Department of Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes
June 22, 2021

Board Members Present:

Zail Berry, MD	Bill Breen, RPh	Renee Mosier, PharmD
Joseph Nasca, MD	Mark Pasanen, MD	Claudia Berger, MD
Patricia King, MD		Andy Miller, RPh

Absent: Margot Kagan, PharmD and Doug Franzoni, PharmD

Staff:

Laurie Brady, RPh, Change HealthCare	Mike Ouellette, RPh, Change Healthcare	Jacqueline Hedlund, MD, Change Healthcare
Carrie Germaine, DVHA	Lisa Hurteau, PharmD, DVHA	Scott Strenio, MD, DVHA
Nancy Hogue, Pharm D, DVHA	Jason Pope, DVHA	

Guests:

Amy Cunningham	Brett White	Kristen Chopas
Elizabeth Lubelczyk, Eli Lilly	David Large	Kristen DiDesidero
Beth D'Ambrosio, Novartis	Dr. Mathew Burke	Kristin Kollecas, Sanofi Genzyme
Gene Muise, Amgen	Elena Minichiello	Mathew Wright
Nikhil Kacker, Genentech	Jandali Rasheed	Rocco Ianntta
Frank Nagy, Xeris Pharmaceuticals	Joe Miller	Russell Smith
Angela Hathaway	Joseph Shaker	
Adam Denman, Global Blood Therapeutics		

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:

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

3. DVHA Pharmacy Administration Update: Lisa Hurteau Pharm.D, DVHA:

- As of June 14, 2021, the state of emergency has been lifted. A physical meeting space is therefore required per Vermont open meeting laws to allow members of the public to attend in person. DVHA staff was present Waterbury to accommodate this requirement.
- September DUR meeting will be in person. Details on the location are currently being worked out but it will tentatively be held at a hotel in South

Burlington . Please follow the Vermont DUR page for more details as they become available.

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

- Waiting for the announcement of the new commissioner.

6. Follow-up Items from Previous Meetings:

- None at this time

Public Comment: No public comment

Board Decision: None needed.

7. RetroDUR/ProDUR: Laurie Brady, RPh, Change Healthcare

- Introduction of RetroDUR: Use of Acute Migraine Treatments After CGRP Initiation

Migraine headaches are a pervasive problem in the US population. Migraines affect 1 in 7 Americans. Notably, 10% of children suffer from migraines and up to 28% of adolescents ages 15-19. 4 million people suffer from chronic migraines with at least 15 migraine days per month. The cost to the US healthcare system is consequential. In 2015, the cost of treating chronic migraine in the US was over 5.4 billion dollars. In addition to medical costs, there are large economic costs in loss of productivity. For people who suffer from frequent migraines, preventative medications have been the mainstay of treatment, although the success in reducing migraines is variable. Historically, anticonvulsants, tricyclic antidepressants, beta-blockers, calcium channel blockers and Botox injections have been used, with additional drug classes (NSAIDs, ergotamines, steroids, opioids) used to treat acute symptoms. The development of triptans has improved the treatment of acute migraines, but improvements in prevention have been lacking. A newer class of medications, the calcium gene-related peptide receptor antagonists (CGRPs) arrived on the scene in 2018 for migraine prevention. 3 monoclonal antibodies (Aimovig, Ajovy and Emgality), given once monthly as subcutaneous self-administered injections. Vyepti is administered in a heath care setting via IV every 3 months. The CGRP antagonists are used in those who have an inadequate response to oral preventative medications. With improvement in prevention, the expectation is that use of medications for acute treatment of migraines will decrease. Additionally, short-acting oral, small molecule CGRPs have been developed, which are used to treat acute migraines, joining triptans in this indication. The combined use of long and short-acting CGRPs is not yet of proven benefit yet is increasingly being used as a headache management strategy.

Change Healthcare will use paid, non-reversed Medicaid pharmacy and medical claims from SFY 2019-2020 (pre-COVID), excluding members with Part D, VMAP and Healthy Vermonters coverage. They will identify members taking a long-acting CGRPs and look at pharmacy and

medical claims to identify the prescribing patterns of acute migraine medications for these members, for the calendar years 2019 and 2020, as well as their compliance with the long-acting injectables. We specifically will look to see if use of acute migraine medication decreased after the initiation of the long-acting CGRP medication.

Recommendation: None at this time.

Public Comment: No public comment.

Board Decision: None needed.

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

Biosimilar Drug Reviews:

- None at this time.

Recommendation: None at this time

Public Comment: No public comment.

Board Decision: None needed.

Full New Drug Reviews:

- Cabenuva® (cabotegravir and rilpivirine kit)

Cabenuva® contains 2 long-acting HIV-1 antiretroviral agents, including cabotegravir co-packaged with rilpivirine. Cabotegravir inhibits HIV integrase by binding to the integrase active site and blocking the strand transfer step of retroviral deoxyribonucleic acid (DNA) integration which is essential for the HIV replication cycle. Rilpivirine is a diaryl-pyrimidine non-nucleoside reverse transcriptase inhibitor (NNRTI) of HIV-1 and inhibits HIV-1 replication by non-competitive inhibition of HIV-1 reverse transcriptase. Rilpivirine does not inhibit the human cellular DNA polymerases α, β, and γ. It is indicated as a complete regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per ml) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine. The efficacy of Cabenuva® was assessed in two phase 3 randomized, multicenter, active-controlled, parallel-arm, open-label, non-inferiority trials (Trail 1 FLAIR; Trial 2 ATLAS) in HIV-1 infected subjects who were virologically suppressed (HIV-1 RNA <50 copies/ml). Cabenuva® must be administered by a healthcare professional and there should be an oral lead-in for about 1 month prior to the initiation of Cabenuva® to assess the tolerability of cabotegravir and rilpivirine. In 2 open-label, active-controlled non-inferiority studies comparing a cabotegravir plus rilpivirine regimen with

current antiretroviral regimen, the primary endpoint (the proportion of subjects with plasma HIV-1 RNA greater than or equal to 50 copies/ml at week 48) was 2% in both studies with the cabotegravir plus rilpivirine regimen as compared with 2% in one study (FLAIR) and 1% in the second study (ATLAS) for the current antiretroviral regimen used.

Recommendation:

- Update subcategory to Single Product Regimens.
- Add Cabenuva®(cabotegravir/rilpivirine) Kit with QTY LIMIT: 600mg/900mg kit = 6mL per month for the first month then 400mg/600mg kit = 4mL per month thereafter to non-preferred.
- Note that all long-acting injectables products require a PA.
    - Clinical criteria:
        - Add Cabenuva: 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 with no history of treatment failure AND medical reasoning beyond convenience or enhanced compliance over preferred agents is provided. Note: oral lead-in with Vocabria® (cabotegravir) and Edurant® (rilpivirine) are provided at no charge and sent directly to the prescriber or patient by a specialty distributor and should be dispensed ONLY for those with prior approval for Cabenuva.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Eysuvis® (loteprednol etabonate)

Loteprednol etabonate, the active ingredient of Eysuvis®, is a corticosteroid. Corticosteroids inhibit the inflammatory response to a variety of inciting agents and delay or slow healing. Corticosteroids inhibit the edema, fibrin deposition, capillary dilation, leukocyte migration, capillary proliferation, fibroblast proliferation, deposition of collagen, and scar formation associated with inflammation. Corticosteroids are thought to inhibit prostaglandin production. It is indicated for the short-term (up to two weeks) treatment of the signs and symptoms of dry eye disease. The safety and efficacy of Eysuvis® for the treatment of dry eye disease were assessed in 4 multicenter, randomized, double-masked, placebo-controlled trials. The use of artificial tears was not allowed during the trials. Patients with dry eye disease received either Eysuvis® or vehicle four times a day for 2 weeks. In addition, it is the first approved treatment specifically designed for short-term treatment of dry eye disease. In 4 clinical studies, Eysuvis® was more effective than vehicle for reducing ocular discomfort and conjunctival hyperemia. The clinical trials, though demonstrating statistical significance, are of uncertain clinical significance given the relatively small absolute effect of Eysuvis® compared to placebo.

Recommendation:

- Add Eysuvis® (loteprednol etabonate ophthalmic suspension) 0.25% to non-preferred.
- Remove individual listing of preferred OTC ocular lubricants and replace with a link to covered agents on the DVHA website.
    - Clinical criteria:
        - Add Eysuvis: The patient has a diagnosis of Dry Eye Disease AND has failed at least a 14-day course of a preferred OTC ocular lubricant AND has a documented side effect, allergy, or treatment failure with 2 preferred ophthalmic corticosteroids, one of which must be a formulation of loteprednol.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Gimoti® (metoclopramide HCl)

Metoclopramide, the active ingredient of Gimoti®, is a dopamine-2 receptor antagonist. Metoclopramide stimulates motility of the upper GI tract without stimulating gastric, biliary, or pancreatic secretions. The exact mechanism of action of metoclopramide in the treatment of GERD and diabetic gastroparesis has not been fully established. It appears to sensitize tissues to the action of acetylcholine. The effect of metoclopramide on motility is not dependent on intact vagal innervation, but it can be abolished by anticholinergic drugs. Metoclopramide increases the tone and amplitude of gastric contractions, relaxes the pyloric sphincter and the duodenal bulb, and increases peristalsis of the duodenum and jejunum resulting in accelerated gastric emptying and intestinal transit. It increases the resting tone of the lower esophageal sphincter. It is indicated for the relief of symptoms in adults with acute and recurrent diabetic gastroparesis. Limitations of use include that Gimoti® is not recommended for use in:

- Pediatric patients due to the risk of developing tardive dyskinesia (TD) and other extrapyramidal symptoms as well as the risk of methemoglobinemia in neonates
- Moderate or severe hepatic impairment, moderate or severe renal impairment, and patients concurrently using strong CYP2D6 inhibitors due to the risk of increased drug exposure and adverse reactions.

Gimoti® has a box warning regarding tardive dyskinesia. The effectiveness of Gimoti® has been established based on studies of oral metoclopramide for the relief of symptoms in adults with acute and recurrent diabetic gastroparesis. The systemic absorption after nasal administration is lower than that after oral administration given the same dose. In addition, it is not recommended for use in moderate or severe hepatic impairment, moderate or severe renal impairment, and patients concurrently using strong CYP2D6 inhibitors. Treatment with metoclopramide (all dosage forms and routes of administration) should be avoided for longer than 12 weeks due to the increased risk of developing tardive dyskinesia with longer-term use. The efficacy of Gimoti® has been established based on studies of oral metoclopramide, which has been available for many years. Gimoti® offers patients and physicians a new dosage form.

Recommendation:

- Add Gimoti (metoclopramide) nasal spray to non-preferred. Note that all nasal spray products require a PA.
    - Clinical criteria:
        - Add Gimoti: The patient has a documented intolerance to metoclopramide tablets and oral solution.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Impeklo® (clobetasol propionate lotion)

Clobetasol propionate, the active ingredient of Impeklo® lotion, is a synthetic fluorinated corticosteroid for topical use. Corticosteroids play a role in cellular signaling, immune function, inflammation, and protein regulation; however, the exact mechanism of action in corticosteroid-responsive dermatoses is not known. It is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in patients 18 years of age or older. Limitations of use include that it should not be used in the treatment of rosacea or perioral dermatitis. In addition, use in patients under 18 years of age is not recommended due to numerically high rates of HPA axis suppression. The efficacy of clobetasol propionate 0.05% lotion was assessed and demonstrated in two trials that included subjects with either moderate to severe plaque psoriasis or moderate to severe atopic dermatitis. Clobetasol lotion was superior to placebo in both trials. The studies included in the Impeklo® lotion 0.05% clinical trials section were the same as those in the clinical trials section of Clobex®, also a clobetasol propionate 0.05% lotion. Brand Clobex® is not currently rebatable under the Medicaid program, but a generic is still available. The generic for Clobex® has been available for many years and is a safe and effective product. There is no evidence at this time to support that Impeklo® lotion is safer or more effective than the other currently preferred, more cost-effective medications.

Recommendation:

- Add Impeklo™ (clobetasol propionate) 0.05% Lotion to non-preferred.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Orladeyo® (berotralstat)

Berotralstat, the active ingredient of Orladeyo®, is a plasma kallikrein inhibitor that binds to plasma kallikrein and inhibits its proteolytic activity. Plasma kallikrein is a protease that cleaves high molecular weight kininogen (HMWK) to generate cleaved HMWK (cHMWK) and bradykinin, a potent vasodilator that increases vascular permeability resulting in swelling and pain associated with hereditary angioedema (HAE). In patients with HAE due to C1-inhibitor (C1-INH) deficiency or dysfunction, normal regulation of plasma kallikrein activity is not present,

which leads to uncontrolled increases in plasma kallikrein activity and results in angioedema attacks. Berotralstat decreases plasma kallikrein activity to control excess bradykinin generation in patients with HAE. It is indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in adults and pediatric patients 12 years of age and older. The safety and efficacy of Orladeyo® for the treatment of acute HAE attacks have not been established. Additional doses or doses of Orladeyo® higher than 150mg once daily are not recommended due to the potential for QT prolongation. The efficacy of Orladeyo® for the prevention of angioedema attacks in patients 12 years of age and older with Type 1 or II HAE was assessed in Part 1 of a multicenter, randomized, double-blind, placebo-controlled, parallel-group study. In double-blind, placebo-controlled trials, Orladeyo® 150mg and 110mg produced statistically significant reductions in the rate of HAE attacks as compared with placebo. Orladeyo® is the first and only oral dosage formulation created to prevent HAE attacks.

Recommendation:

- Add ORLADEYO™ (berotralstat) QTY LIMIT: 1 capsule/day to preferred after clinical criteria are met.
    - Clinical criteria:
        - Add Orladeyo to the Cinryze, Haegarda, Takhzyro clinical criteria.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Zokinvy® (lonafarnib)

Lonafarnib, the active ingredient of Zokinvy®, is a farnesyltransferase inhibitor. It inhibits farnesyltransferase to prevent farnesylation and subsequent accumulation of progerin and progerin-like proteins in the inner nuclear membrane. It is indicated in patients 12 months of age and older with a body surface area (BSA) of 0.39m^2 and above:

- To reduce the risk of mortality in Hutchinson-Gilford Progeria Syndrome (HGPS)
- For the treatment of processing-deficient Progeroid Laminopathies with either:
    - Heterozygous LMNA mutation with progerin-like protein accumulation
    - Homozygous or compound heterozygous ZMPSTE24 mutations

Limitations of use include that Zokinvy® is not indicated for other Progeroid Syndromes or processing-proficient Progeroid Laminopathies. Based upon its mechanism of action, Zokinvy® would not be expected to be effective in these populations. The efficacy of Zokinvy® is based on results from the Observational Cohort Survival Study, which retrospectively compared survival data from two phase 2 studies in patients with HGPS to those from a natural history cohort. There were less deaths in the Zokinvy® group than the untreated group, and the mean survival time increased 2.5 years through the last follow-up time (11 years) compared to untreated patients.

Recommendation:

- Add Zokinvy® (lonafarnib) capsule to non-preferred.

- Clinical criteria:
  - Add Zokinvy: The patient meets FDA approved age and BSA AND the patient has a diagnosis of Hutchinson-Gilford Progeria Syndrome (HGPS) OR the patient has a diagnosis of processing-deficient Progeroid Laminopathies with documentation of either Heterozygous LMNA mutation with progerin-like protein accumulation or Homozygous or compound heterozygous ZMPSTE24 mutations.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

9. New Therapeutic Drug Classes

- None at this time.

10. Therapeutic Drug Classes- Periodic Review:

- **Antifungals, Oral**
  - No new drugs.
  - No new significant clinical changes.

Recommendation:

- Remove Onmel® (itraconazole) tablets from the PDL. They are no longer available.
  - Clinical criteria:
    - Revise Cresemba: patient is completing a course of therapy that was initiated in the hospital OR patient has a diagnosis of mucormycosis OR patient has a diagnosis of invasive aspergillosis and has had a documented side effect, allergy, contraindication, or treatment failure with voriconazole.
    - Add Limitations: Coverage of Onychomycosis agents will NOT be approved solely for cosmetic purposes to Ketoconazole/Itraconazole 100mg cap/Itraconzaole Solution/Sporanox

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- **Antifungals, Topical**
  - No new drugs.
  - No new significant clinical changes.

Recommendation:

- Remove Penlac® Nail Lacquer (ciclopirox 8 % solution), Exelderm® (sulconazole) 1% Cream, Solution, Lamisil RX/OTC® (terbinafine) 1% Cream, Solution, Spray, Gel, Nizoral® (ketoconazole) 2% Shampoo, Lotrisone® (clotrimazole w/ betamethasone) Cream.
- Move nystatin/triamcinolone cream and ointment to preferred.
- Add butenafine (compare to Mentax®) 1% C to non-preferred.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- **Bone Resorption Suppression and Related Agents**
  - No new drugs.
  - No new significant clinical changes.

Recommendation:

- Remove Binosto® (alendronate) 70mg effervescent tablet and Etidronate from the PDL.
- Move Zoledronic Acid Injection (compare to Reclast®) 5 mg/100ml with QTY LIMIT: 5 mg (one dose)/year to preferred.
- Add Zoledronic Acid Injection 4mg/5mL concentrate and 4 mg/100mL IV solution to preferred.
- Add teriparatide (compare to Forteo®) with QTY LIMIT: 1 pen/30 days (lifetime max duration of therapy = 2 years) to non-preferred.
  - Clinical criteria:
    - Add Reclast to the Evista and Fosamax clinical criteria.
    - Revise Forteo, Teriparatide: patient has a diagnosis/indication of postmenopausal osteoporosis in females, primary or hypogonadal osteoporosis in males or glucocorticoid induced osteoporosis AND patient has had a documented side effect, allergy, or treatment failure** to an oral bisphosphonate. AND prescriber has verified that the patient has been counseled about osteosarcoma risk AND for approval of Forteo, the patient has had a documented intolerance to generic Teriparatide.
    - Revise Prolia Injection: patient has a diagnosis/indication of postmenopausal osteoporosis AND patient has had a documented side effect, allergy, or treatment failure** to a preferred bisphosphonate OR medication is being used for another FDA approved indication.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- **Hypoglycemics, Incretin Mimetics/ Enhancers and SGLT2 Inhibitors**
  - No new drugs.
  - No new significant clinical changes.
  - New indication for Farxiga: To reduce the risk of sustained eGFR decline, end-stage kidney disease, cardiovascular death, and hospitalization for heart failure in adults with chronic kidney disease at risk of progression.

Recommendation:

DPP-4 Inhibitors

- No changes

Peptide Hormones including GLP-1 Receptor Agonists

- Remove Bydureon® (exenatide extended- release) from the PDL.

SGLT2 Inhibitors

- No changes.

Public Comments: No public comment.

Board Decision: None needed at this time.

- **Hypoglycemics, Insulin (new drug Lyumjev (insulin lispro-aabc injection) and Semglee (insulin glargine injection) included)**
  - The active ingredient of Lyumjev® is a rapid-acting human insulin analog produced by recombinant DNA technology. Insulin lispro-aabc differs from human insulin in that the amino acid proline at position B28 is replaced by lysine and the lysine in position B29 is replaced by proline. It is indicated to improve glycemic control in adults with diabetes mellitus (DM). The safety and efficacy of Lyumjev® were assessed in two randomized, active-controlled trials of 26 weeks in duration that included adults with type 1 DM or type 2 DM. In healthy subjects and patients with diabetes, insulin lispro-aabc appeared in circulation about 1 minute after injection, the time to 50% maximum insulin lispro-aabc concentration was 13 minutes, and the time to maximum insulin lispro-aabc concentration was achieved at 57 minutes. Furthermore, the results of a study in healthy subjects demonstrated that Lyumjev® 200U/ml is bioequivalent to Lyumjev® 100U/ml after administration of a single 15-unit dose for the area under the serum concentration time curve and maximum concentration. There is no evidence at this time to support that Lyumjev® is safer or more effective than the other currently preferred, more cost-effective medications.
  - Semglee is a biosimilar to insulin glargine injection and is not to be used in those younger than 6 years old.

Recommendation:

- Add Insulin Aspart (compare to Novolog®), Lyumjev® (insulin lispro-aabc), Semglee® (insulin glargine) and Insulin Aspart Protamine/Aspart 70/30 (compare to Novolog Mix 70/30®) to non-preferred.
    - Clinical criteria:
        - Revise Humulin N, Novolin N: patient has been started and stabilized on the requested medication (Note: samples are not considered adequate justification for stabilization.) OR patient has a documented treatment failure to at least one preferred long-acting agent (Lantus or Levemir).
        - Add Semglee to the Basaglar clinical criteria.
        - Add Insulin Aspart and Lyumjev to the Admelog, Fiasp, Insulin Lispro clinical criteria.
        - Add Insulin Aspart Protamine/Aspart 70/30 to the Humulin 70/30, Novolin 70/30 clinical criteria.

Public Comments: Elizabeth Lubelczyk,PharmD from Eli Lilly: Highlighted the attributes of Lyumjev.

Board Decision: The Board unanimously approved the above recommendations.

- **Hypoglycemics, Meglitinides**
    - No new drugs.
    - No significant clinical changes.

Recommendation:

- Remove Prandin® (replaglinide), Starlix® (nateglinide) and Repaglinide/metformin from the PDL.

Public Comments: No public comment

Board Decision: The Board unanimously approved the above recommendations.

- **Hypoglycemics, TZD Agents**
    - No new drugs.
    - No significant clinical changes.

Recommendation:

- Remove Avandia® (rosiglitazone) from the PDL.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- **Hypoglycemics, Miscellaneous**
  - New Drug Zegalogue (dasiglucagon) which is indicated for the rescue treatment of severe hypoglycemia when assistance from others is needed will be reviewed in a future meeting.
  - No significant clinical changes.

Recommendation:

Alpha-glucosidase Inhibitors

- Remove Glyset from the PDL. Add Miglitol to preferred.

Glucagon

- No changes

Biguanides & Combinations

- Remove Glucophage® (metformin) and Glucophage XR® (metformin XR) from the PDL.
- Add Metformin ER modified release (compare to Glumetza®) and Metformin oral solution (compare to Riomet®) to non-preferred.
  - Clinical criteria:
    - Add Metformin ER mod release to the Fortamet, Glumetza, Metformin ER osmotic clinical criteria.
    - Add Metformin oral solution to the Riomet clinical criteria.

Sulfonylureas

- No changes

Public Comments: Elizabeth Lubelczyk,PharmD from Eli Lilly: Highlighted the attributes of Baqsimi.
Frank Naggy, PharmD from Xeris Pharmaceuticals: Highlighted the attributes of Gvoke.

Board Decision: The Board unanimously approved the above recommendations.

- **Immunologic Therapy for Asthma**
  - No new drugs.
  - New indication for Xolair: Add-on maintenance treatment of nasal polyps in adults with inadequate response to nasal corticosteroids.
  - New indication for Nucala: Hypereosinophilic syndrome (HES) for ≥6 months without an identifiable non-hematologic secondary cause
  - A self-administration option was approved for Xolair prefilled syringes in April 2021. Patient-specific factors to establish appropriateness include the following:

- No prior history of anaphylaxis with Xolair or other agents (ie, foods, drugs, biologics).
- At least 3 doses of Xolair have been received under the guidance of an HCP with no hypersensitivity reactions.
- Patient or caregiver is able to recognize anaphylaxis symptoms and is able to treat appropriately.
- Patient or caregiver is able to properly prepare and administer subcutaneous injections with Xolair prefilled syringe following training with an HCP.

Recommendation:

Clinical criteria:

- Update Xolair clinical criteria
  - Diagnosis of moderate to severe persistent asthma
    - Add: For continuation of therapy after the initial 3-month authorization, the patient must 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.
  - Diagnosis of chronic idiopathic urticaria
    - Remove requirement for therapeutic failure or contraindication to a leukotriene receptor antagonist.
    - Add: For continuation of therapy after the initial 3-month authorization, the patient must have documented clinical improvement in symptoms.
  - 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 will use Xolair concurrently with an Intranasal corticosteroid AND For approval of prefilled syringe, a clinically compelling reason must be provided detailing why vials cannot be used AND For continuation of therapy after the initial 3-month authorization, the patient must continue to receive therapy with an intranasal corticosteroid AND there must be documented improvement in nasal symptoms.
- Update Nucala clinical criteria
  - Diagnosis of hypereosinophilic syndrome
    - The patient must be 12 years of age or older AND The patient must have a blood eosinophil count of ≥ 1,000 cells per mcL AND The patient has had at least 2 HES flares within the past 12 months AND The patient is on a stable dose of background HES therapy (chronic or episodic

corticosteroids, immunosuppressive, or cytotoxic therapy) for at least 4 weeks prior to treatment initiation AND The prescriber is an allergist, hematologist, or immunologist

Public Comments: Kristin Kollecas from Sanofi Genzyme: Highlighted the attributes of Dupixent. Nikhil Kacker from Genentech: Highlighted the attributes of Xolair

Board Decision: The Board unanimously approved the above recommendations with the amendment of adding a pulmonologist to the list of acceptable prescribers for Diagnosis of hypereosinophilic syndrome (Nucala only) criteria.

12. Review of Newly-Developed/Revised Criteria:

- **Continuous Glucose Monitoring Supplies**
  - Due to the state of emergency last year, the PA requirement had been temporarily lifted. Target date to reimplement the PA requirement is August 1, 2021.

Recommendation:

- Add Medtronic 670G Guardian Link 3, Medtronic 770G Guardian Link 3, Medtronic MiniLink (includes Enlite Serter) to non-preferred.
- All of the above agents will have the following QTY LIMIT
  - Initial Prescription: 1 transmitter, 5 Sensors.
  - Refill Quantity Limits: 1 transmitter every year, 1 sensor every 7 days (maximum of 5 sensors every 35 days)

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

13. General Announcements:

- None at this time.

Public Comment: No public comment.

Board Decision: No action needed.

14. Adjourn: Meeting adjourned at 7:55 p.m.