

Department of Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes
October 25, 2016

Board Members:

Present:

Zail Berry, MD
Patricia King, MD

Clayton English, PharmD
Alisson Richards, MD

Bill Breen, RPh

Absent: Louise Rosales, NP
Meghan Groth, PharmD

Staff:

Jacquelyn Hedlund, MD Change
HealthCare
Michael Ouellette, RPh Change
Healthcare
Jason Pope, DVHA

Mary Beth Bizzari, RPh, DVHA
Jennifer Egelhof, DVHA
Stacey Baker, DVHA

Carrie Germaine, DVHA
Laurie Brady, RPh, Change
HealthCare

Guests:

Thomas Algozzine, Novartis
Brad Martin, Lundbeck
Shaffee Bacchus, Janssen
Scott Williams, J & J
Zoe Washburn, ParaPro
Ricki Zepeda, ACPHS

Adam Denman, GSK
Christine Dube, MedImmune
Megan Walsh, Abbvie
Rodney Francisco, Sunovion
Brian Calamani, Abbvie

John Kirby, Sanofi
James Kokoszyna, Allergan
John Meyer, Otsuka
Patricia Toland, Lilly
Karen Phillips, Amgen

1. Executive Session:

- An executive session was held from 6:15 p.m. until 6:50 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: Mary Beth Bizzari, RPh DVHA:

- Welcomed new DUR board members Alison Richards and Bill Breen.

4. Medical Director Update: Mike Ouellette, Change Healthcare:

- Dr. Scott Strenio will be leaving the state of Vermont and will be greatly missed as a valued contributor to the DUR board.

5. Follow-up Items from Previous Meetings:

- None at this time.

6. RetroDUR/DUR: Laurie Brady, RPh Change Healthcare, Jacquelyn Hedlund, MD Change Healthcare, and Ricki Zepeda, DVHA Pharmacy Intern:

▪ Data Presentation: Use of Naltrexone in Children

Pharmacy claims were queried to look for any Naltrexone claim in patients ≤ 18 during a 2-year time period (7/1/2014 – 6/30/2016). A total of 40 patients were identified as having filled at least 1 claim for Naltrexone. The data was further analyzed to determine the frequency of prescriptions and patterns of use for these patients. Naltrexone seems to be most prescribed to older patients between the ages of 16 and 18. There were a total of 203 claims, and approximately 75% of those claims were for patients in the older age bracket. 20% of patients had only 1 claim, and those that had 2 or more claims were often filled on an inconsistent basis. It is important to note that the quantity and days' supply submitted are primarily consistent with instructions for daily use.

Recommendation: Many members had more than 1 recorded diagnosis. However, mental retardation, autism, and behavioral diagnoses are not seen. A reasonable conclusion would be that Naltrexone is not used for self-injury based on this data. These findings do not warrant further provider intervention.

Board Decision: The Board unanimously voted no action required.

▪ Introduce: Diabetes: GLP1 Receptor Agonist

GLP-1 (glucagon-like peptide 1 receptor) agonists are incretin mimetics which have several benefits for diabetes management. They suppress post-prandial glucagon release, delay stomach emptying, and increase insulin sensitivity. Significantly lower rates of hypoglycemia accompany GLP-1 therapy than many alternative hypoglycemics including insulin and sulfonylureas. This class also has the side effect of modest weight reduction and reduction of systolic blood pressure. Although they improve glycemic control, there are few long-term

studies of GLP-1 agonists to assess clinically important health outcomes (cardiovascular events, mortality), durability of weight loss, or safety. Many questions remain unanswered regarding clinical use in type 2 diabetes, including long-term benefits and risks and their role in combination with other diabetes medications.

We will use paid, non-reversed Medicaid pharmacy and medical claims data from SFY 2015 and 2016, excluding members with Part D, VMAP and Healthy Vermonters Coverage. We will look for members who are prescribed a GLP-1 medication (exenatide, liraglutide, albiglutide, dulaglutide) with a diagnosis of type II DM, assessing rates of discontinuation by drug and/or poor adherence to a prescribed regimen. We will examine this data using standard measures of compliance including the medication possession ratio (MPR). We will also assess the number and type of additional diabetic medications that a patient is on while on the GLP-1 therapy.

Recommendation: None at this time.

Board Decision: None needed at this time.

▪ **Finalized RetroDUR Initiatives for 2017**

2017 potential RetroDUR initiatives were presented as follows:

- Long term use of skeletal muscle relaxants
- Twice daily PPI use
- Second generation antipsychotics in the treatment of major depressive disorder
- Use of Fluoroquinolones
- Methadone use after prior authorization
- Short acting opiate prescribing
- Adoption of abuse deterrent formulations
- Adherence to guidelines for monitoring DMARD's

The board commented that they would like to look at skeletal muscle relaxant use for any time period greater than 1 month. They also commented that they would like to coordinate with the Vermont Department of Health regarding the short acting opiate prescribing initiative.

Recommendation: None at this time.

Board Decision: None needed at this time.

7. Clinical Update: Drug Reviews: Jacquelyn Hedlund, MD Change Healthcare and Laurie Brady, RPh Change Healthcare

Abbreviated New Drug Reviews:

- None at this time.

Full New Drug Reviews:

a) Onzetra® Xsail (sumatriptan succinate)

- Sumatriptan, the active ingredient of Onzetra® Xsail, is a selective 5-HT₁ agonist. It binds with high affinity to 5-HT_{1B/1D} receptors. It is thought sumatriptan exerts its therapeutic effects through agonist effects at the 5-HT_{1B/1D} receptors on intracranial blood vessels and sensory nerves of the trigeminal system, resulting in cranial vessel constriction and inhibition of pro-inflammatory neuropeptide release. It is indicated for the acute treatment of migraine with or without aura in adults. It is not indicated for the prevention of migraine attacks, and safety and efficacy of use have not been established for the treatment of cluster headaches. Onzetra® Xsail should only be used if a clear diagnosis of migraine has been established. If a patient has no response to the first migraine attack with Onzetra® Xsail, it is recommended to reconsider the diagnosis of migraine before treatment of subsequent attacks. The concomitant use of ergot-containing drugs, other 5-HT₁ agonists, or MAO-inhibitors with Onzetra® Xsail is contraindicated. There have been reports of serotonin syndrome with concomitant use of Onzetra® Xsail and SSRIs, SNRIs, TCAs, and MAO inhibitors. Treatment should be discontinued if serotonin syndrome is suspected. Significant increases in blood pressure, including hypertensive crisis with acute impairment of organ systems, have been reported on rare occasions in patients treated with 5-HT₁ agonists, including patients without a history of hypertension. It is recommended to monitor blood pressure in patients treated with Onzetra® Xsail. Furthermore, Onzetra® Xsail is contraindicated in patients with uncontrolled hypertension. In 2012, the National Institute for Health and Care Excellence (NICE) Guidelines on the management of headache were published (prior to the FDA approval of Onzetra® Xsail). The guidelines do not indicate one triptan is more effective than another, but rather the guidelines recommend that, when prescribing a triptan, the prescriber should start with the triptan with the lowest cost.

Recommendation: The recommendation is for Onzetra® to be non-preferred with quantity limits of 8 doses per 30 days.

Clinical Criteria: deferred until the Zembrace® review.

Public Comment: No public comment

Board Decision: The Board unanimously approved the above recommendation.

b) Zembrace® Sym Touch (sumatriptan)

Sumatriptan succinate, the active ingredient of Zembrace® SymTouch, is a selective 5-HT_{1B/1D} receptor agonist. It binds with high affinity to these receptors and it is thought that it works in the treatment of migraine through agonist effects at these receptors on intracranial blood vessels and sensory nerves of the trigeminal system. This results in cranial vessel constriction and inhibition of

pro-inflammatory neuropeptide release. It is indicated for the acute treatment of migraine with or without aura in adults. Zembrace® SymTouch is not indicated for the prevention of migraine attacks. It should be used only if a clear diagnosis of migraine has been established. If a patient has no response to the first migraine attack treated with Zembrace® SymTouch, reconsider the diagnosis before Zembrace® SymTouch is administered to treat any subsequent attacks. Dose adjustments are not required in patients with mild or moderate hepatic impairment; however, use is contraindicated in patients with severe hepatic impairment. There was no information found regarding use in patients with renal impairment. Significant increases in blood pressure, including hypertensive crisis with acute impairment of organ systems, have been reported on rare occasions in patients treated with 5-HT₁ agonists, including patients without a history of hypertension. It is recommended to monitor blood pressure in patients treated with Zembrace® SymTouch. Furthermore, Zembrace® is contraindicated in patients with uncontrolled hypertension. In 2012, the National Institute for Health and Care Excellence (NICE) Guidelines on the management of headache were published (prior to the FDA approval of Zembrace®). The guidelines do not indicate one triptan is more effective than another, but rather the guidelines recommend that, when prescribing a triptan, the prescriber should start with the triptan with the lowest cost.

Recommendation: The recommendation is for Zembrace® to be non-preferred.

Clinical Criteria for Anti-migraine Triptans:

- Remove the Sumatriptan trial for Relpax under preferred agents.
- Remove Axert from non-preferred agents.
- Move Imitrex injectable and nasal spray to non-preferred.
- Move Sumatriptan injectable and nasal spray to preferred.
- Add Onzetra® Xsail under Nasal Powder to non-preferred.
- Add Zembrace® under Injectable to non-preferred.
- Remove Zecuity transdermal from non-preferred agents.

- Under clinical criteria:
 - Remove Axert and Replax.
 - Add Imitrex Nasal Spray and Onzetra Xsail to the Zomig nasal spray criteria and replace Imitrex with Sumatriptan as a treatment failure.
 - Remove Zecuity criteria.
 - Alsuma, Imitrex, Sumavel Dose Pro Injections, Zembrace: patient has had a documented intolerance to generic sumatriptan injection.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

c) Otiprio® (ciprofloxacin)

Ciprofloxacin, the active ingredient of Otiprio®, is a synthetic fluoroquinolone antibacterial. The bactericidal action of ciprofloxacin results from interference with the enzyme DNA gyrase, which is needed for the synthesis of bacterial DNA. It is indicated for the treatment of pediatric patients with bilateral otitis media with effusion undergoing tympanostomy tube placement. Otiprio® is for intratympanic use only. Use as a single intratympanic administration of one 0.1ml dose into each affected ear, following suctioning of middle ear effusion. Otiprio® use may cause an overgrowth of non-susceptible bacteria and fungi. If infections occur, use alternative treatment. Otiprio® is FDA approved for the treatment of pediatric patients with bilateral otitis media with effusion undergoing tympanostomy tube placement. Use is not recommended in pediatric patients under the age of 6 months. Patients treated with it were found to have fewer treatment failures in clinical studies when compared to sham treatment.

Recommendation: The recommendation is for Otiprio® to be non-preferred.

Clinical criteria:

- Move Cipro-HC from Anti-infective Single Agent to Anti-infective/corticosteroid combination on preferred side.
- Clarify that Neomycin/polymyxin B sulfate/hydrocortisone solution remains preferred.
- Add Otiprio and Neomycin/Polymixin B Sulfate/Hydrocortisone suspension to non-preferred.
 - Under clinical criteria:
 - Remove individual drug specific criteria.
 - Add All non-preferred products: The patient has had a documented side effect, allergy, or treatment failure to two preferred products, one of which must be neomycin/polymixin B/hydrocortisone solution.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

d) Sernivo® spray (betamethasone dipropionate)

Betamethasone dipropionate, the active ingredient of Sernivo® Spray, is a synthetic, fluorinated corticosteroid. It is known that corticosteroids have a role in immune function, inflammation, and protein regulation; however, the exact mechanism of action of Sernivo® Spray for psoriasis treatment is not known. It is indicated for the treatment of mild to moderate plaque psoriasis in adult patients. Shake well before use, and then apply spray to

the affected skin areas twice daily for up to 4 weeks in duration. Treatment beyond 4 weeks is not recommended. Sernivo® Spray should be rubbed in gently and discontinued when control is achieved. Use should be avoided on the face, scalp, axilla, groin, or other intertriginous areas. In addition, the treated areas should not be bandaged, covered, or wrapped unless directed otherwise by a physician.

Recommendation: The recommendation is for Sernivo® spray to be non-preferred with no changes to existing criteria for approval of non-preferred agents.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

e) Taltz® Inj (ixekizumab)

Ixekizumab, the active ingredient of Taltz®, is a humanized immunoglobulin G subclass 4 (IgG4) monoclonal antibody (mAb); it selectively binds with the interleukin 17a (IL-17A) cytokine and inhibits its interaction with the IL-17 receptor. IL-17A is a naturally occurring cytokine that is involved in the normal inflammatory and immune responses, thus ixekizumab inhibits the release of pro-inflammatory cytokines and chemokines. It is indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy. It is recommended to assess for TB infection prior to starting treatment with Taltz®, and not to administer to patients with active TB. Patients receiving Taltz® should be closely monitored for signs and symptoms of active TB during and after treatment. It is recommended to complete all age appropriate immunizations prior to starting treatment with Taltz®. In addition, it is recommended to avoid the use of live vaccines in patients treated with Taltz®. There were 3 randomized, double-blind, placebo-controlled trials (Trials 1, 2 and 3) to assess for the efficacy of ixekizumab in adult patients with plaque psoriasis who had a minimum body surface area involvement of 10%, a static Physician Global Assessment (sPGA) score of ≥ 3 on the overall assessment of psoriasis (on a scale of 0 to 5), a Psoriasis Area and Severity Index (PASI) score ≥ 12 , and who were candidates for phototherapy or systemic therapy. Patients were randomized to either placebo or Taltz® for 12 weeks, and there was an active comparator arm that included etanercept (50mg BIW) in trials 2 and 3. There is some evidence at this time to support that Taltz® is more effective than etanercept for several assessed outcomes in two phase 3 studies. Long-term efficacy of Taltz® up to 60 months was assessed and maintained. Currently, there is no evidence of direct comparisons of Taltz® to drugs other than etanercept for its approved indication.

Recommendation: The recommendation is for Taltz® to be non-preferred.

Clinical Criteria:

- Add Taltz to non-preferred with quantity limits (3 syringes/28 days for the first month, 2 syringes/28 days for months 2 and 3, and 1 syringe/28 days subsequently).

- Combine Stelara and Taltz under the additional criteria for Remicade to state: The prescriber must provide a clinically valid reason why both Humira® and Cosentyx® cannot be used.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

f) Tolak® cream (fluorouracil)

Fluorouracil, the active ingredient of Tolak®, is a nucleoside metabolic inhibitor. It is thought that fluorouracil interferes with the synthesis of DNA, and to a lesser extent inhibits the formation of RNA, both of which are necessary for cell division and growth. Since RNA and DNA are essential for cell division and growth, the effect of fluorouracil may be to cause a thymine deficiency that causes unbalanced growth and death of the cell. It is indicated for the topical treatment of actinic keratosis lesions of the face, ears, and/or scalp. It is recommended to wash, rinse, and dry the treatment areas prior to use. Apply the cream once daily, in a sufficient amount to cover the lesions with a thin film, using the fingertips to massage the medication evenly into the skin. Apply for a period of 4 weeks as tolerated. Tolak® cream contains peanut oil. If sensitivity occurs, discontinue treatment immediately. Topical fluorouracil is associated with photosensitivity reactions, including severe sunburn. It is recommended to minimize exposure to ultraviolet rays, including sunlight, sun lamps, and tanning beds during and immediately following treatment with Tolak®. The safety and efficacy of Tolak® cream were assessed in two randomized, double-blind, vehicle-controlled studies that included subjects with ≥5 visible actinic keratosis lesions on the face, scalp, and/or ears. Treatment was used for four weeks as directed and treatment effect was assessed at 4 weeks post-treatment. After completing the trials, subjects who obtained 100% clearing of actinic keratosis lesions with Tolak® cream were followed for 12 months for lesion recurrence. Of these 204 subjects, 56 remained clear 12 months after treatment.

Recommendation: The recommendation is for Tolak® to be non-preferred.

Clinical Criteria:

- Add Tolak to non-preferred.
- Add Tolak to the Solaraze Gel and Diclofenac Gel criteria to read as follows: the diagnosis or indication is actinic keratosis AND the patient has had a documented side effect, allergy, contraindication or treatment failure with a preferred topical fluorouracil product.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

8. Therapeutic Drug Classes – Periodic Review: Jacquelyn Hedlund, MD Change Healthcare and Laurie Brady, RPH Change Healthcare

a) Bronchodilators, Beta Agonists

- No new drugs.
- Asthma, one of the most common chronic diseases of the airways, is a syndrome involving airflow obstruction, bronchial hyper responsiveness, and underlying inflammation. About 25 million people are known to have asthma in the US, with about 7 million of these being children. In addition, the FDA is requiring a risk management program called a Risk Evaluation and Mitigation Strategy (REMS) for these products. The REMS include a revised medication guide written specifically for patients and a plan to educate healthcare professionals about the appropriate use of LABAs.

Recommendation:

Beta- Adrenergic Agents

Clinical Criteria:

- Remove Maxair Autohaler and Foradil from preferred agents and clinical criteria.
- Under clinical criteria:
 - Remove metered dose inhalers (long-acting) criteria.
 - Combine Ventolin HFA and Xopenex HFA with the ProAir Respiclick criteria. Criteria will be changed to: patient has a documented side effect, allergy, or treatment failure to BOTH preferred short acting metered dose inhalers.
 - Combine Xopenex nebulizer solution criteria with Levalbuterol with statement that for approval of generic, the patient must have a documented intolerance to the brand.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations with the change to Serevent criteria to read as follows: The patient has a diagnosis of asthma and is prescribed an inhaled corticosteroid (pharmacy claims will be evaluated to assess compliance with long term controller therapy) OR the patient has a diagnosis of COPD.

b) Bronchodilators & COPD Agents

- Bevespi Aerosphere™ is a new agent included in the class but has not been reviewed by the DUR board yet.
- Chronic obstructive pulmonary disease (COPD) currently affects 12 million people in the United States, leading to approximately 120,000 deaths each year.

Recommendation:

Anticholinergics

Clinical criteria:

- Remove the quantity limit on Atrovent HFA.
- Remove Combivent.

PDE-4 Inhibitors

Clinical Criteria:

- Update Daliresp criteria to read as follows: The indication for the requested medication is treatment to reduce the risk of COPD exacerbations in patients with severe COPD associated with chronic bronchitis and a history of exacerbations AND the patient has a documented side effect, allergy, treatment failure, or a contraindication to at least one inhaled long-acting anticholinergic AND at least one inhaled long-acting beta agonist AND at least one inhaled corticosteroid.

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Public Comment: Chris Dube from Astra Zeneca highlighted attributes of Bevespi Aerosphere™.

Board Decision: The Board unanimously approved the above recommendation.

c) Cystic Fibrosis Agents

- Orkambi® indications have been updated. It is now indicated for the treatment of cystic fibrosis (CF) in patients age 6 years and older who are homozygous for the F508del mutation in the CFTR gene. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the F508del mutation on both alleles of the CFTR gene. The recommended dosing for pediatric patients age 6 through 11 years: two tablets (each containing lumacaftor 100 mg/ivacaftor 125 mg) taken orally every 12 hours.
- Per the National Heart, Lung, and Blood Institute (NHLBI), CF is an inherited disease of the secretory glands, and is the result of a defective gene and its protein product that causes thick and sticky mucous and very salty sweat. The secretory glands include the mucus and sweat glands, amongst others. Mucus, which is normally a slippery watery substance, lines some organs to help keep them moist and from getting infected. In individuals with CF, the mucus is thick and sticky, which causes blockage of airways/tubes/ducts. Additionally, mucus build-up provides for an environment that promotes bacteria growth. In addition to mucus issues, those with CF also have very salty sweat.

- The Cystic Fibrosis (CF) Foundation published guidelines in 2007 to discuss chronic medication use for maintenance of lung health. These guidelines were updated in 2013 and now include ivacaftor.

Recommendation:

Clinical Criteria:

- Move Bethkis to preferred (effective date 1/1/17) with quantity Limit = 56 vials/56 days; maximum days' supply = 56 days) (2 vials/day for 28 days, then 28 days off).
- Add Bethkis to the Kitabis and Pulmozyme criteria.
- Update TOBI and tobramycin inhalation solutions criteria: Diagnosis or indication is cystic fibrosis and the patient has documented treatment failure or intolerance to Kitabis and Bethkis.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

d) Glucocorticoids, Inhaled

- For asthma treatment, the addition of an inhaled glucocorticoid may help reduce or eliminate the need for systemic corticosteroid use. All indications are for maintenance treatment. The treatment of asthma is done in a step-wise manner, and as the disease worsens, a combination of several agents may be needed.
- While often associated with the same symptoms, chronic obstructive pulmonary disease (COPD) is a disease that gets worse over time and has no cure.

Recommendation:

Clinical Criteria

- Move Aerospan to non-preferred (effective date 1/1/17).
- Move Advair Diskus to preferred (effective date 1/1/17).
- Update Qvar 80mcg/inh quantity limits to 6 inhalers/90 days.
 - Under clinical criteria:
 - Remove the criteria for Advair Diskus.
 - Adjust Breo Ellipta criteria: The patient has a diagnosis of COPD or Asthma AND The patient has had a documented side effect, allergy, or treatment failure to any 2 of the following: Advair, Dulera, or Symbicort.

Public Comment: No public comment

Board Decision: The Board unanimously approved the above recommendation.

e) Pulmonary Anti-hypertensives

- Prostacyclin receptor (IP receptor) agonists selexipag (Uptravi®) is a new agent in this therapeutic class.
- Pulmonary arterial hypertension (PAH) is a frequently misdiagnosed rare blood vessel disorder, with the prevalence of PAH group 1 estimated to be 5 to 15 cases per one million adults. PAH is characterized by an elevation in pulmonary artery pressure that can lead to right ventricular failure and death. Symptoms of PAH, such as shortness of breath during routine activity, fatigue, chest pain, dizzy spells, racing heartbeat, pain on upper right side of abdomen, decreased appetite, and fainting are similar to those of other pulmonary conditions, making diagnosis difficult. This is of particular concern, given that PAH is a chronic disease with no cure, associated with very poor survival rates. There are several classes of medications that are approved with various indications to improve exercise tolerance or delay disease progression. There are several classes discussed in this review: endothelin receptor antagonists, PDE5-Inhibitors, prostacyclins, and soluble guanylate cyclase stimulators. Many medications within these classes require slow titration to help mitigate side effects.

Recommendation:

Pulmonary Arterial Hypertension Medications

Clinical Criteria:

- Move Letairis to non-preferred (effective date 1/1/17).
- Update quantity limits for Uptravi tablets: 200mcg strength, QL = 140 tablets/30 days for the first 2 months then 2 tablets/day subsequently. All other strengths, QL = 2 tablets/day.
 - Under Clinical Criteria:
 - Add Letairis to the Opsumit criteria to read as follows: Patient has a diagnosis of PAH (WHO Group 1) with NYHA Functional Class II or III AND Patient is not pregnant AND Female patients have been enrolled in the REMS Program AND the patient has a documented side effect, allergy, or treatment failure with Tracleer.

Phosphodiesterase-5 Inhibitors

Clinical Criteria:

- Move sildenafil citrate to preferred with quantity limits of 3 tablets per day.

- Add Revatio suspension to non-preferred.
- Remove Viagra from non-preferred.
- Under Clinical Criteria:
 - Remove criteria for Viagra.
 - Add Revatio Suspension: Clinical diagnosis of pulmonary hypertension AND medical necessity for a liquid formulation is provided OR the patient is unable to tolerate a 20mg dose.
 - Adjust criteria for Adcirca (tadalafil) 20 mg, Revatio (sildenafil citrate) 20 mg: Clinical diagnosis of pulmonary hypertension AND No concomitant use of organic nitrate containing products AND the patient has a documented intolerance to generic sildenafil.

Public Comment: No public comment

Board Decision: The Board unanimously approved the above recommendation.

f) Sublingual Allergen Extract Immunotherapy

- No New Drugs.
- Allergic rhinitis is a common diagnosis, with an estimated 10-30% of adults and children in the United States and other industrialized countries affected by it. Allergic rhinitis (AR) is characterized by symptoms of sneezing, rhinorrhea, nasal congestion, and nasal itching, along with other symptoms such as postnasal drip, cough, irritability, and fatigue that are generated by nasal irritation or inflammation.
- To date, there are only a few trials comparing Sublingual immunotherapy (SLIT) vs subcutaneous immunotherapy (SCIT).

Recommendation: No changes to existing clinical criteria.

Public Comment: No public comment.

Board Decision: None needed.

9. New Managed Therapeutic Drug Classes

- None at this time.

10. Review of Newly-Developed/Revised Clinical Coverage Criteria and/or Preferred Products

- **Androgens (effective date 1/1/17)**

Recommendation:

- Move ANDRODERM® Transdermal 2mg, 4mg (testosterone patch) to preferred.
- Move ANDROGEL® GEL (testosterone 1.62% gel packets) to preferred with Quantity limit = 1.25 gm packet (1 packet/day) 2.5 gm packet (2 packets/day).
- Move ANDROGEL® PUMP (testosterone pump bottles) to preferred with Quantity limit = 1 % (4 bottles/30 days) 1.62% (2 bottles/30 days) Quantity limit = 1 patch/day/strength.
- Add Methitest (methyltestosterone) Tablet 10MG to preferred.
- Add Android (methyltestosterone) capsule 10MG to non-preferred.
- Add Methyltestosterone capsule 10MG to non-preferred.
- Add Striant® SR (testosterone) 30MG to non-preferred.
- Add Testred (methyltestosterone) capsule 10MG to non-preferred.
 - Clinical criteria:
 - Add Android, Striant, Methyltestosterone, Testred: patient has a documented side effect, allergy, or treatment failure to Methitest.
 - Adjust criteria for Axiron, Fortesta, Testim, Testosterone Gel 1%, Testosterone Gel 2 %: The patient has had a documented side effect, allergy, or treatment failure to Androgel and Androderm.

Public Comment: No public comment

Board Decision: The Board unanimously approved the above recommendation.

▪ **Alzheimer’s Medications (effective date 1/1/17)**

Recommendation:

Cholinesterase Inhibitors

- Move Donepezil ODT † (compare to Aricept® ODT) (QL = 1 tablet/day) to preferred.
- Move rivastigmine† (compare to Exelon®) capsule (QL = 2 capsules/day) to preferred.
- Move galantamine† tablet § (compare to Razadyne®) Tablet to preferred.
- Move galantamine ER† capsule § (compare to Razadyne® ER) to preferred.\
- Remove Razadyne® oral solution.
 - Clinical criteria:
 - Remove criteria of preferred drugs.
 - Add to Aricept ODT criteria: the patient has a documented intolerance to the generic formulation

NMDA Receptor Antagonist

- Move Namenda and Namenda XR to non-preferred
- Add Memantine tablets to preferred.

- Clinical criteria:
 - Namenda: patient has a documented intolerance to the generic.
 - Namenda XR: patient has not been able to tolerate twice daily dosing of immediate release memantine, resulting in significant clinical impact.

Cholinesterase Inhibitor/NMDA combination

- Under Namzaric replace Namenda with memantine.

Public Comment: No public comment

Board Decision: The Board unanimously approved the above recommendation.

- **Anti-diabetics: Dipeptidyl Peptidase (DPP-4) Inhibitors (effective date 1/1/17)**
 - Move Tradjenta® (linagliptin) (Quantity limit=1 tab/day) to preferred.
 - Move Jentaduetto® (linagliptin/metformin) (Quantity limit=2 tabs/day) to preferred.
 - Move Onglyza® (saxagliptan)(Quantity limit=1 tablet/day) to non-preferred
 - Move Kombiglyze XR® (saxagliptin/metformin ER) (Quantity limit=1 tab/day) to non-preferred.
 - Clinical criteria:
 - Add Tradjenta to the Januvia criteria.
 - Add Onglyza to Nesina criteria.
 - Add Kombiglyze XR to Kazano criteria.
 - Remove Jentaduetto and Kombiglyze XR criteria.
- **Anti-diabetics: SGLT2 Inhibitors (effective date 1/1/17)**
 - Move Jardiance®(empagliflozin) (Quantity limit = 1 tablet/day) to preferred.
 - Move Synjardy® (empagliflozin/metformin) (Quantity Limit = 2 tablets/day) to preferred.
 - Move Farxiga® (dapagliflozin) (Quantity limit = 1 tablet/day) to non-preferred.
 - Move Invokana®(canagliflozin) (Quantity limit = 1 tablet/day) to non-preferred.
 - Clinical criteria:
 - Invokana/Farxiga additional criteria: the patient has a documented side effect, allergy, or contraindication to Jardiance. Note: Existing users as of 1/1/17 will be grandfathered
 - Invokamet/Xigduo XR® additional criteria: The patient has documentation of a failure of therapy with Jardiance used in combination with metformin or Synjardy
 - Remove Jardiance and Synjardy criteria.
- **Anti-diabetics: Peptide Hormone (effective date 1/1/17)**

- Move Bydureon® (exenatide extended-release) (Quantity Limit=4 vials/28 days) to preferred.
- Move Byetta® (exenatide) (Quantity Limit =1 pen/30 days) to preferred.
- Move Tanzeum® (albiglutide) to non-preferred.
 - Clinical criteria:
 - Add Bydureon and Byetta to Victoza criteria.
 - Change criteria for Trulicity and Tanzeum to read as follows: patient has a diagnosis of type 2 diabetes AND patient is at least 18 years of age AND patient has had a documented side effect, allergy, contraindication, or treatment failure with Victoza, Byetta, or Bydureon.

Public Comment: Shaffee Bacchus from Janssen: Highlighted attributes of Invokana.

Board Decision: The Board unanimously approved the above recommendation.

▪ **Growth Hormone (effective date 1/1/17)**

Recommendation:

- Move Genotropin® to preferred.
 - Clinical criteria:
 - HUMATROPE, NUTROPIN AQ, OMNITROPE, SAIZEN, TEV-TROPIN, ZOMACTON: The patient has a documented side effect, allergy, or treatment failure to both preferred agents.

Public Comment: No public comment

Board Decision: The Board unanimously approved the above recommendation.

▪ **Hemophilia Factors (effective date 1/1/17)**

Recommendation:

- Move Novoeight® Vial to preferred.
- Move Xyntha® syringe, vial to preferred.

Public Comment: Clayton English read a letter submitted to the board from The New England Hemophilia Association. The New England Hemophilia Association asks that the state of Vermont continue to exclude the Hemophilia class from being managed and reviewed by the DUR. On behalf of individuals with bleeding disorders in Vermont, the New England Hemophilia Association urge the board to continue allowing patient access to all FDA approved therapies to treat hemophilia and related bleeding disorders.

Dr. Hedlund, a hematologist with Change Healthcare, responded by stating that more and more states are starting to manage these products because there are so many and they are expensive. There are very few trials with head to head comparisons. There are a lot of unknowns with the new drugs as there isn't data regarding the rate of inhibitors in previously untreated patients. Studies, such as the ongoing ATHN-2 study, will give us more information about the benefits, risks, and costs of switching to newer factor products. These products are so diverse now that how they all fit in appropriate usage is unclear. Therefore, it is appropriate for this class to be managed at this time. Vermont Medicaid patients still have access to all FDA approved therapies through the prior authorization process.

Board Decision: The Board unanimously approved the above recommendation.

▪ **Multiple Sclerosis Agents (effective date 1/1/17)**

Recommendation:

- Move Aubagio® (teriflunamide) tablet (QL = 1 tablet/day, maximum 28-day supply per fill) to preferred.
- Add Extavia® (interferon beta-1b) to non-preferred.
 - Clinical Criteria:
 - Remove Aubagio criteria.

Public Comment: Brian Calamari from Abbvie: Highlighted attributes of Zinbryta.

Board Decision: The Board unanimously approved the above recommendation.

▪ **Ophthalmic Antihistamines-Deferred to December's meeting**

▪ **Scabicides/Pediculicides (effective date 1/1/17)**

Recommendation:

- Move Sklice® (ivermectin 0.5%) lotion to preferred.
 - Clinical criteria:
 - Natroba, Sklice: The patient has had a documented side effect, allergy, or treatment failure to OTC permethrin or piperonyl butoxide and pyrethrins.
 - 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 Sklice OR treatment failure with two treatments of OTC permethrin and/or piperonyl butoxide and pyrethrins and one treatment of Natroba or Sklice. For approval of Ovide® Lotion, the patient must also have a documented intolerance to the generic equivalent product.

Public Comment: No public comment

Board Decision: The Board unanimously approved the above recommendation.

- **Gout Agents-Deferred to December's meeting**
- **Bone Resorption Inhibitors (effective date 1/1/17)**

Recommendation:

- Move Binosto® (alendronate) 70 mg effervescent tablet (Quantity Limit=4 tablets/28 days) to preferred.
- Add Alendronate oral solution to non-preferred.
- Alendronate (compare to Fosamax®) tablets will continue to be preferred.
 - Clinical criteria:
 - Alendronate Oral Solution: prescriber provides documentation of medical necessity for the specialty dosage form (i.e. inability to swallow tablets, dysphagia) AND the patient has a documented intolerance to Binosto.
 - Remove Binosto criteria.
 - Reference to treatment failure of Alendronate in other non-preferred agents will specify tablets.
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Public Comment: Karen Phillips from Amgen: Highlighted attributes of Prolia.

Board Decision: The Board unanimously approved the above recommendation.

- **Urinary Antispasmodics-Deferred to December's meeting**
- **Vaginal Anti-infectives-Deferred to December's meeting**

Board Decision: The Board unanimously approved the above recommendation.

11. General Announcements: Provided as written handouts (not verbally discussed during the meeting)

- Selected FDA Safety Alerts

Canagliflozin (Invokana, Invokamet) and Dapagliflozin (Farxiga, Xigduo XR): Drug Safety Communication - Strengthened Kidney Warnings

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm506554.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

Loperamide (Imodium): Drug Safety Communication - Serious Heart Problems With High Doses From Abuse and Misuse

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm505303.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

Zecuity (sumatriptan) Migraine Patch: Drug Safety Communication - FDA Evaluating Risk of Burns and Scars

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm504736.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

FDA Drug Safety Communication: FDA updates warnings for oral and injectable fluoroquinolone antibiotics due to disabling side effects

http://www.fda.gov/Drugs/DrugSafety/ucm511530.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

Lamotrigine Orally Disintegrating Tablet 200 mg by Impax: Recall - Incorrect Labeling of Blister Cards

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm518486.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

Opioid Pain or Cough Medicines Combined With Benzodiazepines: Drug Safety Communication - FDA Requiring Boxed Warning About Serious Risks and Death

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm518710.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

Direct-Acting Antivirals for Hepatitis C: Drug Safety Communication - Risk of Hepatitis B Reactivating

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm523690.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

12. Adjourn: Meeting adjourned at 8:45p.m.