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

October 25, 2022: 5:00 – 8:30 p.m.

Board Members Present:

	Andy Miller, RPH		**Lucy Miller, MD**		**Douglas Franzoni, PharmD**
	Joseph Nasca, MD		**Margot Kagan, Pharm D**		**Mark Pasanen, MD**
	Claudia Berger, MD		**Annie Daly, PharmD**		**Katharina Cahill, PharmD**

DVHA Staff Present:

	Stacy Baker, DVHA		**Ashley MacWalters, DVHA**		**Taylor Robichaud, DVHA**
	Lisa Hurteau, PharmD, DVHA		**Michael Rapaport, MD, DVHA**		

Change Healthcare Staff Present:

	Jacquelyn Hedlund, MD, Change Healthcare		**Laurie Brady, RPh, Change Healthcare**		**Carla Quinlivan, Change Healthcare**

Guests/Members of the Public:

Adam Denman (Global Blood Therapeutics), Amy Cunningham (NZAC), Ashlee Waring (AstraZeneca), Erica Hintze (Abbvie Pharma), Folger Tuggle (Alnylam Pharmaceuticals), Gene Muise (Amgen), Jai Persico (NGU/Zocrine), Jane Guo (Novartis), Janet Rose (SK Life Science), Joe Ward (Abbvie), Kristen Chopas (Gilead Sciences), Michael Dowling (consumer), Natalie Prairie (NTLP), Nikhil Kacker (Genentech), Omer Aziz (Teva Pharmaceuticals), Paul Ford (SCGUS), Punit Patel (US Medical Affairs), Sylvia Poulos, (Recordati Rare Disease, Inc), Terry Masterson (TESE), Dennis Cole, Frank Lanotte, Kevin Gaffney, Lisa L, Patty Arcese, Steve Patterson

1. Executive Session:

- An executive session was held from 5:00 p.m. until 6:00 p.m.

2. Introductions and Approval of DUR Board Minutes:

- Attendance was called and introductions of DVHA and Change Healthcare staff were made.
- The September meeting minutes were accepted as printed.

3. DVHA Pharmacy Administration Update: Lisa Hurteau, PharmD, DVHA and Taylor Robichaud, PharmD, DVHA:

- Welcomed new board member Katharina Cahill, PharmD. She is currently the pharmacy manager at Kinney Drugs in Waterbury.
- DVHA is finishing up the legislative report on "Pharmacy Best Practices and Cost Control" which is due 10/30/22. A final version will be shared with the board once it is available.

4. Medical Director Update: Michael Rapaport, Chief Medical Officer, DVHA

- No updates at this time.

5. Follow-up Items from Previous Meetings: Laurie Brady, RPH Change Healthcare

- None at this time.

6. RetroDUR/ProDUR: Jacquelyn Hedlund, MD and Laurie Brady, RPh, Change Healthcare

- Introduce: Appropriate use of Asthma Controller Medications

The National Heart, Lung and Blood Institute has published Guidelines for the Diagnosis and Management of Asthma. An update was published in 2020 and included a recommendation for as needed low dose inhaled corticosteroid (ICS)-formoterol to be used as preferred initial treatment. Alternatively, a low dose ICS can be taken whenever a short acting beta-agonist (SABA) is taken. For anyone who requires use of a SABA more than twice a month, as-needed low dose ICS-formoterol or daily controller medication is recommended. Higher average use of SABA over a year is associated with a higher risk of severe exacerbations, and in the shorter term, increasing use of as-needed SABA is associated with an increased likelihood of a severe exacerbation in subsequent days or weeks. Therefore, the use of more than one SABA canister (e.g., albuterol 200 puffs per canister) during a one-month period most likely indicates over reliance on this drug and suggests inadequate control of asthma. Additionally, inhaled corticosteroids (ICS) are the preferred long-term maintenance therapy in asthma for all ages. Before considering a regimen with a SABA reliever, it is important to consider whether patients will likely be adherent to daily controller therapy; if not, they will be exposed to the risks of SABA-only treatment. Long-acting beta-adrenergic inhalers (LABAs) should never be used without first using ICS inhalers due to the increased risk of asthma exacerbations and death.

Change Healthcare will use paid, non-reversed Medicaid pharmacy claims from January 2021 through December 2021, excluding members with Part D, VMAP and Healthy Vermonters coverage. Members with a diagnosis of cystic fibrosis, COPD, or emphysema will also be excluded.

Change Healthcare will review Vermont paid, non-reversed pharmacy and medical claims with dates of service from 1/1/2021 through 12/31/2021, excluding members who had a diagnosis of cystic fibrosis, COPD or emphysema. Members will be stratified by age and the number of short acting inhalers used per year, and analysis will be completed on whether an inhaled corticosteroid inhaler is also being prescribed. 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 will be reported. We will compare the rates of ER visits and hospitalizations to the

rates seen in the 2019 analysis, examining whether the educational interventions provided by the Board had an impact in reducing rates of asthma exacerbations, understanding that the populations are not identical. Additional analysis will be done on those using more than 12 short acting inhalers/year and sorted geographically. The prescribers for these members will be identified to look at providers who are possibly practicing outside of guideline recommendations, perhaps identifying those who would be appropriate for more targeted education.

Board Decision: None needed at this time.

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

Biosimilar Drug Reviews:

- None at this time.

Full New Drug Reviews:

- Included with Revised Criteria

Board Decision: None needed.

8. New Therapeutic Drug Classes

- None at this time.

9. Therapeutic Drug Classes- Periodic Review:

Cytokine/CAM Antagonists, including the following PDL categories:

- **Ankylosing Spondylitis**
  - December 14, 2021 The FDA approved the supplemental New Drug Application (sNDA) for XELJANZ® / XELJANZ® XR (tofacitinib) for the treatment of adults with active ankylosing spondylitis (AS) who have had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers.
  - April 29.2022 AbbVie announced that the FDA approved RINVOQ® (upadacitinib; 15 mg, once daily) for the treatment of adults with active ankylosing spondylitis (AS) who have had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers. The FDA approval in AS is supported by efficacy and safety data from the Phase 3 SELECT-AXIS 2 clinical trial (Study 1) evaluating RINVOQ in patients who had an inadequate response or intolerance to one or two biologic

disease-modifying anti-rheumatic drugs (bDMARDs) and the Phase 2/3 SELECT-AXIS 1 clinical trial evaluating RINVOQ in patients who were naïve to bDMARDs and had an inadequate response or intolerance to at least two nonsteroidal anti-inflammatory drugs (NSAIDs). In both SELECT-AXIS 1 and SELECT-AXIS 2 clinical trials, a significantly greater proportion of patients receiving RINVOQ 15 mg achieved an ASAS40* response, the primary endpoint, (51% and 44.5%, respectively) compared to those receiving placebo (26% and 18.2%, respectively) at week 14.

Recommendation:

- Move Avsola® (infliximab-axxq) biosimilar to Remicade® and Inflectra® (infliximab-dyyb) biosimilar to Remicade® to preferred after clinical criteria are met.
- Add XELJANZ® (tofacitinib) tablet with QTY LIMIT: 2 tablets/day and XELJANZ® XR (tofacitinib) tablet with QTY LIMIT: 1 tablet/day; Maximum 30 days supply to preferred after clinical criteria are met.
- Add Rinvoq ® (upadactinib) extended-release tablet with QTY LIMIT: 1 tablet/day; Maximum 30 days supply to non-preferred.
    - Clinical criteria:
        - Update Additional criteria for Taltz, Xeljanz, Xeljanz XR: the patient had a trial and failure or contraindication to a preferred TNF Inhibitor
        - Update Additional criteria for Cimzia, Cosentyx, Simponi: the prescriber must provide a clinically valid reason why at least 2 preferred agents cannot be used.
        - Update Additional criteria for Remicade, Renflexis: the prescriber must provide a clinically valid reason why at least 2 preferred agents cannot be used, and the patient must be unable to use Avsola or Inflectra.
        - Add Additional criteria for Rinvoq: the prescriber must provide a clinically valid reason why at least 2 preferred agents cannot be used, one of which must be Xeljanz or Xeljanz XR.

- **Cryoprin Associated Periodic Syndromes & Periodic Fever Syndrome**

Recommendation:

- Add note that all products require a PA

- **Gastrointestinal Biologics**
    - June 17, 2022 Abbvie's SKYRIZI® (risankizumab-rzaa) Receives FDA Approval as the First and Only Specific Interleukin-23 (IL-23) to Treat Moderately to Severely Active Crohn's Disease in Adults. In two induction and one maintenance clinical trials, SKYRIZI demonstrated

significant improvements in endoscopic response (defined as a decrease of greater than 50% from the baseline Simple Endoscopic Score in CD [SES-CD] or for patients with isolated ileal disease and SES-CD of 4, at least a 2-point reduction from baseline) and clinical remission (defined as a Crohn's Disease Activity Index [CDAI] of less than 150), compared to placebo, as both an induction and maintenance therapy.

- March 16, 2022 The FDA approved Abbvie's RINVOQ® (upadacitinib) for the treatment of adults with moderately to severely active ulcerative colitis (UC) who have had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers. This FDA approval is the first indication for RINVOQ in gastroenterology and is supported by efficacy and safety data from three Phase 3 randomized, double-blind, placebo-controlled clinical studies. The two induction studies (U-ACHIEVE and U-ACCOMPLISH) utilized RINVOQ 45 mg once daily for 8 weeks, and then 15 mg or 30 mg once daily for the maintenance study (U-ACHIEVE maintenance) through 52 weeks.1-4 Across all clinical trials, significantly more patients treated with RINVOQ achieved clinical remission at weeks 8 and 52, the primary endpoint based on the mMS: stool frequency subscore (SFS) ≤ 1 and not greater than Baseline, rectal bleeding subscore (RBS) = 0, endoscopy subscore (ES) of ≤ 1 without friability, compared to placebo. In addition, the studies met all ranked secondary endpoints, including endoscopic improvement and histologic-endoscopic mucosal improvement (HEMI), as well as corticosteroid-free clinical remission in the maintenance study. All primary and ranked secondary endpoints achieved p-values of <0.001 versus placebo**.**
- May 27, 2021 The FDA approved Zeposia® (ozanimod) 0.92 mg for the treatment of adults with moderately to severely active ulcerative colitis (UC), a chronic inflammatory bowel disease (IBD). Zeposia, an oral medication taken once daily, is the first and only sphingosine 1-phosphate (S1P) receptor modulator approved for patients with moderately to severely active UC. The mechanism by which Zeposia exerts therapeutic effects in UC is unknown but may involve the reduction of lymphocyte migration into the intestines. It is thought that by targeting S1P receptors on lymphocytes, a type of immune system cell, Zeposia reduces the number of lymphocytes in peripheral blood. The approval is based on data from True North, a Phase 3 trial

evaluating Zeposia as an induction and maintenance therapy versus placebo in adult patients with moderately to severely active UC. During induction at Week 10 (Zeposia N=429 versus placebo N=216) the trial met its primary endpoint of clinical remission (18% versus 6%, p<0.0001) as well as key secondary endpoints, including clinical response (48% versus 26%, p<0.0001), endoscopic improvement (27% versus 12%, p<0.0001) and endoscopic-histologic mucosal improvement (13% versus 4%, p<0.001) for Zeposia versus placebo, respectively. During maintenance at Week 52 (Zeposia N=230 versus placebo N=227) the trial met its primary endpoint of clinical remission (37% versus 19%, p<0.0001) as well as key secondary endpoints, including clinical response (60% versus 41%, p<0.0001), endoscopic improvement (46% versus 26%, p<0.001), corticosteroid-free clinical remission (32% versus 17%, p<0.001) and endoscopic-histologic mucosal improvement (30% versus 14%, p<0.001) for Zeposia versus placebo, respectively. Decreases in rectal bleeding and stool frequency subscores were observed as early as Week 2 (i.e.,1 week after completing the required 7-day dosage titration) in patients treated with Zeposia.

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Recommendation:

- Move Avsola® (infliximab-axxq) biosimilar to Remicade® and Inflectra® (infliximab-dyyb) biosimilar to Remicade® and XELJANZ® XR (tofacitinib) tablet with QTY LIMIT: 1 tablet/day to preferred after clinical criteria are met.
- Move Remicade® (infliximab) and Renflexis™ (infliximab-abda) biosimilar to Remicade® to non-preferred.
- Add Skyrizi® (risankizumab-rzaa) with QTY LIMIT: 360 mg(2.4ml)/56 days after initial IV loading dose, Rinvoq ® (upadactinib) extended-release tablet with QTY LIMIT: 1 tablet/day; Maximum 30 days supply, and Zeposia® (ozanimod) capsule with QTY LIMIT: 1 capsule/day to non-preferred.
- Add QTY Limit: 90mg (1ml)/56 days after initial IV loading dose to Stelara® (ustekinumab).
    - Clinical Criteria:
        - Update Clinical Criteria for approval of ALL drugs (Crohn's Disease): Patient has a diagnosis of moderate to severe Crohn's disease and has already been stabilized on the medication OR patient meets additional criteria outlined below:
            - Avsola, Humira, Inflectra: The patient has had a treatment failure with at least one conventional agent (e.g.

methotrexate, corticosteroids) OR there is evidence of severely active disease and early introduction of a biologic without prior medication trials is medically necessary.

- Cimzia, Entyvio, Simponi, Stelara, Tysabri: The patient never responded to anti-TNFα therapy (primary nonresponse) OR the patient previously responded to infliximab (secondary nonresponse) and has a documented side effect, allergy, or treatment failure with adalimumab.
- Remicade, Renflexis: The prescriber must provide a clinically compelling reason why Avsola or Inflectra would not be suitable alternatives.
- Skyrizi: The patient has a documented side effect, allergy, or treatment failure to a 12-week course of therapy with a preferred TNF inhibitor AND the patient has a documented side effect, allergy, or treatment failure to a 12-week course of therapy with either Entyvio or Stelara.

- Update Clinical Criteria for approval of ALL drugs (Ulcerative Colitis): Patient has a diagnosis of moderate to severe Ulcerative Colitis and has already been stabilized on the medication OR patient meets additional criteria outlined below:
  - Avsola, Humira, Inflectra: The patient has had a treatment failure with at least one conventional agent (e.g. 5-ASA, corticosteroids) OR there is evidence of severely active disease and early introduction of a biologic without prior medication trials is medically necessary.
  - Entyvio, Simponi, Stelara, Zeposia: The patient has had a treatment failure with at least one conventional agent (e.g. 5-ASA, corticosteroids) AND the patient has a documented side effect, allergy, or treatment failure with at least one preferred biologic.
  - Rinvoq: The patient has had a treatment failure with at least one conventional agent (e.g. 5-ASA, corticosteroids) AND the patient has a documented side effect, allergy, or treatment failure with a preferred TNF inhibitor AND the patient has a documented side effect, allergy, or treatment failure with Xeljanz or Xeljanz XR.
  - Xeljanz, Xeljanz XR: The patient has had a treatment failure with at least one conventional agent (e.g. 5-ASA, corticosteroids) AND the patient has a documented side effect, allergy, or treatment failure with at least one preferred TNF Inhibitor. Note: Induction of Xeljanz 10mg twice daily or XR 22mg once daily will be limited to 16 weeks. Treatment should be discontinued after 16 weeks if adequate therapeutic

response is not achieved. For patients with loss of response during maintenance treatment with 5mg twice daily or XR 11mg once daily, approval of 10mg twice daily or XR 22mg once daily will be considered and limited to the shortest duration possible.

- **Hidradenitis Suppurativa**

Recommendation:

- Add new PDL category Hidradenitis Suppurtiva.
- Add HUMIRA® (adalimumab) with QTY LIMIT: 6 syringes/28 days for the first month (HS starter kit);4 syringes/28 days subsequently to preferred after clinical criteria are met.
  - Clinical criteria:
    - The patient has a diagnosis of moderate-severe hidradenitis suppurativa (Hurley Stage II-III) AND The medication is being prescribed by, or in consultation with, a dermatologist AND The patient has not responded to a 12-week course of standard antibiotic therapy with an oral tetracycline (e.g. Doxycycline) or clindamycin plus rifampin, unless contraindicated.

- **Psoriasis Biologics**
  - No new drugs.
  - No other significant clinical changes.

Recommendation:

- Move Avsola® (infliximab-axxq) biosimilar to Remicade® and Inflectra® (infliximab-dyyb) biosimilar to Remicade® to preferred after clinical criteria are met.
- Update Skyrizi™ (risankizumab-rzaa) QTY LIMIT: 150 mg/28 days for the first month and 150mg/84 days thereafter, Stelara® (ustekinumab) QTY LIMIT: 45 mg (0.5 ml) or 90 mg (1 ml) per dose (90mg dose only permitted if patient weight > 100kg) One dose/28 days for the first month and one dose/84 days thereafter, and Tremfya® (guselkumab) QTY LIMIT: 1 syringe/28 days for the first month, then 1 syringe every 56 days thereafter.
  - Clinical criteria:
    - Update Additional Criteria for Taltz: The prescriber must provide evidence of a trial and failure or contraindication to a preferred TNF Inhibitor.
    - Update Additional Criteria for Cimzia, Cosentyx, Ilumya, Siliq, Skyrizi, Stelara, Tremfya: The prescriber must provide a clinically valid reason why both a preferred TNF Inhibitor and Taltz® cannot be used.

- Update Additional Criteria for Remicade, Renflexis: The prescriber must provide a clinically valid reason why Humira®, Taltz®, and Avsola/Inflectra cannot be used.

- **Rheumatoid, Juvenille, & Psoriatic Arthritis**
  - January 21, 2022 The FDA approved SKYRIZI® (risankizumab-rzaa) for the treatment of adults with active psoriatic arthritis (PsA), a systemic inflammatory disease that affects the skin and joints and impacts approximately 30 percent of patients with psoriasis. The FDA approval is supported by data from two pivotal studies, KEEPsAKE-1 and KEEPsAKE-2, which evaluated the efficacy and safety of SKYRIZI in adults with active PsA, including those who had responded inadequately or were intolerant to biologic therapy and/or non-biologic disease-modifying antirheumatic drugs (DMARDs). Across the two Phase 3 studies, SKYRIZI met the primary endpoint of ACR20 response at week 24 compared to placebo and demonstrated significant improvements across several other manifestations of PsA, including swollen, tender and painful joints.
  - July 14, 2020 The FDA approved Janssen's TREMFYA® (guselkumab) for adult patients with active psoriatic arthritis (PsA), a chronic progressive disease characterized by painful joints and skin inflammation. TREMFYA is the first treatment approved for active PsA that selectively inhibits interleukin (IL)-23. The safety and efficacy of TREMFYA in PsA have been demonstrated in two pivotal Phase 3 clinical trials. TREMFYA is administered as a 100 mg subcutaneous injection every eight weeks, following two starter doses at weeks 0 and 4. TREMFYA can be used alone or in combination with a conventional Disease Modifying Anti-Rheumatic Drug or DMARD (e.g., methotrexate).

Recommendation:

- Move Avsola® (infliximab-axxq) biosimilar to Remicade® and Inflectra® (infliximab-dyyb) biosimilar to Remicade® and XELJANZ® XR (tofacitinib) tablet with QTY LIMIT: 1 tablet/day to preferred after clinical criteria are met.
- Add Actemra® (tocilizumab) ACT Pen with QTY LIMIT: 4 pens (3.6ml)/28 days, Skyrizi™ (risankizumab-rzaa) with QTY LIMIT: 150 mg/28 days for the first month and 150mg/84 days thereafter, and Tremfya® (guselkumab) with QTY LIMIT: 1 syringe/28 days for the first month, then 1 syringe every 56 days thereafter to non-preferred.

- Updated Stelara® (ustekinumab) QTY LIMIT: 45 mg (0.5 ml) or 90 mg (1 ml) per dose (90 mg dose only permitted for pt weight > 100 kg) One dose/28 days for the first month and one dose/84 days thereafter on non-preferred.
    - Clinical criteria:
        - Update Taltz, Xeljanz, Xeljanz XR additional criteria: patient must be ≥ 18 years of age AND the prescriber must provide evidence of a trial and failure or contraindication to a preferred TNF Inhibitor.
        - Update Actemra, Cimzia, Cosentyx, Kevzara, Orencia and Tremfya Simponi (subcutaneous), Skyrizi, Stelara additional criteria: The prescriber must provide clinically valid reason why at least 2 preferred agents cannot be used.
        - Update Remicade, Renflexis additional criteria: The prescriber must provide a clinically valid reason why at least 2 preferred agents cannot be used AND the patient must be unable to use Avsola or Inflectra
        - Update Olumiant, Rinvoq additional criteria: The patient must be ≥ 18 years of age AND The prescriber must provide a clinically valid reason why at least two preferred agents cannot be used, one of which must be Xeljanz or Xeljanz XR.

Public Comments: Punit Patel from US Medical Affairs: Highlighted the attributes of Rinvoq and Skyrizi.
Jane Guo from Novartis: Highlighted the attributes of Cosentyx.

Board Decision: The Board unanimously approved the above recommendations.

10. Review of Newly-Developed/Revised Criteria (all changes will be effective 1/1/23):

- ADHD/Long-acting Methylphenidate

Recommendation:

- Move Methylphenidate CR, IR/ER, 30:70% (compare to Metadate CD®) to preferred.
- Add Methylphenidate patch (compare to Daytrana®) with QTY LIMIT: 1 patch/day to non-preferred.
    - Clinical criteria:
        - Update Daytrana patch, Methylphenidate patch: patient has a documented medical necessity for a specialty non-oral dosage form AND for approval of generic Methylphenidate patch, the patient must have a documented intolerance to brand Daytrana.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- ADHD/Non-stimulant

Recommendation:

- Move Qelbree™ (viloxazine hydrochloride) ER capsule with QTY LIMIT: 100 mg = 1 capsule/day, 150 mg = 2 capsules/day, 200 mg = 3 capsules/day, FDA maximum recommended dose= 600 mg/day to preferred after clinical criteria are met.
  - Clinical criteria:
    - Update Qelbree: The patient has had a documented side effect, allergy, or treatment failure to atomoxetine.
    - Update Wakix: Patient has no known risk factors for increased QT prolongation (e.g. cardiac arrhythmias, symptomatic bradycardia, hypokalemia, or congenital prolongation of the QT interval) AND medication is not being used in combination with other drugs known to prolong the QT interval (e.g. antipsychotics, erythromycin, tricyclic antidepressants) AND patient has had a documented side effect, allergy, or treatment failure to at least 3 agents (may be preferred or nonpreferred; may be stimulant or non-stimulant), one of which must be Sunosi.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Antibiotics/Inhaled

Recommendation:

- Move Bethkis® (tobramycin) inhalation solution with QTY LIMIT: 56 vials/56 days; maximum day supply = 56 days (2 vials/day for 28 days, then 28 days off) to non-preferred.
  - Clinical criteria:
    - Update Bethkis, TOBI, tobramycin inhalation solutions (300mg/4mL): Diagnosis or indication is cystic fibrosis and the patient has a documented failure or intolerance to two preferred formulations of tobramycin inhalation solution.
    - Update Initial Criteria ≥ 1 year of age for Orkambi or ≥ 6 years of age for Symdeko or Trikafta.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Anticonvulsants

Recommendation:

- Move Epidiolex® (cannabidiol) oral solution to Preferred After Clinical Criteria Are Met.
- Add Rufinamide (compare to Banzel®) tablet, oral suspension with QTY LIMIT: 400 mg = 8 tabs/day, 200mg = 16 tabs/day, oral suspension = 80 ml/day (3200 mg/day) to non-preferred.
- Add QTY Limit for Clobazam oral suspension = 16 ml/day (40mg/day)
    - Clinical criteria:
        - Update Banzel, Rufinamide: diagnosis or indication is treatment of Lennox-Gastaut Syndrome. AND patient has had a documented side effect, allergy, treatment failure/inadequate response or a contraindication to at least TWO preferred anticonvulsants used for the treatment of Lennox-Gastaut syndrome (topiramate, lamotrigine, valproic acid) AND for approval of the oral suspension, patient must have medical necessity for a specialty dosage form AND for approval of generic rufinamide, the patient must have a documented intolerance to brand Banzel.
        - Update Epidiolex: The patient is unable to tolerate or has had an inadequate response to at least 2 of the following medications: clobazam, levetiracetam, valproate, lamotrigine, topiramate, rufinamide, or felbamate Note: This is processed via automated (electronic step therapy).

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Antidiabetics/GLP-1 RA (new drug review Mounjaro® (tirzepatide) included)
    - Tirzepatide, the active ingredient of Mounjaro®, is a glucose-dependent insulinotropic polypeptide (GIP) receptor and glucagon-like peptide-1 (GLP-1) receptor agonist that selectively binds to and activates both the GIP and GLP-1 receptors (the targets for native GIP and GLP-1). Tirzepatide lowers fasting and postprandial glucose concentration, decreases food intake, and reduces body weight in patients with type 2 diabetes mellitus (DM). It is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 DM. It has not been studied in patients with a history of pancreatitis and is not indicated for use in patients with type 1 DM. Mounjaro® delays gastric emptying, and

thus has the potential to impact the absorption of concomitantly administered oral medications. Mounjaro® has been associated with gastrointestinal adverse reactions, which include nausea, vomiting, and diarrhea. These events may lead to dehydration, which if severe could cause acute kidney injury. In patients treated with GLP-1 receptor agonists, there have been post marketing reports of acute kidney injury and worsening of chronic renal failure. Some of these events have been reported in patients without known underlying renal disease. Monitor renal function when starting or increasing doses of Mounjaro ® in patients with renal impairment reporting severe gastrointestinal adverse reactions. The safety and efficacy of Mounjaro® as an adjunct to diet and exercise to improve glycemic control in adults with type 2 DM were established in 5 trials. In these trials, Mounjaro® was studied as monotherapy (SURPASS-1); as an add-on to metformin, sulfonylureas, and/or sodium-glucose co-transporter 2 inhibitors (SGLT2 inhibitors; SURPASS-2, -3, and -4); and in combination with basal insulin with or without metformin (SURPASS-5). In these trials, Mounjaro® (5mg, 10mg, and 15mg SC QW) was compared with placebo, semaglutide 1mg, insulin degludec, and/or insulin glargine. In adult patients with type 2 DM, treatment with Mounjaro® produced a statistically significant reduction from baseline in HbA1c as compared to placebo. In an open-label study, Mounjaro® 10mg and 15mg SC once weekly for 40 weeks resulted in a statistically significant reduction in HbA1c as compared with semaglutide 1mg SC once weekly. Note that semaglutide SC, under the brand name Ozempic®, is also available as a higher 2mg dose that was not utilized in this study. The NNT was calculated for the outcome of the percentage of patients achieving HbA1c <7% in this study; results suggested that the NNT was 15 for Mounjaro® 10mg vs semaglutide 1mg and 15 for Mounjaro® 15mg vs semaglutide 1mg. (Note that Mounjaro® 5mg also had a statistically significant reduction in HbA1c.). There is some evidence at this time to suggest that Mounjaro® may be more effective than semaglutide SC 1mg (mid-range dose), insulin degludec, and insulin glargine for HbA1c reduction and weight reduction in phase 3 studies, as well as more effective than the lowest dulaglutide dose in a Japanese phase 3 study; however, there is no direct comparator evidence at this time to support that Mounjaro® is safer or more effective than the other currently preferred, more cost-effective medications.

Recommendation:

- Move Ozempic® (semaglutide) with QTY LIMIT: 9mL/84 days to preferred after clinical criteria are met. All drugs in this class will also now require confirmation of Type 2 DM diagnosis.
- Add Mounjaro™ (tirzepatide) with QTY LIMIT: 4 pens/28 days to non-preferred.

- Clinical criteria:
  - Add Clinical criteria for all drugs: patient has a diagnosis of Type 2 Diabetes Mellitus.
  - Update Additional criteria for Adlyxin, Byetta, Bydureon BCise, Mounjaro: patient has a documented side effect, allergy, contraindication, or treatment failure with two preferred GLP-1 Receptor Agonists. Treatment failure is defined as < 1% reduction in HbA1c after 12 weeks at the maximally tolerated dose.
  - Update Additional criteria for Rybelsus: patient has a documented side effect, allergy, contraindication, or treatment failure with one preferred SGLT2 inhibitor AND patient has a documented side effect, allergy, contraindication, or treatment failure with two preferred GLP-1 Receptor Agonists, one of which must be Ozempic, or has a clinically valid reason for being unable to administer an injection (e.g. visual impairment, impaired dexterity). Treatment failure is defined as < 1% reduction in HbA1c after 12 weeks at the maximally tolerated dose.
  - Update Soliqua/Xultophy: Patient has a documented side effect, allergy, contraindication, or treatment failure with at least one preferred GLP-1 Receptor Agonist used in combination with Lantus or Levemir. Treatment failure is defined as < 1% reduction in HbA1c after 12 weeks at the maximally tolerated dose.
  - Update Symlin: patient is at least 18 years of age. AND patient is on insulin

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Antiretrovirals/Single Product Regimens

Recommendation:

- Move Juluca® (dolutegravir/rilpivirine) to non-preferred with grandfathering of existing patients.
- Add TRIUMEQ® PD tablets for oral suspension (abacavir/lamivudine/dolutegravir) to preferred.
  - Clinical criteria:
    - Add Juluca: The patient has been started and stabilized on the requested medication (Note: samples are not considered adequate justification for stabilization.) OR patient is

virologically suppressed (HIV-1 RNA < 50 copies per mL) on a stable oral antiretroviral regimen for at least 6 months AND medical reasoning beyond convenience or enhanced compliance over preferred agents is provided.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Carglumic Acid

Recommendation:

- Move Carbaglu® dispersible tablets (carglumic acid) to non-preferred.
- Add CARGLUMIC ACID (compare to Carbaglu®) dispersible tablets to preferred after clinical criteria are met.
  - Clinical criteria:
    - Update Carbaglu, Carglumic Acid: The diagnosis or indication for the requested medication is hyperammonemia due to N-acetylglutamate synthetase (NAGS) deficiency, propionic acidemia, or methylmalonic acidemia AND The prescriber is a specialist in metabolic disorders (e.g., medical geneticist) or prescriber is in consultation with a specialist AND for approval of brand name Carbaglu, the patient has had a documented intolerance to the generic equivalent of the requested medication.

Public Comments: Sylvia Poulos from Recordati Rare Disease, Inc: Highlight the attributes of Carbaglu.

Board Decision: The Board unanimously approved the above recommendations.

- Contraceptives/Patch

Recommendation:

- Move Zafemy (norelgestromin/ ethinyl estradiol) patch to non-preferred.
  - Clinical criteria:
    - Add Zafemy: Trial with at least three preferred contraceptive products including the preferred formulation of the requested non-preferred agent.

Public Comments: No public comment.

Board Decision: The Board approved the above recommendations with Joe Nasca abstaining.

- Cardiovascular/Heart Failure

Recommendation:
- Remove clinical criteria for Entresto® (valsartan/sacubitril).

Public Comments: Jane Guo from Novartis: Highlighted the attributes of Entresto.

Board Decision: The Board unanimously approved the above recommendations.

- GI/Bowel Evacuants

Recommendation:
- Move Suprep® to non-preferred.
- Move Clenpiq® to preferred.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- GNRH-LNRH Antagonists

Recommendation:
- Move MYFEMBREE® (relugolix/estradiol/norethindrone) tablet with QTY LIMIT: 1 tab/day to preferred after clinical criteria are met.
  - Clinical criteria:
    - Update Myfembree, Orilissa, Oriahnn: Patient has a documented side effect, allergy, or treatment failure to at least TWO medications from at least 2 different classes (oral contraceptives, NSAIDs, progestins). Note: Use of GnRH receptor antagonists will be limited to 2 years.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Hemophilia Factor VIII/Extended Half-Life

Recommendation:
- Move Esperoct® to non-preferred.
- Move Jivi® to preferred.
  - Clinical criteria:
    - Update 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 suitable alternatives. For approval of Adynovate, Eloctate, or Esperoct, documentation must include why the member is unable to use the preferred extended half-life concentrate Jivi.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations

- Hematopoietics/Colony Stimulating Factors

Recommendation:

- Move Udenyca™ (pegfilgrastim-cbqv) to non-preferred.
  - Clinical criteria:
    - Update Granix, Leukine, Nivestym, Releuko, Zarxio: The prescriber must provide a clinically compelling reason for the use of the requested medication including reasons why Neupogen would not be a suitable alternative.
    - Add Nyvepria, Udenyca: The prescriber must provide a clinically compelling reason for the use of the requested medication including reasons why any of the preferred pegfilgrastim products would not be suitable alternatives.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations

- Hematopoietics/ Erythropoietic Stimulating Agents

Recommendation:

- Move Mircera® (methoxypolyethylene glycolepoetin beta) to preferred after clinical criteria are met.
- Move Retacrit® (epoetin alpha-epbx) to non-preferred.
  - Clinical criteria:
    - Update Aranesp, Procrit, Epogen, Retacrit: diagnosis or indication for the requested medication is anemia due to one of the following: Chronic kidney disease/renal failure, Post-renal transplant, use of zidovudine for the treatment of human immunodeficiency virus (HIV) (other causes of anemia, such as iron/folate/vitamin B12 deficiency have been eliminated), Surgery patients at high risk for perioperative blood loss, Cancer chemotherapy, Use of ribavirin or

interferon therapy for Hepatitis C, Myelodysplastic syndrome. Hemoglobin level at initiation of therapy is <10 g/dL OR for patients currently maintained on therapy, hemoglobin level is < 11 g/dL in dialysis patients with chronic kidney disease, < 10 g/dL in non-dialysis patients with chronic kidney disease, or < 12 g/dL in patients treated for other indications AND for approval of Aranesp, Procrit, or Retacrit the patient has had a documented side effect, allergy, or treatment failure to Epogen.

- Update Mircera: The diagnosis or indication for the requested medication is anemia due to chronic kidney disease/renal failure AND Hemoglobin level at initiation of therapy is <10g/dl OR For patients currently maintained on therapy, hemoglobin level is ≤11 g/dL in dialysis patients with chronic kidney disease, ≤10 g/dL in non-dialysis patients with chronic kidney disease.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations

- Hypoglycemia Treatments

Recommendation:

- Move Baqsimi® (glucagon nasal powder) 3mg with QTY LIMIT: 2 devices/28 days and Zegalogue® (dasiglucagon SC injection) 0.6 mg with QTY LIMIT: 2 prefilled syringes or auto-injectors/28 days to preferred.
- Remove GLUCAGON EMERGENCY KIT (glucagon for injection) 1mg (Lilly labeler code 00002) from preferred since the manufacturer will be discontinuing the product 12/31/22.
    - Clinical criteria:
        - Update Glucagon Emergency Kit, Gvoke: Patient has recurrent episodes of symptomatic or severe hypoglycemia (<55 mg/dL) requiring the assistance of another individual AND the preferred formulations would not be suitable alternatives.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- MABS-Anti-IL, Anti-IgE (Immunologic Therapies for Asthma PDL Category) (new drug review Tezpire® (Tezepelumab-ekko) included)

- Tezepelumab-ekko, the active ingredient of Tezspire®, is a thymic stromal lymphopoietin (TSLP) blocker, a human monoclonal antibody IgG2λ that binds to human TSLP with a dissociation constant of 15.8pM and blocks its interaction with the heterodimeric TSLP receptor. TSLP is a cytokine mainly derived from epithelial cells and occupies an upstream position in the asthma inflammatory cascade. Blocking TSLP with tezepelumab-ekko reduces biomarkers and cytokines associated with inflammation including blood eosinophils, airway submucosal eosinophils, IgE, FeNO, IL-5, and IL-13; however, the mechanism of action in asthma has not been definitely established. Tezspire® is indicated for the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma. Tezspire® is not indicated for the relief of acute bronchospasm or status asthmaticus. It is the first and only biologic indicated for severe asthma that does not have a phenotype or biomarker limitation within its approved indication. The safety and efficacy of Tezspire® were assessed in two randomized, double-blind, placebo-controlled studies, and the primary endpoint of the two studies was the rate of clinically significant asthma exacerbations measured over 52 weeks. Results suggested that patients receiving Tezspire® had significant reductions in the annualized rate of asthma exacerbations compared to placebo. There were also fewer exacerbations requiring emergency room visits and/or hospitalization in patients treated with Tezspire® compared with placebo.
- May 20, 2022 The FDA approved Dupixent® (dupilumab) 300 mg weekly to treat patients with eosinophilic esophagitis (EoE) aged 12 years and older, weighing at least 40 kg. With this approval, Dupixent becomes the first and only medicine specifically indicated to treat EoE in the United States. EoE is a chronic inflammatory disorder in which eosinophils, a type of white blood cell, are found in the tissue of the esophagus. In adults and adolescent patients with EoE, common symptoms include difficulty swallowing, difficulty eating, and food getting stuck in the esophagus. Dupixent is a monoclonal antibody that acts to inhibit part of the inflammatory pathway.
- The efficacy and safety of Dupixent in EoE was studied in a randomized, double-blind, parallel-group, multicenter, placebo-controlled trial, that included two 24-week treatment periods (Part A and Part B) that were conducted independently in separate groups of patients.
    - In Part A and Part B, patients received either placebo or 300 milligrams of Dupixent every week. The two primary measurements of efficacy were the proportion of patients who achieved a certain level of reduced eosinophils in the esophagus at week 24, as determined by assessing patients' esophageal tissue under a microscope, and the change in the patient-

reported Dysphagia Symptom Questionnaire (DSQ) score from baseline to week 24. The DSQ is a questionnaire designed to measure difficulty swallowing associated with EoE, with total scores ranging from 0 to 84; higher DSQ scores indicate worse symptoms. In Part A of the trial, 60% of the 42 patients who received Dupixent achieved the pre-determined level of reduced eosinophils in the esophagus compared to 5% of the 39 patients who received a placebo. Patients in Part A who received Dupixent experienced an average improvement of 22 points in their DSQ score compared to 10 points in patients who received placebo. In Part B, 59% of the 80 patients who received Dupixent achieved the pre-determined level of reduced eosinophils in the esophagus compared to 6% of the 79 patients who received a placebo. Patients in Part B who received Dupixent experienced an average improvement of 24 points in their DSQ score compared to 14 points in patients who received placebo. Assessments incorporating the perspectives from patients with EoE supported that the DSQ score improvement in patients who received Dupixent in the clinical trial was representative of clinically meaningful improvement in dysphagia.

- September 29, 2022 the FDA approved Dupixent® (dupilumab) for the treatment of adults with prurigo nodularis (PN). This is the first FDA-approved treatment for PN. PN is a rare skin disease that causes hard, itchy lumps (nodules) to form on the skin. The itching can be intense, causing people to scratch themselves to the point of bleeding or pain. Scratching can also cause more skin lesions to appear. The disease affects approximately 87,000 adults per year according to the National Organization for Rare Diseases database. Safety and effectiveness of Dupixent to treat PN among adults were evaluated in two clinical trials, EFC16459 (PRIME) and EFC16460 (PRIME2). Each trial evaluated 300 mg of Dupixent administered every 2 weeks following an initial dose of 600 mg. The treatment lasted for 24 weeks. Effictiveness was mainly assessed by the proportion of subjects whose itchy skin (pruritus) improved by more than four points on the Worst Itch Numeric Rating Scale, the proportion of subjects who achieved score of 0 or 1 on Investigator's Global Assessment PN-stage scale (the equivalent of 0-5 nodules), and the proportion of subjects who achieved a response on both scales at week 24. In the trials for the PN indication, the primary endpoint and key

secondary endpoints were considered significant when compared to placebo.

- July 29, 2021 The FDA approved Nucala (mepolizumab), a monoclonal antibody that targets interleukin-5 (IL-5), as a treatment for patients with chronic rhinosinusitis with nasal polyps (CRSwNP). This new indication for mepolizumab is for the add-on maintenance treatment of CRSwNP in adult patients 18 years of age and older with inadequate response to nasal corticosteroids. The approval of mepolizumab as a treatment for CRSwNP is based on data from the pivotal SYNAPSE study which explored the effect of mepolizumab vs. placebo in over 400 patients with CRSwNP. Mepolizumab achieved significant improvement in reducing the size of nasal polyps and nasal obstruction. All patients in the study received standard care, had a history of previous surgery (approximately one in three had ≥3 surgeries) and were in need of further surgery due to severe symptoms and increased size of their polyps. SYNAPSE showed that there was a 57% reduction in the proportion of patients who had surgery in the group treated with mepolizumab vs. placebo, HR=0.43 (95% CI 0.25, 0.76). In addition, the proportion of patients requiring systemic corticosteroid use during the 52-week treatment period was lower in patients who received mepolizumab.

Recommendation:

- Move Xolair® (omalizumab) subcutaneous injection vial, prefilled syringe with QTY LIMIT: 900 mg every 28 days to preferred after clinical criteria are met.
- Add Tezspire™ (tezepelumab-ekko) subcutaneous injection, pre-filled syringe with QTY LIMIT: 1.91 ml every 28 days to non-preferred.
    - Clinical criteria:
        - Update Xolair: Diagnosis of moderate to severe persistent asthma: For continuation of therapy after the initial 6-month authorization, the patient must continue to receive therapy with an ICS/LABA AND have either a decreased frequency of exacerbations, decreased use of maintenance oral corticosteroids, reduction in the signs and symptoms of asthma, or an increase in predicted FEV1 from baseline.
        - Add Nucala Diagnosis of Chronic Rhinosinusitis with Nasal Polyps
            - Patient is 18 years of age or older AND
            - Prescriber is an allergist or ENT specialist AND

• Patient has had an inadequate response to at least a 3-month trial of 2 different nasal corticosteroids AND
• Patient has had an inadequate response to at least a 10–14-day course of oral corticosteroids AND
•Patient must have a documented side effect, allergy, or treatment failure with Dupixent or Xolair AND
• Patient will use Nucala concurrently with an intranasal corticosteroid
• For continuation of therapy after the initial 6-month authorization, the patient must continue to receive therapy with an intranasal corticosteroid AND there must be documented improvement in nasal symptoms.

- Add Dupixent Diagnosis of Eosinophilic Esophagitis:
  • Patient is 12 years of age or older, weighing at least 40kg AND
  •Prescriber is an allergist or gastroenterologist AND
  •Diagnosis is confirmed by endoscopic esophageal biopsy showing ≥ 15 intraepithelial eosinophils per high-power field AND
  •Symptoms of esophageal dysfunction are present (e.g. pain while swallowing, sensation of food being stuck in the throat or chest) AND
  •The patient has had an inadequate response after a minimum trial of 8 weeks to at least two of the following: Dietary modification (e.g. elimination diet), swallowed topical corticosteroids (e.g. Budesonide), or high-dose proton inhibitor.
  • For continuation of therapy after the initial 6-month authorization, there must be documented improvement in EoE symptoms.
- Add Dupixent Diagnosisis of Prurigo Nodularis:
  • The patient must be 18 years of age or older AND
  • Diagnosis is confirmed based on the following: chronic pruritis lasting ≥ 6 weeks, history and/or signs of repeated scratching, and multiple localized or generalized pruriginous skin lesions (e.g. whitish or pink papules, nodules and/or plaques) AND
  • The patient has had a documented side effect, allergy, or treatment failure (defined as daily treatment for at least one month) with at least one moderate to high potency topical corticosteroid and one preferred topical calcineurin inhibitor within the last 6 months

•For continuation of therapy after the initial 6-month authorization, there must be documented improvement in PN symptoms.

- Update Limitations: Dupixent®, Fasenra®, Nucala® and Cinqair® will not be considered in patients who are currently smoking or in combination with omalizumab or Tezepelumab.
- Add Tezspire:
  • The patient must be 12 years of age or older AND
  • The patient has a history of uncontrolled asthma symptoms (symptoms occurring almost daily or waking at night with asthma at least once a week) or 2 or more exacerbations in the previous year despite regular use of medium-high dose ICS/LABA for a minimum of 3 consecutive months, with or without oral corticosteroids. Pharmacy claims will be evaluated to assess compliance with therapy. AND
  • The prescriber is an allergist, immunologist, or pulmonologist AND
  • If the patient has an eosinophilic phenotype (as defined by pretreatment blood eosinophil count of ≥ 150 cells per mcL within the previous 6 weeks or ≥ 300 cells per mcL within 12 months prior to initiation of therapy), there must have been a documented side effect, allergy, or treatment failure with Dupixent or Fasenra AND
  • For continuation of therapy after the initial 6 month authorization, the patient must continue to receive therapy with an ICS/LABA AND have either a decreased frequency of exacerbations OR decreased use of maintenance oral corticosteroids OR reduction in the signs and symptoms of asthma OR an increase in predicted FEV1 from baseline.
  Limitations: Tezspire will not be considered in patients who are currently smoking or in combination with anti-IgE, anti-IL4, or anti-IL5 monoclonal antibodies.

Public Comments: Gene Muise from Amgen: Highlighted the attributes of Tezspire.

Board Decision: The Board unanimously approved the above recommendations.

- Migraine Prophylaxis

Recommendation:

- Move Aimovig™ (erenumab-aooe) with QTY LIMIT: 1 injection (1mL) per 30 days to preferred after clinical criteria are met.
    - Clinical criteria:
        - Update Nurtec ODT, Quilipta, Vyepti additional criteria: The patient must have a documented side effect, allergy, or treatment failure to two preferred CGRP Inhibitors.

Public Comments:
Gene Muse from Amgen highlighted the attributes of Aimovig.
Omer Aziz from Teva yielded his time back to the committee.
Punit Patel from US Medical Affairs: Highlighted the attributes of Qulipta.

Board Decision: The Board unanimously approved the above recommendations.

- Migraine Acute Treatment

Recommendation:

- Add Zolmitriptan (compare to Zomig®) nasal spray with QTY LIMIT: 2.5 and 5 mg nasal spray = 12 units/30 days to non-preferred.
- Move Naratriptan (compare to Amerge®) with QTY LIMIT: 9 tablets/30 days and Zolmitriptan (compare to Zomig®) tablets with QTY LIMIT: 2.5 mg = 12 tablets/30days, 5 mg = 6 tablets/30 days to preferred.
- Remove Amerge® (naratriptan) 1 mg, 2.5 mg from the PDL.
    - Clinical criteria:
        - Add Non-preferred single agents: The patient has had a documented side effect, allergy, or treatment failure with at least two preferred triptans. If a product has an AB rated generic, there must have also been a trial of the generic formulation.
        - Update Zolmitriptan Nasal Spray, Zomig Nasal Spray, Imitrex Nasal Spray, Onzetra Xsail, Tosymra: patient has had a documented side effect, allergy or treatment failure with Sumatriptan Nasal Spray
        - Update Imitrex Injection, Zembrace: patient has had a documented intolerance to generic sumatriptan injection.

Public Comments: Punit Patel from US Medical Affairs: Highlighted the attributes of Ubrelvy.

Board Decision: The Board unanimously approved the above recommendations.

- Pituitary Suppressants-Central Precocious Puberty

Recommendation:

- Move Fensolvi® (leuprolide acetate) subcutaneous injection with QTY LIMIT: 1 vial every 6 months to preferred.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Respiratory/Steroid Inhalers and Combinations

Recommendation:

- Add Fluticasone propionate HFA (compare to Flovent® HFA) with QTY LIMIT: 3 inhalers (36 gm)/90 days to non-preferred.
- Move Qvar® Redihaler™ 40mcg/inh with QTY LIMIT: 2 inhalers (21.2 gm)/90 days and
- Qvar® Redihaler™ 80mcg/inh with QTY LIMIT: 3 inhalers (31.8 gm)/90 days to non-preferred with grandfathering of existing patients.
- Add age limit of ≥ 12 years for Advair® HFA (fluticasone/salmeterol).
    - Clinical criteria:
        - Add Advair HFA (age < 12 years): The patient has had a documented side effect, allergy, or treatment failure to Dulera or Symbicort.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

11. General Announcements:

- None at this time.

12. Adjourn: Meeting adjourned at 8:02 p.m.