

Department of Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes
February 23, 2016

Board Members:

Present:

Zail Berry, MD
Janet Farina, RPh
Clayton English, PharmD

Louise Rosales, NP
Michael Biddle, PharmD

James Marmar, RPh
Patrica King, MD

Absent:

Staff:

Jacquelyn Hedlund, MD
GHS/Change HealthCare
Mike Ouellette, RPh, GHS/Change
HealthCare
Tom Simpatico, MD, DVHA
Scott Strenio, MD, DVHA

Mary Beth Bizzari, RPh, DVHA
Jennifer Egelhof, DVHA
Stacey Baker, DVHA
Daljit Clark, DVHA
Nancy Hogue, PharmD, DVHA

Jason Pope, DVHA
Laurie Pedlar, RPh, GHS/Change
HealthCare
Laureen Biczak, DO, GHS/Change
HealthCare

Guests:

Thomas Currier, Purdue
Christine Dube, MedImmune
Jai Persico, Otsuka
Nicholas Primpas, Indivior
Marie Roache, Pfizer
Maggie Glassman, Alkermes

Kevin Losty, GSK
Anne Obrien, State Rep
Darren Keegan, Allergan
Hannah Parker, AstraZeneca

John Belvisu, Boehringer
Ingelheim
George Small, AstraZeneca
Shawna Williams, PX Pierce

1. Executive Session:

- An executive session was held from 6:00 p.m. until 6:25 p.m.

2. Introductions and Approval of DUR Board Minutes:

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

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

- Thanked Michael Biddle, PharmD, for his contribution to the board as this meeting was his last meeting.
- DVHA is moving forward with getting new board members.

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

- DVHA looked into Cognitive Behavioral Therapy (CBT) availability as possible criteria for sedative hypnotics and availability seemed to be an issue.
- DVHA will follow up with VCCI and BluePrint on CBT.

5. Follow-up Items from Previous Meetings: Laureen Biczak, DO GHS/Change Healthcare

- **Appropriate use of Asthma controller medications:**
NIH Guidelines state that the frequency of short acting beta adrenergic inhaler (SABA) use can be clinically useful as a measure of disease activity since increased use of a SABA has been associated with increased risk for death or near death in patients who have asthma. Use of more than one SABA canister every month is also associated with an increased risk of an acute exacerbation. GHS reviewed Vermont paid non-reversed pharmacy and medical claims with dates of service from 7/1/2014 through 6/30/2015 and excluded members who had a diagnosis of cystic fibrosis, chronic obstructive pulmonary disease or emphysema. Members were sorted by age group and the number of short acting inhalers used per year. In addition, the number of members in each group who had an ER visit or hospitalization associated with an asthma diagnosis during the study period was determined and reported.
 - Conclusions based on the sub-groups by age are limited due to the small size of the sub-groups.
 - In the largest group (> 18 years of age), increasing use of SABA was associated with increased use of the ER for asthma related diagnosis.
 - The current data analysis does not indicate whether there is a difference in ER visits or admissions between those with or without the controller medications.
 - For all members who received prescriptions for SABA during this time period, the vast majority received fewer than 13 Rx/year (98.4% overall and 99.3% of those < 18 and 97.7% of those 18+).

- Overall, 30% of those who received > 12 SABA Rx/year did not have a prescription for a concurrent long acting controller medication.
 - a. 43% of those < 18 years of age
 - b. 28% of those 18 + years of age
 - c. 21 members < 18 and 67 members 18+
- Only a small number of prescribers are associated with more than a single member of this group.
- Asthma is listed as a diagnosis for 2,255 ER visits and 496 admissions during the time period studied, suggesting it remains a significant contributor to the number of ER visits and hospitalizations for Vermont Medicaid members.

Recommendation: The recommendation is an educational mailing regarding the current recommendations for the treatment of asthma. This mailing could be targeted to prescribers of SABA medications or to specific groups of providers. Given the significant health impact of appropriate asthma treatment, the data suggests a potentially significant percentage of members who receive > 12 SABA Rx/year are not on concurrent controller medication usage. This would seem to be consistent with self-reported asthma medication use in a July 2014 report by the Vermont Department of Health.

Board Decision: Rerun the analysis for all of calendar year 2015. Based on those results, send out a provider letter that is patient specific that includes information on the asthma guidelines. In addition, they recommend member education that may be able to be accomplished through the VCCI and BluePrint programs. Finally, they recommended sending a patient specific educational letter to the patients' pharmacies.

6. RetroDUR/DUR: Mike Ouellette, RPh GHS/Change Healthcare

a) 2016 RetroDUR Initiatives Schedule

Presented calendar for 2016 RetroDUR initiatives. It was clarified that due to a scheduling conflict, the June 21st meeting is going to be moved to July 12th. An email will be sent out confirming this change.

Recommendation: None needed.

Board Decision: The Board unanimously approved the RetroDUR Initiatives Schedule.

7. Clinical Update: Drug Reviews: Laureen Biczak, DO GHS/Change Healthcare and Mike Ouellette, RPh

Abbreviated New Drug Reviews:

a) Kalydeco® Tab (ivacaftor)

- Ivacaftor, the active ingredient of Kalydeco®, is a potentiator of the cystic fibrosis transmembrane conductance regulator (CFTR) protein, which is a chloride channel at the surface of epithelial cells in many organs. Ivacaftor aids in increased chloride transport by potentiating the channel-open probability (or gating) of the CFTR protein. It is indicated for the treatment of cystic fibrosis (CF) in patients 2 years of age and older who have one of the following mutations in the *CFTR* gene: *G551D*, *G1244E*, *G1349D*, *G178R*, *G551S*, *S1251N*, *S1255P*, *S549N*, or *S549R* AND for the treatment of CF in patients 2 years of age and older who have an R117H mutation in the CFTR gene. There is a new dosage form of unit dose packets of oral granules: 50mg and 75mg.

Recommendation: The recommendation is for Kalydeco® to remain non-preferred and to update the gene mutations, age limit and new dosage forms on the PDL.

Clinical Criteria:

- Add the R117H mutation
- Change the age requirement from > 6 to ≥2years old
- Add the dosage form and quantity limit for the granules: “Quantity limit= 2 packets/day, maximum days supply=30 days.”

Public Comment: Erin Gleason,Vertex

Board Decision: The Board unanimously approved the above recommendation.

Full New Drug Reviews:

a) Praluent® Inj (alirocumab)

- Alirocumab, the active ingredient of Praluent®, is a human monoclonal antibody that binds to proprotein convertase subtilisin kexin type 9 (PCSK9). PCSK9 binds to low-density lipoprotein receptors (LDLR) on hepatocytes to promote LDLR degradation within the liver. LDLR is the main receptor that clears LDL, thus a decrease in LDLR levels by PCSK9 results in higher LDL-C blood levels. By inhibiting the binding of PCSK9 to LDLR, alirocumab increases the number of LDLRs available to clear LDL, thus lowering LDL-C levels. The indication is for it to be adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease, who require additional lowering of LDL

cholesterol. The effect of Praluent® on cardiovascular morbidity and mortality has not been determined.

Recommendation: The recommendation is for Praluent® to be non-preferred, requiring clinical criteria consistent with the current FDA labeling.

Clinical Criteria:

ALL

- Age > 18 years of age **or** > 13 and dx of homozygous familial hypercholesterolemia (HoFH)
- Concurrent use with statin therapy
- Documented adherence to prescribed lipid lowering medications for the previous 90 days
- Recommended or prescribed by a lipidologist or cardiologist
- Diagnosis of heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease **or** (Repatha only) homozygous familial hypercholesterolemia
 - with additional criteria for each as outlined below

Additional criteria for the diagnosis of heterozygous familial hypercholesterolemia (HeFH): (both are required)

- Total cholesterol > 290 mg/dL **OR** LDL-C > 190 mg/dL **AND** one of the following
 - Presence of tendon xanthomas **OR**
 - In 1st or 2nd degree relative-documented tendon xanthomas, MI at age ≤ 60 years **or** TC > 290 mg/dL **OR**
 - Confirmation of diagnosis by gene or receptor testing **AND**
- Unable to reach goal LDL-C with maximally tolerated dose of statin and ezetimibe 10 mg daily + another concurrently administered lipid lowering agent
 - A trial of 2 or more statins, at least one of which must be either atorvastatin or rosuvastatin, is required.

Additional criteria for the diagnosis of clinical atherosclerotic cardiovascular disease: (both are required)

- History of MI, angina, coronary or other arterial revascularization, stroke, TIA, or PVD of atherosclerotic origin **AND**
- Unable to reach goal LDL-C with maximally tolerated doses of stain + ezetimibe 10 mg daily
 - A trial of 2 or more statins, at least one of which must be either atorvastatin or rosuvastatin, is required.

Additional criteria for the diagnosis of homozygous familial hypercholesterolemia (Repatha only): (both are required)

- Total cholesterol and LDL-C > 600 mg/dL and TG within reference range **OR**
- Confirmation of diagnosis by gene testing **AND**
- Unable to reach goal LDL-C with maximally tolerated dose of statin and ezetimibe 10 mg daily + another concurrently administered lipid lowering agent
 - A trial of 2 or more statins, at least one of which must be either atorvastatin or rosuvastatin, is required.

Public Comment: None

Board Review: The Board unanimously approved the above recommendation.

b) Repatha® Inj (evolocumab)

- Evolocumab, the active ingredient of Repatha®, is a human monoclonal immunoglobulin G2 (IgG2) that is directed against human proprotein convertase subtilisin kexin 9 (PCSK9). The indication is for it to be used as adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (CVD) who require additional lowering of low density lipoprotein cholesterol (LDL-C) AND as adjunct to diet and other LDL-lowering therapies (e.g. statins, ezetimibe, LDL apheresis) for the treatment of patients with homozygous familial hypercholesterolemia (HoFH) who require additional lowering of LDL-C. Repatha® should be warmed to room temperature for at least 30 minutes prior to use. Repatha® is the second FDA approved PCSK9 inhibitor, a class of drugs that has been shown to significantly reduce LDL-C. There is no conclusive evidence that, in the absence of concurrent statin therapy, PCSK9 inhibitors have any effect on cardiovascular morbidity or mortality.

Recommendation: The recommendation is for Repatha® to be non-preferred requiring clinical criteria consistent with the current FDA labeling.

Clinical Criteria:

- See criteria listed for Praluent®

Public Comment: No public comment.

Board Review: The Board unanimously approved the above recommendation.

8. Therapeutic Drug Classes – Periodic Review: Laureen Biczak, DO GHS/Change Healthcare and Laurie Pedlar, RPH GHS/Change Healthcare

a) Ophthalmic Antibiotics

- A new generic is available for neomycin/polymyxin/HCl.
- One source strengthened the caution about the use of antibiotics with steroids for eye infections.
- No other significant changes.

Recommendation:

- Aminoglycosides- Garamycin® solution, Tobrex® ointment/solution, Pred-G® ointment/suspension, Tobradex® ST suspension and Zylet® suspension are recommended to become preferred.
- Quinolones- Ciloxan® ointment, Moxeza® solution, Ocuflox® solution, and Vigamox® solution are recommended to become preferred.

- Miscellaneous- Sulfacetamide Sodium ointment and Neosporin® solution are recommended to become preferred.
- Many other agents became non-rebatable or are no longer being made, and are therefore recommended to be taken off the PDL.

Clinical Criteria:

- Aminoglycosides: remove 'at least ONE'. The patient has had a documented side effect, allergy or treatment failure with a preferred ophthalmic aminoglycoside or aminoglycoside combination.
- Quinolones: The patient has had a documented side effect, allergy or treatment failure with a preferred quinolone.

Public Comment: No public comment.

Board Decision: The Board requested that the criteria be modified to require a documented side effect, allergy or treatment failure with TWO preferred agents in both the aminoglycoside and quinolone categories. In the aminoglycoside category, one of the failures must be Tobradex. The Board unanimously approved these changes.

b) Ophthalmics, Glaucoma Agents

- A new generic is available for Lumigan.
- It is of some significance to note that a 2015 study is considered by the authors to be the first actual objective study demonstrating that IOP lowering therapy preserved visual fields in patients with open angle glaucoma as most studies to date have documented only the "proxy" outcome of lowered IOP.
- A recent (2016) meta-analysis by Li et al suggested that within class differences between glaucoma medications were small.
- No other significant changes.

Recommendation:

- Bimatoprost 0.03% (Lumigan®) is recommended to become non-preferred.
- Many other agents became non-rebatable or are no longer being made, and are therefore recommended to be taken off the PDL.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

c) Ophthalmic Anti-Inflammatories & Miscellaneous Agents

- Cystaran was added to the class review.
- No significant new studies or changes.

Recommendation:

- Corticosteroids: Topical- Alrex® (loteprednol) 0.2% suspension, Flarex® (fluorometholone acetate) 0.1% suspension, FML® (fluorometholone) ointment, Maxidex® (dexamethasone) suspension, Pred Mild® (prednisolone acetate) 0.12% suspension, and Vexol® (rimexolone) 1% suspension are recommended to become preferred.
- NSAIDS- Ilevro® (nepafenac) 0.3% suspension and Nevanac® (nepafenac) 0.1% suspension are recommended to become preferred.
- Voltaren solution became non-rebatable and no longer available and is therefore recommended to be taken off the PDL.

Clinical Criteria:

- Remove Ilevro, Nevanac and Voltaren from non-preferred clinical criteria section.

Public Comment: No public comment.

Board Decision: The Board requested that the criteria for topical corticosteroids be modified to require a documented side effect, allergy, or treatment failure with TWO preferred agents. The board unanimously approved this change and the above recommendation for NSAID clinical criteria.

d) Ophthalmic Allergic Conjunctivitis

- Most of the newest studies compared various olopatadine formulations with some minor improvements in symptoms noted with the most recent .77% formulation.
- No other significant new studies or changes.

Recommendation:

- Antihistamines- Olopatadine 0.1% is recommended to be non-preferred with quantity limits equal to 1 bottle per month.

Clinical Criteria:

- Olopatadine 0.1% - the patient has had a documented side effect, allergy or treatment failure to Pataday or Patanol.

Public Comment: No public comment

Board Decision: The Board unanimously approved the above recommendation.

9. New Managed Therapeutic Drug Classes: Jacquelyn Hedlund, MD, GHS/Change HealthCare

a) Iron Chelating Agents

- In 2005, the oral iron chelating agent deferasirox (Exjade®) was FDA approved. Deferiprone (Ferriprox®), another oral chelating agent, was subsequently approved in 2011. In 2015, the FDA approved a new formulation of deferasirox (Jadenu®) to help simplify administration. Exjade® dissolves into water, orange juice or apple juice and is then drunk whereas Jadenu is a capsule. There are no head to head trials of these drugs and they all reduce iron.
- Dr. Hedlund discussed the general therapeutic area and the importance of these drugs for iron overload states.

Recommendation:

- Add Iron Chelating Agents as a new category to the PDL.
- Exjade® (deferasirox) and Ferriprox® (deferiprone) are recommended to be listed as preferred agents.
- Jadenu® (deferasirox) is recommended to be non-preferred.

Clinical Criteria:

- Jadenu® (deferasirox)- patient has had a documented side effect, allergy, or treatment failure to Exjade®; Jadenu® will not be approved without compelling clinical reason why Exjade® cannot be used as they are different forms of the same medication.

Public Comment: No public comment

Board Decision: The Board unanimously approved the above recommendations.

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

- None at this time.

11. General Announcements:

- Selected FDA Safety Alerts

Children's Guaifenesin Grape Liquid and Guaifenesin DM Cherry Liquid by Perrigo Company: Recall - Potential Defect with Dosage Cup

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm481563.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

FDA Drug Safety Communication: FDA cautions about dosing errors when switching between different oral formulations of antifungal Noxafil (posaconazole); label changes approved

http://www.fda.gov/Drugs/DrugSafety/ucm479352.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

FDA Drug Safety Communication: FDA eliminates the Risk Evaluation and Mitigation Strategy (REMS) for rosiglitazone-containing diabetes medicines

http://www.fda.gov/Drugs/DrugSafety/ucm476466.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

12. Adjourn: Meeting adjourned at 8:16 p.m.

DRAFT