

Department of Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes
April 5, 2016

Board Members:

Present:

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

Louise Rosales, NP

James Marmar, RPh
Patrica King, MD

Absent:

Staff:

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

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

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

Guests:

Thomas Algozzine, Novartis
Kristen Bruno-Doherty,
Astrazeneca
Thomas Currier, Purdue
Adam Denman, GSK
Dave Downey, Abbott Labs
Christine Dube, MedImmune
Marie Roache, Pfizer
Maggie Glassman, Alkermes

Brad Martin, Lundbeck
John Meyer, Otsuka
Scott Williams, J&J
Darren Keegan, Allergan
Hannah Parker, AstraZeneca
David Halpin, AstraZeneca

Micheala Jones, Grifols
Julee Oh, Baxakta
Evelyn Gittinger, Adapt Pharma
Margaret Fisher, Novo Nordisk
George Small, AstraZeneca

1. Executive Session:

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

2. Introductions and Approval of DUR Board Minutes:

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

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

- None at this time.

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

- Introduced guest speaker Rhonda Williams from VDH Asthma Program

5. Follow-up Items from Previous Meetings: Rhonda Williams

- **VDH Asthma Program**
 - Presented slides on asthma with Vermont specific data compiled from 2007-2014. Priorities of the program were also outlined. VDH is planning outreach and educational mailings this fall.

Recommendation: None needed.

Board Decision: None needed.

6. RetroDUR/DUR: Laureen Biczak, DO GHS/Change Healthcare & Jacquelyn Hedlund, MD GHS/Change Healthcare

a) Appropriate use of Asthma controller medication

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 reran the analysis for all of calendar year 2015 of Vermont paid non-reversed pharmacy and medical claims 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.

- Finding/conclusions are not significantly different when looking at the time period of 7/1/2014-6/30/2015 and 1/1/2015-12/31/2015.

- 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, 98.2% received fewer than 13 RX/year.
- Overall, 31% of those who received > 12 SABA Rx/year were not concurrently on long acting controller medication.
 - a. 27% of those < 18 years of age
 - b. 31% of those 18 + years of age
 - c. 16 members < 18 and 85 members 18+
- A small number of prescribers are associated with more than a single member of this group.
- Asthma is listed as a diagnosis for 2,081 ER visits and 395 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: This data suggest similar findings to the earlier time frame. Given this, consistent with the recommendation of the DUR Board, an educational mailing with patient specific information regarding the current recommendations for the treatment of asthma is still recommended for both prescribers and pharmacies with sharing of information to appropriate care management entities (VCCI and BluePrint).

Board Decision: No decision was made at this time. DVHA and GHS will discuss how to best coordinate the Board's efforts with the VDH Asthma Program.

b) Use of Valproic Acid in Women of Child-bearing Age

Prenatal exposure to antiepileptic drugs is associated with a greater risk of congenital malformations with evidence suggesting that the risk is higher with valproic acid as compared to no therapy and to other anticonvulsants. GHS reviewed Vermont paid non-reversed pharmacy claims with dates of service from 7/1/2014 through 6/30/2015 of women age 15-52 and excluded member with a diagnosis of tubal ligation or hysterectomy in their medical claims history. Dual eligibles were also excluded as were TPL claims.

- More than half of the members of this cohort of women of child-bearing age who used valproic acid in 2015 did NOT have a seizure disorder diagnosis.
- While claims data is not specific for individual prescriptions, the common non-seizure diagnoses most likely associated with valproic acid use were: depression, anxiety, bipolar disorder and headache. Some of the diagnoses that are less specific could imply neurogenic pain sources.
- The majority of patients on valproic acid have 1 prescriber of the medication.
- 70% of women of child-bearing age who are on valproic acid for a non-seizure related diagnosis may not be on appropriate birth control.

- 74% of women of child-bearing age who are on valproic acid and have a seizure disorder diagnosis may not be on appropriate birth control.

Recommendation: The recommendation is to consider a targeted mailing to all prescribers of valproic acid to educate them about the potential risks of prescribing valproic acid to women of child bearing age. It is recommended that for the members identified by this data analysis that the mailing include the patient information so that changes could be implemented is appropriate.

Board Decision: The Board decided that they will reach out to the nursing and medical board to see if collaboration can be done to send out the information within their electronic newsletters.

c) Use of Butalbital-containing medications

Butalbital containing medications, combined with other analgesics, are indicated for the relief of the symptom complex tension headache. Tension type headache (TTH) is the most common headache in the general population. Combination analgesics with butalbital may be used for moderate to severe intensity TTH, but evidence supporting the efficacy and safety of these butalbital combinations in the treatment of multiple, recurrent headaches is unavailable. Butalbital containing medications should be used no more than 3 days per month. This initiative will examine the frequency and intensity of the use of butalbital in the Vermont Medicaid population, and evaluate information about the quantities used, the diagnoses seen, other medications used for headache, and the number of prescribers involved to try to discern if there is evidence of overuse of this medications.

Recommendation: The recommendation is to identify members who are using these medications chronically and whose use is more frequent than 3 days per month by identifying all users of butalbital containing medications in 2015. Results will be divided into groups receiving 18 or fewer tablets in a thirty day period or greater than 18. Focusing on those receiving >18 tables in any given 30 day period, we will identify which providers are prescribing these medications. We will evaluate how often there is a headache diagnosis present and review the other common diagnoses found. We will evaluate how often preventative therapies are seen as well as look at triptan use in this population.

Board Decision: The Board unanimously approved the above recommendation.

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

Abbreviated New Drug Reviews:

- None at this time.

Full New Drug Reviews:

a) Aristada® Inj (aripiprazole lauroxil)

- Aripiprazole lauroxil, the active ingredient of Aristada®, is an atypical antipsychotic and a prodrug of aripiprazole. While the exact mechanism of action of aripiprazole is not known, it is thought its efficacy is mediated through a combination of partial agonist activity at dopamine D2 and serotonin 5-HT1a receptors, and antagonist activity at 5-HT2A receptors. Actions at other receptors could explain some of the adverse reactions of aripiprazole (e.g. orthostatic hypotension due to antagonist activity at adrenergic alpha1 receptors). The indication is for the treatment of schizophrenia. There is no pregnancy category associated with Aristada®; however, the risk summary indicates that neonates exposed to antipsychotics during the third trimester of pregnancy are at risk of extrapyramidal and/or withdrawal symptoms following delivery. Limited data on aripiprazole use in pregnant women are not sufficient to inform any drug-associated risks for birth defects or miscarriage. It is recommended to advise pregnant women of the potential risk to a fetus. As with all atypical antipsychotics, Aristada® carries a box warning regarding the increased mortality in elderly patients with dementia-related psychosis treated with antipsychotic drugs. Aristada® is not approved for the treatment of patients with dementia-related psychosis. The efficacy of Aristada® was established, in part, on the basis of efficacy data from the clinical trials of the oral aripiprazole formulation when used for the treatment of schizophrenia. In addition, the efficacy of Aristada® was established in a 12-week, randomized, double-blind, placebo-controlled study in adult patients with schizophrenia (N=622). After establishing tolerability to oral aripiprazole, patients received IM injections of Aristada® or placebo on days 1, 29, and 57, in addition to oral aripiprazole or placebo daily for the first 3 weeks.

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

Clinical Criteria:

- Quantity limit 1 syringe/28 days
- The patient has been started and stabilized on the medication OR Document clinically compelling information supporting the choice of a non-preferred agent on a General Prior Authorization Request Form. Medical necessity for a specialty dosage form has been provided (non-compliance with oral medications) AND Tolerability has been established previously with oral aripiprazole for at least 2 weeks AND the patient has documented treatment failure with Abilify Maintena®

Public Comment: Maggie Glassman, Alkermes: Had no other information to present.

Board Decision: The Board unanimously approved the above recommendation.

b) Narcan® NS (naloxone hydrochloride)

- Naloxone hydrochloride (HCl), the active ingredient of Narcan® Nasal Spray, is an opioid antagonist that antagonizes opioid effects by competing for the same receptor sites. It reverses the effects of opioids, including respiratory depression, sedation, and hypotension. For the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system (CNS) depression. Narcan® Nasal Spray (NS) is intended for immediate administration as emergency therapy in settings where opioids may be present. Narcan® NS is not a substitute for emergency medical care. A dose should be administered as soon as possible, and additional doses may be required until emergency medical assistance becomes available. Each nasal spray contains a single dose and cannot be re-used. Re-administer Narcan® NS, using a new nasal spray, every 2 to 3 minutes if the patient does not respond or responds and then relapses into respiratory depression. Use the NS in alternate nostrils with each dose. There is no evidence at this time to support that Narcan® Nasal Spray is safer or more effective than the currently available, more cost effective medications. However, this product has a clear advantage of being pre-packaged for use which may allow for more widespread availability when needed.

Recommendation: The recommendation is for Narcan® NS to be made preferred with quantity limits of 2 single use sprays/28 days. Clinical criteria for approval of non-preferred agents will be modified to state that the patient must have a clinically compelling reason why a rescue kit comprised of naloxone plus atomizer OR Narcan®NS cannot be used.

Public Comment: Evelyn Gittinger, Adapt Pharma: Highlighted attributes of Narcan® NS.

Board Decision: After much discussion the Board unanimously approved Narcan® NS to be preferred with NO quantity limits. Use of this drug will be monitored and brought back to the next meeting as well as speaking with Dr. Chen on this topic.

c) Synjardy® tabs (empagliflozin/metformin hydrochloride)

- Synjardy® is a combination product that contains two active ingredients with complementary mechanisms of action to aid in glycemic control. Empagliflozin is an inhibitor of sodium glucose co-transporter 2 (SGLT2); SGLT2 is the main transporter that works to reabsorb glucose from the glomerular filtrate back into the circulation. The indication is as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (DM) who are not adequately controlled on a regimen containing empagliflozin or metformin, or in patients already being treated with both empagliflozin and metformin. Due to the metformin component, Synjardy® has a box warning regarding the increased

risk of lactic acidosis. There is evolving data regarding SGLT2 inhibitors and cardiovascular disease that may better define a role for these agents.

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

Clinical Criteria:

- Quantity limit 2 tablets/day.
- The patient has documentation of a failure of therapy with the combination of the single agent drugs Jardiance plus metformin.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

d) Zecuity® transdermal (sumatriptan succinate iontophoretic transdermal system)

- Sumatriptan, the active ingredient of Zecuity®, is a selective 5-hydroxy-tryptamine receptor subtype 1 (5-HT₁) agonist which binds to human cloned 5-HT_{1B/1D} receptors. Per the prescribing information, Zecuity® is a disposable, single-use system constructed to deliver sumatriptan through the skin using iontophoresis. Iontophoresis is a non-invasive method of delivering a drug through the skin using a low electrical current. The indication is for the acute treatment of migraine with or without aura in adults. Zecuity® is not intended for the prevention of migraine attacks. It is recommended to use only if a clear diagnosis of migraine has been established. Individually sealed iontophoretic transdermal system: 86mg sumatriptan that delivers 6.5mg over 4 hours; Zecuity® contains lithium-manganese dioxide batteries. Once the transdermal system has been applied, the activation button must be pushed and a red light emitting diode (LED) will turn on. Once the dosing is completed, the system stops working and the activation light shuts off. The safety and efficacy of Zecuity® was established in a randomized, double-blind, placebo-controlled study with adults used for the acute treatment of migraine headaches with or without aura. The primary endpoint was the proportion of patients who had no headache pain at 2 hours post transdermal system activation

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

Clinical Criteria:

- Quantity limit 4 transdermal systems/28days.
- Patient has a medical necessity for a specialty topical dosage form (i.e. dysphasia, swallowing disorder, compliance, nausea/vomiting) AND has a

documented side effect, allergy or treatment failure with a preferred ODT, nasal, and injectable formulation.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

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

a) Androgenic Agents

- No new drugs.
- No other significant changes.
- The American Association of Clinical Endocrinologists (AACE)/American College of Endocrinology (ACE) published a position statement in 2015 in regards to the association of testosterone and cardiovascular risk. The statement recommends the following: We advise the practicing clinician to be extra cautious in the symptomatic elderly with demonstrably low testosterone levels prior to embarking on replacement therapy and to avoid treatment of the frail elderly until better outcome data are available.

Recommendation:

- Add Testosterone 1% Gel Packets to non-preferred with quantity limits: 2.5gm packet (1packet/day), 5gm packet (2 packets/day).
- Update Androderm® Transdermal to 2mg, 4mg.
- Remove Androgel® 1.25gm packet as it is no longer available.

Clinical Criteria:

- Clarify that the AndroGel® 1% gel packets are preferred.

Public Comment: No public comment.

Board Decision: The Board unanimously approved these changes.

b) Antibiotics, Topical

- No significant new studies or changes.

Recommendation:

- Remove Neosporin® and Polysporin® from PDL due to non-rebateable status.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

c) Hemophilia Factors

- This will be a newly managed category due to the increasing amount of factor drugs available.
- Medications in this category are best classified by the clotting factors they contain.
- Factors are produced by either pooled human plasma or recombinant technology.
- There are no studies or randomized trials to compare factor drugs. Differences between products include the source, purification and viral inactivation processes, and storage requirements. There is insufficient evidence to suggest any agent in this class is clinically superior to another within a given indication.
- Prophylaxis is recommended in patients with severe factor VIII deficiency to reduce the risk of joint damage.

Recommendation:

- Previous PDL had a blanket statement that all Hemophilia Factors are preferred. Now the PDL will be more detailed, listing the Preferred/Non-preferred medications and associated criteria for approval of a non-preferred factor.
- Factor VII preferred add Novoseven[®] Vial.
- Factor VIII preferred add Advate[®] Vial, Helixate FS[®] Vial, Hemofil[®] M Vial, Kogenate FS[®] Vial, Monoclate-P[®] Kit, Obizur[®] Vial, Recombinate[®] Vial. Non-preferred add Adynovate[®] Vial, Eloctate[®] Vial, Novoeight[®] Vial, Nuwiq[®] Vial, Xyntha[®] Syringe.
- Factor IX preferred add Alphanine[®] SD Vial, Bebulin[®] vial, Benefix[®] Kit, Mononine[®] Kit. Non-preferred add Alprolix[®] Vial, Ixinity[®] Vial, Kcentra[®] Vial, Profilnine[®] Vial, Rixubis[®] Vial.
- AHF-Von Willebrand Factor preferred add Alphanate[®] Vial, Humate-P[®] Vial, Koate[®]-DVI Kit, Wilate[®] Kit.

Clinical Criteria:

- Factor VIII and Factor IX criteria for All Non-Preferred Products: The prescriber must provide a clinically compelling reason for the use of the requested medication including reasons why any of the preferred products would not be a suitable alternative.

Public Comment: Margaret Fisher, Noro Nordisk: Highlighted attributes of Novoeight.

Board Decision: The Board unanimously approved the above recommendations.

d) Prenatal Vitamins

- No significant new studies or changes.

Recommendation:

- Remove Prenaplus, Prenatate AM tab 1mg.
- Add Prenate AM, Preplus, Virt-PN DHA Cap, Virt-PN Plus Cap, Vol-Plus to preferred.

Clinical Criteria:

- Remove DHA Containing prenatal vitamins clinical criteria as there are now preferred options with DHA.

Public Comment: No public comment

Board Decision: The Board unanimously approved the above recommendation.

e) Steroids, Topical

- No significant new studies or changes.

Recommendation:

- Corticosteroids Low potency: move Desonide 0.05% to non-preferred. Remove Hydrocortisone Acetate 1%, Aclovate® 0.05%, Nucort 2% lotion, Verdeso® 0.05%
- Corticosteroids Medium potency: move Hydrocortisone Valerate 0.2% to non-preferred. Remove Cutivate® 0.05%, Locoid® 0.1% and Westcort®. Add to preferred: Betamethasone Valerate 0.12% and Clacortolone 0.1%.
- Corticosteroids Very high potency: remove Alphatrex 0.05%, Apexicon 0.05%, Cormax 0.05%. Move Clobetasol propionate 0.05% to non-preferred. Add Diprolene® AF 0.05% to non-preferred.

Clinical Criteria:

- Remove: LIMITATIONS: Corticosteroid spray formulations (eg. Topicort® Spray) not covered –use alternate dosage forms.

Public Comment: No public comment

Board Decision: The Board unanimously approved the above recommendation.

9. New Managed Therapeutic Drug Classes:

- None at this time.

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

- None at this time.

11. General Announcements Mike Ouellette, RPh GHS/Change Healthcare

- Selected FDA Safety Alerts

Eye Drops: FDA Statement - Potential Risk of Loose Safety Seals

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm490862.htm>

Fluconazole Injection, USP, (in 0.9 Percent Sodium Chloride) 200mg per 100ml: Recall - Elevated Impurity

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm489316.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

12. Adjourn: Meeting adjourned at 8:38 p.m.