterol sulfate (a relatively selective, short-acting beta2-adrenergic agonist) and micronized budesonide (a corticosteroid) for oral inhalation. It is indicated for the as-needed treatment or prevention of bronchoconstriction and to reduce the risk of exacerbations in patients with asthma 18 years of age and older. The efficacy of Airsupra® was assessed in MANDALA and DENALI as described below. While patients 12 to 17 years of age were included in these trials, Airsupra® is not approved for this age group; thus, efficacy results are presented for adults only. There is some evidence in a phase 3 study to suggest that Airsupra® 180mcg/160mcg may be more effective than albuterol 180mcg regarding the primary endpoint of time to first severe asthma exacerbation; however, there is no evidence at this time to support that Airsupra® is safer or more effective than the other currently preferred, more cost-effective medications, including using the combination of budesonide and albuterol or the combination of any preferred SABA and inhaled corticosteroid. It is therefore recommended that Airsupra® remain non-preferred and require prior authorization and be available to those who are unable to tolerate or who have failed on preferred medications.

Recommendation:

- Add Airsupra® (albuterol/budesonide inhalation) to non-preferred.

- Clinical Criteria:
    - Add **Airsupra:** The patient is ≥ 18 years of age AND the patient has had a documented side effect, allergy, treatment failure or a contraindication to Symbicort and Dulera being as needed for asthma exacerbations (SMART therapy) AND the patient is unable to use Albuterol and Budesonide as individual agents.

Public Speaker: None at this time.

Board Decision: A board member asked if there are any LABA/ICS combo inhalers that are FDA approved for rescue use. Another board member confirmed that Symbicort is approved for SMART therapy. The board unanimously approved the above recommendations.

- Furoscix® (furosemide injection)

Furosemide, the active ingredient of Furoscix®, is a loop diuretic, which is an anthranilic acid derivative. It mainly inhibits the reabsorption of sodium and chloride in the proximal and distal tubules and in the loop of Henle. The high degree of diuresis is mainly due to the unique site of action. The action on the distal tubule is independent of any inhibitor effect on carbonic anhydrase and aldosterone. It is indicated for the treatment of congestion due to fluid overload in adult patients with New York Heart Association (NYHA) Class II and Class III chronic heart failure. Limitations of use include that Furoscix® is not indicated for use in emergency situations or in patients with acute pulmonary edema. The On-Body Infusor will deliver only an 80mg-dose of Furoscix®. There was no clinical trial section found in the prescribing information for Furoscix®. Furosemide has been available for many years, is available in several dosage forms, and is a safe and effective treatment. In patients with NYHA Class II-III congestive heart failure, SC infusion of Furoscix® (30mg furosemide over the first hour followed by 12.5mg per hour for the subsequent 4 hours, 80mg furosemide total), the bioavailability was 99.6% with a median Tmax of 4 hours relative to 80mg intravenous furosemide (two 40mg bolus doses separated by 120 minutes). The On-Body Infusor will deliver only an 80mg dose of Furoscix®. The single-use, On-Body Infusor with prefilled cartridge is pre-programmed to deliver 30mg of Furoscix® over the first hour followed by 12.5mg per hour for the subsequent 4 hours. This product allows for at-home treatment for patients with fluid overload, administered subcutaneously.

Recommendation:

- Add new subcategory LOOP DIURETICS
- Add Furoscix® (furosemide) injection *QTY LIMIT:* 4 injections/30 days (Maximum 30-day supply), Ethacrynic Acid (compare to Edecrin®), Edecrin® (ethacrynic acid) tablet, and Lasix® (furosemide) tablet to non-preferred.
- Add BUMETANIDE (compare to Bumex®) tablet, FUROSEMIDE (compare to Lasix®) tablet, oral solution and TORSEMIDE (compare to Demadex®) tablet to preferred.
    - Clinical Criteria:
        - Add Ethacrynic Acid, Edecrin: The patient has had a documented side effect, allergy, or treatment failure to at least two preferred agents and for Ethacrynic acid the patient has a documented intolerance to brand Edecrin.

- Add Furoscix: The indication for use is the treatment of congestion due to fluid overload in adults with NYHA Class II or Class III chronic heart failure AND the medication is being prescribed by or in consultation with a cardiologist AND the patient is experiencing symptoms despite compliance with oral loop diuretic therapy AND oral loop diuretic therapy will be resumed as soon as practical AND medical reasoning beyond convenience is provided for not pursuing therapy in an outpatient infusion setting. PA approval will be authorized for 1 month.
- Add Lasix: The patient has a documented intolerance to generic furosemide.

Public Speaker: None at this time.

Board Decision: The Board unanimously approved the above recommendations with the following modification to the Furoscix criteria: "initial prior authorization approval will be for one month. Subsequent approvals will be for one year duration."

- Lyuzeh™ (latanoprost)

Latanoprost, the active ingredient of Iyuzeh™, is a prostaglandin F2α analogue that is believed to reduce the IOP by increasing the outflow of aqueous humor. Studies in animals and man suggest that the main mechanism of action is increased uveoscleral outflow. Elevated IOP represents a major risk factor for glaucomatous field loss. The higher the level of IOP, the greater the chance of optic nerve damage and visual field loss. It is indicated for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension. There was limited information in the clinical trials section of Iyuzeh™. In randomized, controlled clinical trials of patients with open angle glaucoma or ocular hypertension with mean baseline IOP of 19-24mmHg, Iyuzeh™ lowered IOP by 3-8mmHg versus 4-8mmHg by latanoprost ophthalmic solution preserved with benzalkonium chloride. There is no evidence at this time to support that Iyuzeh™ is safer or more effective than the other currently preferred, more cost-effective medication

Recommendation:

- Add Lyuzeh™ (latanoprost) to non-preferred.
  - Clinical criteria:
    - Add Lyuzah to the Bimatoprost, Tafluprost, Travoprost, Vyzulta, Xalatan, Xelpros criteria.

Public Speaker: None at this time.

Board Decision: The Board unanimously approved the above recommendations.

- Likmez™ (metronidazole)

Metronidazole, the active ingredient of Likmez™, is a nitroimidazole antimicrobial. Once metronidazole enters the organism by passive diffusion and activated in the cytoplasm of susceptible anaerobic bacteria, it is reduced. Because of this alteration of the metronidazole molecule, a concentration gradient is created and maintained, which promotes the drug's intracellular transport. The reduced form of metronidazole and free radicals can interact with DNA, leading to inhibition of DNA synthesis and DNA degradation leading to death of the bacteria. The exact mechanism of action of metronidazole is not clear. It is indicated for the treatment of: Trichomoniasis:

- Symptomatic trichomoniasis caused by *Trichomonas vaginalis* in adult females and males when the diagnosis is confirmed by appropriate laboratory procedures.
- Asymptomatic trichomoniasis caused by *Trichomonas vaginalis* in adult females when the organism is associated with endocervicitis, cervicitis, or cervical erosion.
- Because trichomoniasis is a sexually transmitted disease with potentially serious sequelae, treat sexual partners of patients simultaneously to prevent re-infection.

Amebiasis:

- For the treatment of acute intestinal amebiasis (amoebic dysentery) and amebic liver abscess in adults and pediatric patients. In amebic liver abscess, treatment with Likmez™ does not obviate the need for aspiration or drainage of pus.

Anaerobic Bacterial Infections: Likmez™ is indicated in the treatment of the following serious infections caused by susceptible anaerobic bacteria in adults:

- Intra-abdominal infections, including peritonitis, intra-abdominal abscess, and liver abscess
- Skin and skin structure infections
- Gynecologic infections, including endometritis, endomyometritis, tubo-ovarian abscess, and postsurgical vaginal cuff infection.
- Bacterial septicemia
- Bone and joint infections (as adjunctive therapy)
- Central nervous system (CNS) infections, including meningitis and brain abscess
- Lower respiratory tract infections, including pneumonia, empyema, and lung abscess
- Endocarditis

There was no clinical trials section in the Likmez™ prescribing information. Metronidazole tablets and brand Flagyl® (metronidazole) capsules have been available for many years and have the same indications as Likmez™ suspension. It has a box warning regarding the potential for carcinogenicity. Avoid unnecessary use of Likmez™ and reserve its use only for its approved indications. There are no new clinical trials with Likmez™. Metronidazole tablets and brand Flagyl® capsules are available and have the same indications as Likmez™. Likmez™ is currently the only ready-to-use liquid oral suspension of metronidazole approved by the FDA.

Recommendation:

- Add new subcategory Nitroimidazole Antimicrobial.

- Add Likmez™ (metronidazole oral suspension) to non-preferred.
- Add metronidazole to preferred.
    - Clinical criteria:
        - Add Likmez: patient has a medical necessity for a non-solid oral dosage form.

Public Comment: None at this time.

Board Decision: The Board unanimously approved the above recommendations.

- Miebo® (perfluorohexyloctane)

Perfluorohexyloctane, the active ingredient of Miebo®, is a semi fluorinated alkane. It contains 6 perfluorinated carbon atoms and 8 hydrogenated carbon atoms. Perfluorohexyloctane forms a monolayer at the air-liquid interface of the tear film which can be expected to reduce evaporation. The exact mechanism of action for its approved indication is not known. It is indicated for the treatment of the signs and symptoms of dry eye disease (DED). In two randomized, multicenter, double-masked, saline-controlled trials (GOBI and MOJAVE), patients (N=1,217) with a history of DED and clinical signs of meibomian gland dysfunction were randomized to Miebo® or saline 0.6% to assess the safety and efficacy after receiving Miebo® QID for 57 days. The effects on symptoms of DED were assessed with the eye dryness score. At days 15 and 57, a statistically significant reduction in VAS eye dryness score favoring Miebo® was observed in both studies. Miebo® is the first and only FDA approved prescription agent for DED that directly targets tear evaporation. Head-to-head comparator studies with other agents were not found at this time.

Recommendation:

- Add Miebo® (perfluorohexyloctane ophthalmic solution) to non-preferred.
    - Clinical criteria:
        - Add Miebo: The patient has a diagnosis of Dry Eye Disease AND is ≥ 18 years of age AND has a documented side effect, allergy, treatment failure or contraindication to Restasis and Xiidra AND Miebo will not be used in combination with cyclosporine, lifitegrast or varenicline.

Public Comment: None at this time.

Board Decision: The Board unanimously approved the above recommendations.

- Rykindo® (risperidone injection, extended release)

Risperidone, the active ingredient of Rykindo®, is an atypical antipsychotic. The mechanism of action of risperidone in schizophrenia is unclear. The drug's therapeutic activity could be mediated through a combination of dopamine Type 2 (D2) and serotonin Type 2 (5HT2) receptor antagonism. The clinical effect from risperidone results from the combined concentrations of risperidone and its major active metabolite, 9-hydroxyrisperidone (paliperidone). Antagonism at receptors other than D2 and 5HT2 may explain some of the other effects of risperidone. It is indicated for the treatment of schizophrenia in adults and as

monotherapy or as adjunctive therapy to lithium or valproate for the maintenance treatment of bipolar I disorder in adults. The efficacy of Rykindo® in the treatment of schizophrenia is based on an adequate and well-controlled study with risperidone long-acting injection (intramuscular). The effectiveness of risperidone long-acting injection (intramuscular) was established, in part, on the basis of the established effectiveness of the oral formulation of risperidone as well as in a 12-week, placebo-controlled trial in adult inpatients and outpatients who met the DSM-IV criteria for schizophrenia. The results of this trial were included in the prescribing information. The efficacy of Rykindo® for schizophrenia, for maintenance treatment of bipolar I disorder as monotherapy, and as an adjunct to treatment with lithium or valproate for the maintenance treatment of bipolar I disorder, is based on an adequate and well-controlled study with risperidone long-acting injection (intramuscular). The studies in the prescribing information for Rykindo® were the same as in the prescribing information for Risperdal® Consta (a long-acting IM injection).

Recommendation:

- Add Rykindo® (risperidone injection, extended release) to non-preferred.
  - Clinical criteria:
    - Add Rykindo to Uzedy clinical criteria.

Public Comment: None at this time.

Board Decision: The Board unanimously approved the above recommendations.

- Sohonos™ (palovarotene)

Palovarotene, the active ingredient of Sohonos™, is an orally bioavailable retinoid that acts as a retinoic acid receptor (RAR) agonist with particular selectivity at the gamma subtype of RAR. It is indicated for the reduction in volume of new heterotopic ossification in adults and pediatric patients aged 8 years and older for females and 10 years and older for males with fibrodysplasia ossificans progressiva (FOP). Sohonos™ is a retinoic acid receptor agonist indicated for the reduction in volume of new heterotopic ossification in adults and pediatric patients aged 8 years and older for females and 10 years and older for males with fibrodysplasia ossificans progressiva (FOP). It carries a box warning regarding embryo-fetal toxicity and premature epiphyseal closure in growing pediatric patients. Dosing for Sohonos™ includes both chronic daily dosing and flare-up dosing. Its efficacy was assessed in a single arm study that included subjects with FOP (N=97) and utilized the Natural History Study (NHS, N=101) as an external control. The primary efficacy endpoint was annualized volume of new HO. Results suggested that the mean annualized new HO was 9.4 cm^3/year in subjects receiving the chronic/flare-up Sohonos™ treatment and 20.3 cm^3/year in untreated subjects in the NHS based on a linear mixed effect model (treatment effect was about 10.9 cm^3/year).

Recommendation:

- Add Sohonos™ (palovarotene) to non-preferred.
    - Clinical criteria:
        - Add Sohonos: The patient has a diagnosis of fibrodysplasia ossificans progressiva (FOP) AND has a confirmed R206H mutation in the activin receptor IA (ACVR1) gene AND patient is a female ≥ 8 years of age or a male ≥ 10 years of age. Initial approval will be authorized for 1 year. For re-approval, the patient must have documentation of a positive response to therapy defined as a reduction in new heterotopic ossification (HO) volume.

Public Comment: Phong Pham from Ipsen Biopharmaceuticals highlighted the attributes of Sohonos™ .

Board Decision: The Board unanimously approved the above recommendations with modification of the last line of criteria to: For re-approval, the patient must have documentation of a positive response to therapy defined as a reduction in new heterotopic ossification (HO) symptoms.

- Xdemvy® (lotilaner)

Lotilaner, the active ingredient of Xdemvy®, is a member of the isoxazoline family of compounds. It is a gamma-aminobutyric acid (GABA)-gated chloride channel inhibitor selective for mites. Inhibition of these GABA chloride channels causes a paralytic action in the target organism leading to its death. It is indicated for the treatment of Demodex blepharitis. The safety and efficacy of Xdemvy® for the treatment of Demodex blepharitis were assessed in two randomized, multicenter, double-masked, vehicle-controlled studies (Saturn-1 and Saturn-2) that were of 6 weeks duration. Patients (N=833) were randomized to either Xdemvy® or vehicle dosed twice daily in each eye. In both studies, Xdemvy® was significantly more effective than vehicle for the primary endpoint. In addition, Xdemvy® was significantly more effective than vehicle for mite eradication and erythema cure in both studies. It is currently the only FDA-approved treatment for Demodex blepharitis.

Recommendation:

- Add Xdemvy® (lotilaner ophthalmic solution) QTY LIMIT: 20 ml per approval (6 weeks of treatment) to non-preferred.
    - Clinical criteria:
        - Add Xdemvy: Patient is ≥ 18 years of age AND has a diagnosis of Demodex blepharitis AND has the presence of all the following in at least one eye: 1) more than 10 lashes with collarettes present on the upper lid (collarette scale grade 2 or worse), 2) at least mild erythema of the upper eyelid margin, and 3) average mite density of ≥1.5 mites per lash (upper and lower eyelids combined) AND symptoms persist despite the use of standard eyelid hygiene (i.e., warm compress, tea tree oil scrubs)

Public Comment: Anita Gulmiri from Tarsus Pharmaceuticals highlighted the attributes of Xdemvy.

Board Decision: The Board unanimously approved the above recommendations with modification to the clinical criteria: "Patient is ≥ 18 years of age AND has a diagnosis of Demodex blepharitis AND has the presence of the following in at least one eye: more than 10 lashes with collarettes present on the upper lid (collarette scale grade 2 or worse) AND at least mild erythema of the upper eyelid margin.

New Managed Therapeutic Drug Classes

- None at this time

Therapeutic Drug Classes – Periodic Review

Alpha-1 Proteinase Inhibitors

Recommendation:

- No change.

Anti-parasitics, Topical

Recommendation:

- Add Crotan 10% lotion to non-preferred.
    - Update clinical criteria for all nonpreferred products in this class: Non-preferred Scabicides: The patient has had a documented side effect or allergy to permethrin cream and Natroba or treatment failure with two treatments of permethrin cream and Natroba. Non-Preferred Pediculicides: The patient has had a documented side effect or allergy to OTC permethrin and piperonyl butoxide and pyrethrins and one treatment of Natroba OR treatment failure with two treatments of OTC permethrin and/or piperonyl butoxide and pyrethrins and one treatment of Natroba.

Public Comment: None at this time

Board Decision: The Board unanimously approved the above recommendations.

Atopic Dermatitis

Recommendation:

- No change.

Public Comment: Annie Vong from Abbvie highlighted the attributes of Rinvoq.

Bladder Relaxants

Recommendation:

- Move Fesoterodine ER (compare to Toviaz®) to preferred.
- Add bethanechol to preferred.
    - Clinical criteria:
        - Update Gemtesa: The patient has had a documented side effect, allergy, treatment failure, or contraindication with one preferred urinary antimuscarinic agent and Myrbetriq.

Public Comment: None at this time

Board Decision: The Board unanimously approved the above recommendations.

BPH Agents

Recommendation:

- Remove Avodart from the PDL as no longer rebated by manufacturer.

Public Comment: None at this time

Board Decision: No vote required

Hematopoietics

Recommendation:

Colony Stimulating Factors

- Move Nivestym™ (figrastim-aafi) Vial, Syringe to preferred.

Board Decision: The Board unanimously approved the above recommendations.

Erythropoiesis Stimulating Agents

- No change.

Public Comment: None at this time.

Board Decision: No vote required

Idiopathic Pulmonary Fibrosis

Recommendation:

- Move Pirfenidone (compare to Esbriet®) QTY LIMIT:267 mg tablets/capsules = 270 Tabs/Caps per month, 801 mg tablets/capsules = 90 Tabs/Caps per month to preferred.

Public Comment: None at this time

Board Decision: The Board unanimously approved the above recommendations.

Immunosuppressants, Oral

Recommendation:
- Move Azathioprine 50MG tablet to preferred,
- Move Azathioprine 75MG and 100MG tablet to non-preferred.

Public Comment: None at this time

Board Decision: The Board unanimously approved the above recommendations.

Movement Disorder Agents

Recommendation:
- No change.

Public Comment: Omer Aziz from Teva Pharmaceutical highlighted the attributes of Austedo and Austedo XR.
Mark Golick from Neurocrine Biosciences yielded time back to the Board.

Board Decision: No vote required

Select Contraceptive Products

Recommendation:
Monophasic Agents
- Remove Beyaz (drospirenone/ethinyl estradiol/levomefol) and Sayfral (drospirenone/ethinyl estradiol/levomefol) from the PDL as no longer available.
- Add Yaz (drospirenone/ ethinyl estradiol) and Yasmin 28 (drospirenone/ ethinyl estradiol) to preferred.

Biphasic Agents
- Move Lo Loestrin FE (norethindrone/ ethinyl estradiol/FE) to preferred.

Triphasic Agents
- No change.

Extended Cycle
- No change.

Progestin Only Contraceptives
- No change.

Injectable Contraceptives
- No change.

Vaginal Ring
- Add Enilloring (Etonogestrel/ethinyl estradiol vaginal ring) and Haloette (Etonogestrel/ethinyl estradiol vaginal ring) to non-preferred.

Long Acting Reversible Contraceptives (LARCs)
- No change.

Topical Contraceptives
- No change.

Vaginal Contraceptives
- No change.

Emergency Contraceptives
- No change.

Public Comment: None at this time

Board Decision: The Board unanimously approved the above recommendations.

Review of Newly-Developed/Revised Criteria
- None at this time

General Announcements
- Amylyx Pharmaceuticals Announces Formal Intention to Remove RELYVRIO®/ALBRIOZA™ from the Market

Additional Discussion

Consent Agenda
- DVHA discussed future changes to the DUR Board Agendas with the Board. DVHA intends to utilize a consent agenda, when applicable, for future meetings that would allow the Board to vote on multiple updates at once in order to expedite meetings.

Board Decision: The Board agreed with the consent agenda updates.

Adjourn **8:15 pm**