



Department of Vermont Health Access  
Pharmacy Benefit Management Program  
**DUR Board Meeting Minutes**  
September 15, 2015

**Board Members:**

**Present:**

Clayton English, PharmD  
Janet Farina, RPh  
Mark Pasanen, MD

Louise Rosales, NP  
Michael Biddle, PharmD  
Jaskanwar Batra, MD

James Marmar, RPh  
Joseph Lasek, MD, Chair

**Absent:**

**Staff:**

Michael Ouellette, RPh,  
GHS/Emdeon

Laureen Biczak, DO, GHS/Emdeon

Jason Pope, DVHA

Nancy Hogue, PharmD, DVHA  
Stacey Baker, DVHA

Mary Beth Bizzari, RPh, DVHA  
Jennifer Egelhof, DVHA  
Carrie Germaine, DVHA

Laurie Pedlar, RPh, GHS/Emdeon  
Scott Strenio, MD, DVHA  
Howard Pallotta, DVHA

**Guests:**

Rita Baglini, APS Health Care  
Gina Black, Vertex Pharmaceuticals  
David Downey, Abbott  
Andrea Hayes, Sanofi  
James Hayes, Abbvie  
Robert Mcsparren, Bristol- Myers  
Squibb  
Laurie Eddy  
Thomas Lahiri, MD

Thomas Currier, Purdue  
Shaffee Bacchus, Jansen  
Ben Carr, Abbvie  
Emily Ahrens, Sanofi  
Andrew Revel, Sanofi  
Jason Pelletier, Sanofi  
Kevin Losty, GSK  
Erin Gleason, Vertex

Scott Williams, J&J  
Jai Persico, Otsuka  
Lance Nicholls, Pfizer  
Marie Roache, Pfizer  
Thomas Algozzine, Novartis  
Shari Orbach, Bristol-Myers Squibb  
Drew Revel, Sanofi

Joseph Lasek, MD, Chair, called the meeting to order at 6:30 p.m. at the DUR Board meeting site in Williston.

**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 June meeting minutes were accepted as printed.

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

- Howard Pallotta, DVHA presented DVHA's new conflict of interest policy.

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

- DVHA will be sending out quality of care letters to prescribers, requesting chart notes and will be communicating with prescribers on quality of care issues.

#### **5. Follow-up Items from Previous Meetings: Mike Ouellette, RPh, GHS/Emdeon & Laureen Biczak, DO, GHS/Emdeon**

##### **a) Recommendation on Multiple Benzo Data Mike Ouellette, RPh, GHS/Emdeon**

After refining the analysis to eliminate those members transitioning from one benzodiazepine to another benzodiazepine the total number of users identified was narrowed to 45 members. These 45 members had a total of 71 prescribers identified for prescribing the benzodiazepines of which 23 members had multiple prescribers. The majority of prescribers involved in the instances of prescribing multiple benzodiazepines for these patients were involved with only one instance of the 45 members. However, there was one prescriber who was involved in 5 patients, one with 4 patients and seven with 2 patients. Generally the prescribers were prescribing both benzodiazepines. We also looked at the top 15 diagnoses, some examples were anxiety state, unspecified, post-traumatic stress disorder, lumbago and backache unspecified.

**Recommendation:** Edits will be placed in the system to require prior authorization for multiple benzodiazepines when being utilized concurrently for greater than 45 days. After the board discussion, it was decided that Clonazepam will be included in the edit and changes to concurrently for greater than 60 days. Additionally, a new analysis will be presented at the next meeting to include non-benzodiazepine sedative/hypnotics (Z drugs).

**Board Decision:** The Board unanimously approved the above recommendation.

#### **6. Retro DUR/DUR:**

##### **a) Present data on Hep C adherence Laureen Biczak, DO, GHS/Emdeon**

GHS evaluated paid, non-reversed pharmacy claims with dates of service from 1/1/2014 through 6/30/2015 for any of the following medications: Sovaldi, Olysio, Harvoni and Viekira Pak. The analysis excluded duals and evaluated only those patients who had continuous Medicaid eligibility during the targeted time frame. To analyze the adherence to treatment, for each patient GHS estimated both Medication Possession Ratio (MPR) and Proportion of Days Covered (PDC). Medication adherence has historically been reported to be around 50-60% for many chronic medications. For the purposes of this evaluation, GHS evaluated compliance at both the 80% and 90% rates. The results suggested adherence rates of 84-86%. The interpretation was that the adherence rates of 84-86% was encouraging and suggests that current systems are producing adherence rates above those commonly reported for chronic medications and that no specific new interventions are recommended. It was also noted, however, that there is not data available to relate 85% compliance to outcomes with this class of medications.

**Recommendation:** None at this time.

**Board Action:** None required.

**b) Present plan for testosterone therapy Laureen Biczak, DO, GHS/Emdeon**

There is general clinical consensus that replacement of testosterone in those who are clearly deficient can help alleviate symptoms. There is also general consensus that the appropriate use of testosterone is limited to those with DOCUMENTED low testosterone levels in association with signs and/or symptoms of hypogonadism. It is recommended that total testosterone levels be measured 2-3 months after initiation of therapy and then be monitored for 6-12 months to ensure the level is stable, if there are symptoms or a dose change. Due to the risk of polycythemia, a CBC is recommended pre-treatment, after 2-3 months of therapy and annually.

**Recommendation:** GHS will review Vermont paid, non reversed pharmacy claims with dates of service from 7/1/2014 through 6/30/2015 for any of the following medications: Testosterone cypionate, propionate and combinations fluoxymesterone, methyltestosterone, testosterone, testosterone enanthate, and undecanoate. The analysis will exclude duals and third party liability claims. Medical claims will be evaluated to look for any instances of testosterone levels and for screening for polycythemia. Date of first fill during this time period will be noted. Data to be reported: number of unique members receiving testosterone therapy, age breakdowns by age decile, number of members started on therapy with no pre-treatment testosterone or CBC in preceding year. For members continued on therapy for at least 4 months during this period, we will also look at how many had appropriate follow up CBC or testosterone level in the first 3-4 months of therapy.

**Board Action:** None required.

**7. Clinical Update: Drug Reviews:**

**Abbreviated New Drug Reviews**

None at this time.

**Full New Drug Reviews: Mike Ouellette, RPh, GHS/Emdeon & Laureen Biczak, DO, GHS/Emdeon**

**a) Afrezza® Inhal (human insulin)**

- Will be included in the Therapeutic Class Review

**Recommendation:** PDL placement and criteria will be recommended when TCR is reviewed.

*Public Comment:* No public comment.

**Board Decision:** Defer decision - to occur with the class review.

**b) Arnuity Ellipta® Inhal (fluticasone furoate)**

- For the once-daily maintenance treatment of asthma as prophylactic therapy in patients aged ≥12 years. A limitation of use is that it is NOT indicated for the relief of acute bronchospasm.

**Recommendation:** It is recommended that Arnuity Ellipta® be placed in the non-preferred position on the Preferred Drug List (PDL) requiring prior authorization with a quantity limit of 90/90 and no changes to the current criteria.

*Public Comment:* No public comment.

**Board Decision:** The Board unanimously approved the above recommendation.

**c) Incruse Ellipta® Inhal (umeclidinium bromide)**

- For the long-term, once-daily maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema. Administer one inhalation orally once daily. The safety and efficacy was established in 3 dose-ranging studies, 2 placebo-controlled studies (one 12-week study and one 24-week study), and a 12 month long-term safety study.

**Recommendation:** It is recommended that Incruse Ellipta® be placed in the non-preferred position on the Preferred Drug List (PDL) requiring prior authorization with a quantity Limit of one inhaler for 30 days, and criteria, patient has had a documented side effect, allergy or treatment failure to Spiriva®. Also Duoneb is no longer available and will be removed from the PDL.

*Public Comment:* No public comment.

**Board Decision:** The Board unanimously approved the above recommendation.

**d) Movantik® Tab (naloxegol)**

- For the treatment of opioid-induced constipation (OIC) in adult patients with chronic non-cancer pain. Two replicated, randomized double-blind, placebo-controlled 12 week studies were performed to assess the safety and efficacy of Movantik® in adults with opioid-induced constipation and non-cancer related pain.

**Recommendation:** It is recommended that Movantik® be placed in the non-preferred position on the Preferred Drug List (PDL) requiring prior authorization with a quantity limit of one tablet per day. Criteria will be that the patient must have documented opioid-induced constipation AND the patient has had documented side effect, allergy or treatment failure to a 1 week trial each of at least 2 preferred laxatives from the Bulk-Producing Laxative or Osmotic Laxative categories. Also, under clinical criteria for Amitiza we added "OR opioid-induced constipation".

*Public Comment:* No public comment.

**Board Decision:** The Board unanimously approved the above recommendations.

**e) Glyxambi® Tab (empagliflozin & linagliptin)**

- Will be included in the Hypoglycemics, Incretin Mimetics/Enhancers & SGLT-2 Inhibitors Therapeutic Class Review (TCR).

**Recommendation:** PDL placement and criteria will be recommended when Hypoglycemics, Incretin Mimetics/Enhancers & SGLT-2 Inhibitors Therapeutic Class Review (TCR) is discussed.

*Public Comment:* No public comment.

**Board Decision:** Defer decision to occur with the class review.

**f) Hysingla ER® Tab (hydrocodone bitartrate, extended-release)**

- For the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Hysingla® ER is not indicated as an as-needed analgesic. It was concluded that while the data showed Hysingla® ER to have physical and chemical properties to deter and reduce intranasal and oral abuse when chewed, it is still possible for it to be abused by the IV, intranasal, and oral routes.

**Recommendation:** It is recommended that Hysingla ER® be placed in the non-preferred position on the Preferred Drug List (PDL) requiring prior authorization with a quantity limit of one tablet per day. Hysingla ER® will be added to the Zohydro ER criteria which states “Available with PA for those unable to tolerate any preferred medications. All requests will go to the DVHA Medical Director for approval.” Also, added the generic name to Zohydro ER®.

*Public Comment:* No public comment.

**Board Decision:** The Board approved the above recommendation with one dissenting vote to not cover the product at all.

**g) Savaysa® Tab (edoxaban)**

- To reduce the risk of stroke and systemic embolism (SE) in patients with non-valvular atrial fibrillation (NVAF) AND for the treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) following 5-10 days of initial therapy with a parenteral anticoagulant. A limitation of use for the NVAF indication includes that Savaysa® should not be used in patients with CrCl >95ml/min because of an increased risk of ischemic stroke as compared to warfarin. Bleeding was the most common reason for treatment discontinuation (3.9% vs 4.1% in the Savaysa® 60mg vs warfarin groups). In the overall population, major bleeding was lower in the Savaysa® group vs warfarin (hazard ratio [HR] 0.80; p<0.001).

**Recommendation:** It is recommended that Savaysa® be placed in the non-preferred position on the Preferred Drug List (PDL) requiring prior authorization with a quantity limit of one tablet per day. Clinical Criteria will be: Savaysa: Diagnosis or indication is nonvalvular atrial fibrillation or the indication is treatment of DVT or PE following 5-10 days of parenteral anticoagulation or the indication is reduction of risk of recurrent DVT or PE following initial therapy AND creatinine clearance is documented to be < 95 ml/min AND prescriber has provided another clinically valid reason why generic warfarin, Pradaxa, Xarelto or Eliquis cannot be used. Also, the recommendation is that Pradaxa, Xarelto and Eliquis be moved to

the preferred position on the Preferred Drug List and the current clinical criteria will be removed.

*Public Comment:* No public comment.

**Board Decision:** The Board unanimously approved the above recommendation and added the requirement of obtaining a yearly creatinine clearance with the renewal of the prior authorization request.

**h) Cosentyx® Inj (secukinumab)**

- Treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy. Cosentyx® is an injection: 150mg/ml solution in a single-use Sensoready pen OR in a single-use prefilled syringe given at week 0,1, 2, 3, and 4 followed by 300mg Q4W; for some patients. There is a single comparator trial with good quality evidence that suggests that Cosentyx® may have a higher response rate as measured by the PASI 75 and improved IGA than Enbrel® (etanercept).

**Recommendation:** It is recommended that Cosentyx® be placed in the preferred position on the Preferred Drug List (PDL), but require prior authorization and be available to those who are unable to tolerate or who have failed a trial of Humira® (adalimumab). Quantity limit of 8 pens or vials month one, then 4 pens or vials monthly. Clinical criteria: it was recommended to remove the words “Enbrel®/Humira®” and make the initial clinical criteria listed in this category apply to all drugs with additional criteria for specific drugs as noted. It is recommended that the criteria that were specific to Humira® be removed. For additional criteria for Remicade® and Stelara®, it is recommended that the language be, “prescriber must provide a clinically valid reason why Humira® or Cosentyx® cannot be used”. It is further recommended that the following be added, “Additional Criteria for Cosentyx®: prescriber must provide evidence of a trial of Humira®”.

*Public Comment:* Thomas Algozzine, Novartis: Highlighted some of the attributes of Cosentyx®.

**Board Decision:** The Board unanimously approved the above recommendation.

**i) Ryтары® Tab (carbidopa & levodopa, extended-release)**

- Treatment of Parkinson’s disease, post-encephalitic Parkinsonism, and Parkinsonism that may follow carbon monoxide intoxication or manganese intoxication. Two registration trials were performed to assess the safety and efficacy of Ryтары® in patients with Parkinson’s disease. Study 1 was a double-blind, randomized, placebo-controlled, fixed-dose 30-week study that included adults with early Parkinson’s disease (N=381). Study 2 was a multicenter, randomized, double-blind, levodopa-containing active-control, double-dummy 22-week study that included adults with advanced Parkinson’s Disease (N=393) who had been maintained on a stable regimen of ≥400mg/day of levodopa prior to entering the study. Although there is some evidence of improvement in “off” time with Ryтары® versus IR carbidopa/levodopa, the difference is modest.

**Recommendation:** It is recommended that Ryтары® be placed in the non-preferred position on the Preferred Drug List (PDL) requiring prior authorization. Clinical criteria recommended were “The patient has a diagnosis of Parkinson’s disease, post-encephalitic parkinsonism, or

parkinsonism following intoxication from carbon monoxide or manganese AND the prescriber is a neurologist AND the patient is having breakthrough symptoms despite a combination of concurrent IR and ER formulations of carbidopa/levodopa". Also we will be removing Parodel® (bromocriptine) since it is no longer available.

*Public Comment:* No public comment.

**Board Decision:** The Board unanimously approved the above recommendation.

**j) Toujeo® Inj (secukinumab)**

- PDL placement and criteria will be recommended when the Anti-diabetic Agent: Insulins therapeutic class reviewed.

**Recommendation:** PDL placement and criteria will be recommended when TCR is reviewed.

*Public Comment:* No public comment.

**Board Decision:** Defer decision to occur with the class review.

**k) Evekeo® Tab (amphetamine sulfate)**

- Evekeo® is indicated for narcolepsy AND Attention Deficit Disorder with Hyperactivity (ADHD). There is no evidence at this time to support that Evekeo® is safer or more effective than the currently available, more cost effective medications.

**Recommendation:** It is recommended that Evekeo® be placed in the non-preferred position on the Preferred Drug List (PDL) requiring prior authorization. Clinical criteria for Evekeo® recommended were: "patient has a diagnosis of ADHD or narcolepsy AND the patient has had a documented side-effect, allergy, or treatment failure of at least 3 preferred agents, including one of each two distinct chemical entity (amphetamine/dextroamphetamine, methylphenidate)". GHS also recommended moving the authorized generic for Concentra® which is listed on the Preferred Drug List as Methylphenidate SA OSM IR/ER, 22.78% to preferred and non-authorized generic be the same as that for the brand Concentra® and the criteria be amended to include an intolerance to the authorized generic.

*Public Comment:* No public comment.

**Board Decision:** The Board unanimously approved the above recommendation.

**l) Asmanex HFA® Inhal (mometasone)**

- For maintenance treatment of asthma as prophylactic therapy in patients who are ≥12 years of age. Asmanex® HFA is NOT indicated for the relief of acute bronchospasm. There is no evidence at this time to support that Asmanex® HFA is more efficacious or safer than the currently available, more cost effective medications.

**Recommendation:** It is recommended that Asmanex® HFA be placed in the non-preferred position on the Preferred Drug List requiring prior authorization. Clinical criteria for Asmanex® HFA will be the same for the other metered-dose inhalers, which require a

documented side effect, allergy or treatment failure to at least two preferred agents.  
Quantity limit of 3 inhalers for 90 days.

*Public Comment:* No public comment.

**Board Decision:** The Board unanimously approved the above recommendation.

**m) Pazeo® OP Sol (olopatadine)**

- Treatment of ocular itching associated with allergic conjunctivitis. There is no consistent evidence at this time to support that Pazeo® is safer or more effective than the currently available, more cost effective medications.

**Recommendation:** It is recommended that Pazeo® be placed in the non-preferred position on the Preferred Drug List requiring prior authorization. Clinical criteria recommended for Pazeo® will include a quantity limit of 1 bottle for one month. Pazeo® will also be added the the clinical criteria currently used for other non-preferred drugs in the category, specifically: "The patient has had a documented side effect, allergy, or treatment failure to Pataday or Patanol. If the product has a generic equivalent, the patient must also have had a documented intolerance to the generic equivalent."

*Public Comment:* No public comment.

**Board Decision:** The Board unanimously approved the above recommendation.

**n) Daklinza® Tab (daclatasvir)**

- PDL placement and criteria will be recommended when the Hepatitis C Treatments class is reviewed.

**Recommendation:** PDL placement and criteria will be recommended when Hepatitis C Treatment TCR is reviewed.

*Public Comment:* No public comment.

**Board Decision:** Defer decision to occur with the class review.

**o) Technivie® Tab (ombitasvir/paritaprevir/ritonavir)**

- PDL placement and criteria will be recommended when the Hepatitis C Treatment TCR is reviewed.

**Recommendation:** PDL placement and criteria will be recommended when Hepatitis C Treatment TCR is reviewed.

*Public Comment:* No public comment

**Board Decision:** Defer decision to occur with the class review.

**p) Orkambi® Tab (lumacaftor/ivacaftor)**

- For the treatment of cystic fibrosis (CF) in patients 12 years of age 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. Numerous drug interactions are listed with Orkambi®. The most frequently reported adverse events include dyspnea and nasopharyngitis. Serious liver-related adverse events related to elevated transaminases have been reported in patients with CF taking Orkambi®, thus it is recommended that ALT, AST, and bilirubin levels be monitored.

**Recommendation:** It is recommended that Orkambi® be placed in the non-preferred side of the Preferred Drug List (PDL) requiring prior authorization with a quantity limit of 120/30days; maximum 30 days supply.

Initial Criteria

- ≥ 12 years of age
- Patient must be determined to be homozygous for the F508del mutation in the CFTR gene as confirmed by an FDA-approved CF mutation test AND
- Patient has a baseline forced expiratory volume in one second (FEV1) between 40 to 90 percent of the predicted normal value AND
- If the patient is between the ages of 12-18, they must have undergone a baseline ophthalmic examination to monitor for lens opacities/cataracts
- Prescriber is a CF specialist or pulmonologist

Ongoing Approval Criteria

- Patient has stable or improved FEV1
- Patient has LFTs/bilirubin monitored every 3 months for the first year of therapy and annually after the first year
- ALT or AST ≤ 5 X the upper limit of normal or ALT/AST ≤ 3 X the upper limits of normal and bilirubin is ≤ 2 X the upper limit of normal
- Between the ages of 12 and 18, have follow up ophthalmic exam at least annually

*Public Comment:* Laurie Eddy, spoke on behalf of families with CF patients.

Thomas Lahiri, MD, spoke as a CF care provider.

Erin Gleason, Vertex, highlighted some of the attributes of Orkambi®.

**Board Decision:** The Board recommended the criteria be amended to remove the upper limit (90%) of the FEV1 for the initial approval. The Board unanimously approved the amended recommendation.

**8. Therapeutic Drug Classes- Periodic Review: Mike Ouellette, RPh, GHS/Emdeon and Laureen Biczak, DO, GHS/Emdeon**

**a) Hypoglycemics, Incretin Mimetics/Enhancers & SGLT-2 Inhibitors**

- In this category, Glyxambi® was presented as a new drug.

- A meta-analysis by Esposito included 43 randomized controlled trials (N=19,101) to assess the efficacy of dipeptidyl peptidase-4 (DPP-4) inhibitors for the reduction of HbA1c levels to a target of <7% in those diagnosed with type 2 Diabetes Mellitus. The DPP-4 inhibitors included were sitagliptin, saxagliptin, vildagliptin (not approved in the U.S.), and alogliptin (not approved in the U.S.). Results suggest that there was a statistically significant reduction in HbA1c when using a DPP-4 inhibitor as compared with placebo. Additionally, it was estimated that approximately 40% using a DPP-4 inhibitor obtained the target HbA1c goal of <7%. However, when compared with other antidiabetic drugs, there were similar reductions in HbA1c. Safety issues exist and need to be taken into consideration when prescribing the GLP-1 agonists, as they have warnings regarding acute pancreatitis and acute renal failure. Additionally, all GLP-1 agonists except Byetta® have a black box warning regarding the potential for increased risk of thyroid c-cell tumors with use. A 2014 systematic review and mixed-treatment comparison by Craddy et al<sup>223</sup> included 83 randomized controlled trials to assess the safety and efficacy of DPP-4 inhibitors when used as treatment for type 2 Diabetes Mellitus in patients with inadequate glycemic control. Results suggested that there were no differences between DPP-4 inhibitors. A 2014 systematic review and meta-analysis by Wang included 4 randomized comparator studies (N=1755) to assess the safety and efficacy of GLP-1 analogues as compared with the DPP-4 inhibitor sitagliptin for the management of type 2 Diabetes Mellitus. Results suggested that compared to sitagliptin, the GLP-1 analogues were more effective in reducing HbA1c (weighted mean difference) and body weight, as well as having a higher proportion who achieved the HbA1c target of <7%. However, the GLP-1 analogues were found to have a higher incidence of GI adverse events compared to sitagliptin.

**Recommendation:** It is recommended that Glyxambi® be placed in the non-preferred position on the Preferred Drug List and requiring prior authorization with a quantity limit of 1 tablet/day. Glyxambi® additional criteria: The patient has documentation of a failure of therapy with the combination of the single agent drugs Invokana plus a preferred DPP-4 inhibitor. Also, remove Juvisyne from the Preferred Drug List and its criteria as it is no longer being made.

*Public Comment:* Shaffee Bacchus, Jansen: Highlighted some of the attributes of Invokana® and Invokamet®.

**Board Decision:** The Board unanimously approved the above recommendation with the change in criteria by replacing “single agent drugs Invokana” with “preferred SGL2”.

#### **b) Hypoglycemics, Insulins**

- Afrezza® and Toujeo® were presented as new drugs. Afrezza® and Toujeo® are FDA approved to improve glycemic control in adult patients with Diabetes Mellitus. Afrezza® Human insulin inhaled is not a substitute for long-acting insulin and must be used in combination with long-acting insulin in patients with type 1 Diabetes Mellitus. In addition, the safety and efficacy of use in individuals who smoke have not been established; thus, use of Afrezza® in individuals who smoke or who have recently stopped smoking is not recommended. Toujeo® is a long acting agent: similar to Lantus®. There is some evidence that Toujeo® may cause less nocturnal hypoglycemia than other long acting insulins. There

is no evidence found that Afrezza® or Toujeo® is safer or more effective than currently available, more cost effective preferred agents.

**Recommendation:** It is recommended that Arfezza® and Toujeo® be placed in the non-preferred position on the Preferred Drug List requiring prior authorization Also, GHS will remove Relion from the Preferred Drug List as it is no longer available.

Clinial criteria:

**Toujeo®**

- Diagnosis of Diabetes Mellitus AND
- Prescription is initiated by an Endocrinologist AND
- The person is currently on insulin glargine U100 and cannot achieve glycemic control (defined as hemoglobin A1c  $\leq 7\%$ ) because dose increases cannot be tolerated due to at least one severe low blood sugar event (requiring assistance from another) despite attempts at manipulating dosing time or splitting the dose.

**AFREZZA INHALED INSULIN:**

- Baseline PFT with FEV1  $\geq 70\%$  predicted
- Patient does not have underlying lung disease (Asthma, COPD)
- Patient is a non-smoker or has stopped smoking more than six months prior to starting Afrezza
- Patient is currently using a long-acting insulin
- Patient has failed to achieve HbA1c goal (defined as  $\leq 7\%$ ) on a short-acting insulin in combination with a long-acting insulin
- Initial approval is for 3 months and improved glycemic control must be documented for further approvals

**Diabetes Mellitus Type 2 Additional Criteria**

- Patient is intolerant to, or is not a candidate for, or has failed to achieve HbA1c goal, (defined as  $\leq 7\%$ ) despite therapy with two or more oral hypoglycemic agents

*Public Comment:* Drew Revel, Sanofi: Highlighted some of the attributes of Afrezza® and Toujeo®.

**Board Decision:** The Board unanimously approved the above recommendation.

**a) Hypoglycemics, Meglitinides**

- No clinically significant changes.

**Recommendation:** No changes recommended to the category or criteria.

*Public Comment:* No public comment.

**Board Decision:** The Board unanimously approved the above recommendation.

**d) Hypoglycemics, TZD Agents**

- No clinically significant changes.

**Recommendation:** It is recommended to remove “and, in consultation with their health care professional, decide not to take pioglitazone for medical reasons and the patient acknowledges that they understand the risk” from the clinical criteria of Avandia.®

*Public Comment:* No public comment.

**Board Decision:** The Board unanimously approved the above recommendation.

#### e) Alpha 1 proteinase inhibitors

- No clinically significant changes.

**Recommendation:** It is recommended to remove Prolastin® from the Preferred Drug List as it is no longer available.

*Public Comment:* No public comment.

**Board Decision:** The Board unanimously approved the above recommendation.

#### f) Sedative Hypnotics

- No clinically significant changes
- Review includes Belsomra® which had been discussed as a new drug review. Concerns about long term use of these drugs remain.

**Recommendation:** It is recommended to remove Zolpimist® and quazepam (Doral®) from the Preferred Drug List (PDL) and criteria as these products are not available.

*Public Comment:* No public comment.

**Board Decision:** The Board unanimously approved the above recommendation.

#### g) Movement Disorder Agents

- The only drug in this category is Xenazine®.
- No clinically significant changes.

**Recommendation:** No changes.

*Public Comment:* No public comment.

**Board Decision:** The Board unanimously approved the above recommendations.

#### h) Hepatitis C Treatments

- In this category, Daklinza® and Technivie® were presented as new drugs. Technivie® is a fixed dose combination of ombitasvir, a hepatitis C virus NS5A inhibitor, paritaprevir, a hepatitis C virus NS3/4A protease inhibitor, and ritonavir, a CYP3A inhibitor and is indicated in combination

with ribavirin for the treatment of patients with genotype 4 chronic hepatitis C virus (HCV) infection without cirrhosis. Daklinza® is a hepatitis C virus (HCV) NS5A inhibitor indicated for use with sofosbuvir for the treatment of chronic HCV genotype 3 infection.

**Recommendation:** It is recommended that Daklinza® be placed in the non-preferred position on the Preferred Drug List (PDL) requiring prior authorization and Technivie® be placed in the preferred position on the Preferred Drug List (PDL) with clinical criteria. A new version of the Hepatitis C prior authorization form will be revised to incorporate the new drugs and the newest AASLD/IDSA recommendations. The new form will be posted to the DVHA website at <http://dvha.vermont.gov/for-providers/pharmacy-prior-authorization-request-forms>

*Public Comment:* Shari Orbach, Bristol Meyers- Squibb: Highlighted some of the attributes of Daklinza®.

**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/Emdeon**

- Selected FDA Safety Alerts
  - Non-aspirin Nonsteroidal Anti-inflammatory Drugs (NSAIDs): Drug Safety Communication - FDA Strengthens Warning of Increased Chance of Heart Attack or Stroke  
<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicinalProducts/ucm454141.htm>
  - Unapproved Prescription Ear Drop (Otic) Products: Not FDA Evaluated for Safety, Effectiveness and Quality  
<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicinalProducts/ucm453430.htm>
  - Codeine Cough-and-Cold Medicines in Children: Drug Safety Communication - FDA Evaluating Potential Risk of Serious Side Effects  
<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicinalProducts/ucm453379.htm>
  - FDA Issues the Drug Supply Chain Security Act (DSCSA) Implementation: Product Tracing Requirements for Dispensers–Compliance Policy Guidance  
<http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/default.htm>
  - FDA Drug Safety Communication: FDA reporting permanent skin color changes associated with use of Daytrana patch (methylphenidate transdermal system) for treating ADHD  
[http://www.fda.gov/Drugs/DrugSafety/ucm452244.htm?source=govdelivery&utm\\_medium=email&utm\\_source=govdelivery](http://www.fda.gov/Drugs/DrugSafety/ucm452244.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery)

- Brintellix (vortioxetine) and Brilinta (ticagrelor): Drug Safety Communication - Name Confusion  
<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicinalProducts/ucm456569.htm>
- Picato (ingenol mebutate) Gel: Drug Safety Communication - FDA Warns of Severe Adverse Events, Requires Label Changes  
[http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicinalProducts/ucm459311.htm?source=govdelivery&utm\\_medium=email&utm\\_source=govdelivery](http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicinalProducts/ucm459311.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery)
  - **Tabled until next months meeting**

**13. Adjourn:** Meeting adjourned at 8:32 p.m.

DRAFT