Washington State Pharmacy and Therapeutics Committee
Drug Utilization Review Board
Meeting Transcription
June 16, 2021

Ginni Buccola: Good morning, everybody. I'm Virginia Buccola, the chair of the P and T committee. It's nice to see everybody. We want to start by introducing and giving a warm welcome to our two new committee members. So Dr. Kavita Chawla and Michael Corsilles. [unrelated discussion]. And you're a PA, yeah?

Michael Corsilles: Yep. A PA and an ND.

Ginni Buccola: And an ND. Wonderful, welcome. Welcome to both of you. I'm going to go ahead and read off the names of the participating attendees. And if you can just unmute and say here when I call your name. So if I don't hear you I'll just give you a minute to unmute and we'll move on if I don't hear anything. But raise your hand if for some reason you're having any audio troubles. So for P and T committee meeting members, we'll start with Alex Park.

Alex Park: Good morning. Here.

Ginni Buccola: Good morning. Diane Schwilke.

Diane Schwilke: Good morning. I'm here.

Ginni Buccola: Morning. Jordan Storhaug.

Jordan Storhaug: Here.

Ginni Buccola: And Nancy Lee. I think she's not here yet this morning. Leah Marcotte.

Leah Marcotte: Here.

Ginni Buccola: And Susan Flatebo.

Susan Flatebo: Here.

Ginni Buccola: And Catherine Brown.

Catherine Brown: Here.

Ginni Buccola: And Michael Corsilles.

Michael Corsilles: Here.

Ginni Buccola: Great. And our Health Care Authority members starting with Leta Evaskus.

Leta Evaskus: Here.

Ginni Buccola: Donna Sullivan.

Donna Sullivan: I'm here.

Ginni Buccola: Ryan Pistoresi.

Ryan Pistoresi: Here.

Ginni Buccola: Luke Dearden. Might not be here yet. Ryan Taketomo.

Ryan Taketomo: Here.

Ginni Buccola: Marissa Tabile.

Marisa Tabile: Here.

Ginni Buccola: Amy Irwin. I see Amy connecting. We'll come back to her. Joey Zarate. And just reading from the chat, Luke Dearden is noting himself as here. And Nancy Lee is here. Our Magellan Medicaid Administration member Umang Patel.

Umang Patel: Here.

Ginni Buccola: And our Managed Care Organization representatives are Greg Simas with Molina, Heidi Goodrich with Molina. I can see Heidi. Petra Eichelsdoerfer with United Healthcare. Oman Daoud of Community Health Plan of Washington. And Geoffrey Natividad with Community Health Plan of Washington. I think the only person that I didn't read off the chat is to confirm that Amy Irwin is here. Alright, so I'll hand it back to Leta to go over meeting logistics.

Leta Evaskus: Hi, this is Leta Evaskus. We are using a new meeting platform today, Zoom Webinar. Looks like we're not having any technical difficulties so far so I'm very happy. The panelists can mute and unmute themselves. So please mute yourself when you're not speaking to limit background noise. Presenters, please share your cameras when you're presenting and the committee, if you could please share your camera's when you're deliberating. The meeting is being recorded so please state your name each time that you speak. For stakeholder participation, the chair will read the list of stakeholders who pre-registered to speak I will unmute you. It may take me a little bit longer to get people off of mute because there's more of a process with Zoom. So thank you ahead of time for your patience. After, the chair will ask if there are any other stakeholders. Use the raise hand icon and I will call on you and unmute you. You can also use the question function and I will address your questions during the stakeholder time. Thanks.

Ginni Buccola: Okay, so we'll go ahead then and convene the drug utilization review board. And we are going to start with Umang presenting to us on asthma and COPD agents.

Umang Patel: Perfect. [unrelated discussion] Leta, if you could share the slides. While Leta's pulling up the slides, I'll just give a quick background here. So we looked at relevant clinical information within the last about 12 months of the last review of said classes. If there are no significant clinical updates, we obviously skip right over the class. Usually guidelines that are over a year old I'll try to keep in the appendices for the committee's reference. But we will not go over that in detail as they are over a year old. Slide three. [unrelated discussion]. So, the COPD class is the first class we'll be going over. The Apple Health PDL has specific sub classes here and so as you can see, we have anticholinergics, PDE 4 inhibitors, long acting muscarinic and beta agonist combinations, along with long acting muscarinic agents solo. Onto the next slide. So just a little bit of background here. COPD is a disease state characterized by the presence of airflow obstruction due to chronic bronchitis and emphysema. The airflow obstruction is generally progressive and may be accompanied by airway hyperreactivity and may be partially reversible. This progressive, persistent obstruction and limitation of airflow is associated with an enhanced chronic inflammatory response in both the airways and the lungs to the noxious particles or gases, and exacerbations and comorbidities contribute to the overall severity in individual patients. COPD continues to be a leading cause of chronic morbidity and mortality worldwide, carrying with it significant economic and social burdens. It is

projected by the World Health Organization to be the third leading cause by 2030. In their 2017 NHI survey, the CDC reported that the percent of adults who were diagnosed with chronic bronchitis in the past year was 3.5% and those that have ever been diagnosed with emphysema is 1.4%. The US Preventive Services Task Force recommends against routine screening in asymptomatic adults. On the next slide here, although the precise distinction between chronic bronchitis and emphysema are a subject of debate, common belief holds that chronic bronchitis is responsible for 85% of COPD patients with chronic bronchitis experienced intermittent airway inflammation and excessive mucus production that leads to frequent prolonged episodes of productive cough. In contrast, 15% of patients with COPD suffer primarily from emphysema in which destruction of the infrastructure of alveoli and distal air spaces that provide gas exchange. Both chronic bronchitis and emphysema predispose patients to a common collection of symptoms and impairments in respiratory functions, such as reduction of forced expiratory volume, forced vital capacity, and forced expiratory flow. On the next slide here we have the gold guidelines in 2020. Just to remind the committee, these guidelines that bold the relevant information. And so the global initiative for chronic obstructive lung disease. But the main updates they made here for group A, a short acting inhaled bronchodilator used on an as-needed basis or a long acting bronchodilator is recommended as a first choice. No significant changes in Group B as in beta or group C as in Charlie And group D as in delta, initial therapy with a LAMA is recommended as it has effects on both breathlessness and exacerbation. Patients with more severe symptoms can be initiated in the LABA/LAMA combo. Patients may consider a LABA inhaled corticosteroid for patients with blood eosinophil counts of 300 cells per microliter or greater as a combination of the greatest likelihood of reducing exacerbations or maybe preferred in patients with a history of asthma. Some evidence for use of triple therapy, a corticosteroid, a LABA and a LAMA in patients with persistent breathlessness or exercise limitation. If exacerbations still occur with triple therapies and the oral PDE 4 inhibitors, Daliresp, which is indicated to decrease the frequency of exacerbations or worsening of symptoms of severe COPD may be added in patients with an FEV 1 less than 50% of predicted and chronic bronchitis. Long term monotherapy with an inhaled corticosteroid at any stage has been shown to be less effective than its use in combination with LABA. And following initial therapy, patients should be reassessed for attainment of treatment goals and therapy adjusted as needed. On the next slide here, according to the American Thoracic Society last year in 2020, they released additional guidelines for the pharmacological management of COPD. These

guidelines focus on addressing specific questions developed by an ATS panel regarding significant COPD management issues, including when to use dual and triple therapy and ICS use in COPD patients with blood eosinophils. They strongly recommend the use of dual LABA/LAMA therapy over solo LABA or LAMA monotherapy in COPD patients who complain of exercise intolerance or dyspnea based on pooled evidence demonstrating decreased hospital admissions and exacerbations and improvements in patient quality of life and dyspnea. Additionally, they suggest triple ICS LABA/LAMA in patients with a history of one or more exacerbations requiring hospitalization, oral steroids, or antibiotics in the past year, who, despite LABA/LAMA dual therapy complain of exercise intolerance or dyspnea. Additionally, for patients receiving triple combo therapy who experienced no exacerbations over the course of one year, they suggest that the ICS therapy can be discontinued. The guidelines suggest the addition of ICS in COPD patients with blood eosinophilia, defined as two or more percent blood eosinophils or greater than 150 or greater cells per microliter have experienced one or more exacerbations requiring hospitalization, oral steroids, or antibiotics in the last 12 months. Additional management recommendations regarding treatment approaches outside of the therapeutic class review are detailed in the guidelines. On the next and final slide, the American Board of Internal Medicine last year had an initiative called Choosing Wisely released guidelines based on American Academy of Pediatrics information. Five key evidence based recommendations regarding therapies and practices used to treat asthma and sleep disorders in pediatric patients were highlighted. One, to assess the adherence to asthma medication before stepping up therapy, two, to not use LAVA steroid combination as initial therapy for intermittent or mild persistent asthma, three, to avoid nebulized medications by “blow by” or placing the mask or nebulizer tubing near the child's nose mouth rather than secure the mass of the child's face or use a t-piece, four, do not interpret pediatric sleep studies using adult standards. And lastly, do not routinely use airway clearance therapy when asthma, bronchiolitis or pneumonia are present. That is the final slide I have for the COPD section. I'll go ahead and pause there for the committee.

Ginni Buccola: And this is Virginia. Thanks, Umang. That is very helpful. I don't hear any questions. Are there anything else from the committee? Okay, Umang, let me just ask, do we want to keep these asthma and COPD agents in two separate motions?

Leta Evaskus: This is Leta. They will be in separate motions.

Ginni Buccola: Okay, thank you for letting me clarify that. Umang, are we ready to go to stakeholders then?

Umang Patel: Yeah, if there are going to be two separate motions, absolutely.

Ginni Buccola: Okay. Since we don't have any questions from the committee for Umang, we do have one stakeholder, Mark Maneval with Boehringer Ingelheim Pharmaceuticals. When you're ready to speak, Mark, you'll have three minutes. If you could just state your name and your affiliation.

Mark Manvel: My name is Mark Maneval. I'm a pharmacist and health economics and outcomes research liaison for Boehringer Ingelheim. And Stiolto Respimat is a combination anticholinergic and long acting beta agonist indicated for the long term once daily maintenance treatment of patients with COPD, including chronic bronchitis and/or emphysema. Stiolto is not indicated to treat acute deterioration of COPD and it's not indicated to treat asthma. LAMAS and LAMA/LABAs continue to be the preferred initial treatment for patients in gold groups B, C, and D and remain the cornerstone of COPD maintenance treatment. However, on average, 55% of patients with COPD do not receive long acting bronchodilator treatment. Among patients who receive bronchodilator treatment, triple therapy was often prescribed in a way that is inconsistent with current gold recommendations. In 2020, un retrospective real world analysis of more than 230,000 patients with COPD found that 47% of patients initiating triple therapy had no history of exacerbations. Prescribing compliance to gold recommendation continues to be low, the primary driver appears to be the overuse of the inhaled corticosteroid component. A retrospective claims analysis showed annual COPD related medical costs per patient on gold compliant care are 700 to $2200 lower than those whose regimens are not compliant with gold guidelines. These costs were driven by inpatient hospitalizations primarily associated with the side effects of inhaled corticosteroids, pneumonia. This same analysis found an eight to 12% lower risk of exacerbations among those patients on gold compliant treatment compared to those not on gold compliant regimens. Stiolto Respimat is a treatment option that has been shown to offer clinical and economic value. In a commercial population, COPD related total costs were 114% higher for patients prescribed triple therapy versus Stiolto Respimat.. In a Medicare population, COPD related total costs were 53 to 70% higher for patients prescribed triple therapy versus Stiolto Respimat. In a commercial and Medicare population, emergency department costs were

21 to 27% higher for patients prescribed other LAMA/LABAs versus Stiolto Respimat. When compared to triple therapy or LAMA/LABA combinations, Stiolto Respimat has favorable outcomes and lower costs to the health plan when used in concordance with gold guidelines. We are asking for Stiolto Respimat to stay on the PDL. Our team is here to answer any questions you may have. Thank you.

Ginni Buccola: Thank you, Mark. Are there any questions from the committee? Are there any other stakeholders? Okay, it looks as if we're ready to go to the motion then. So committee members, if you can unmute and turn your cameras on.

Nancy Lee: This is the Nancy. I move that all products in the drug class listed on slide two are considered safe and efficacious for their medically accepted indications and are eligible for our preferred status and grandfathering at the discretion of HCA. Products in this class may require prior authorization to determine medical necessity. All nonpreferred products require a trial of one preferred product with the same indication before a nonpreferred drug will be authorized unless contra indicated or not clinically appropriate.

Catherine Brown: This is Catherine Brown. I second.

Ginni Buccola: All those in favor, please say aye.

All: Aye.

Ginni Buccola: Are there any opposed? Then the motion carries.

Leta Evaskus: Ginni, this is Leta Evaskus. Craig Sexton had a question about what was slide two. This was slide two, Craig.

Ginni Buccola: Any other questions before we move forward? Okay, thanks, Leta. I'm sorry, I didn't see that question. Okay, so we'll go back to Umang to continue asthma and COPD agents.

Umang Patel: Perfect. Thank you. So in this class, it will be the inhaled glucocorticoids. It's going to encompass the inhaled corticosteroids and their combinations. On the next slide here, I know we kind of alluded to asthma in the last class, but with asthma and COPD, sometimes there's a little bit of overlap. So I did want to give some background for asthma specifically. In 2018, total asthma prevalence was estimated to be 7.5% of the population or approximately 27

million Americans. Further, the National Health Statistics report shows that asthma appears to disproportionately affect minority groups, females, children, and individuals of low socioeconomic status, which can place a significant pressure on public health systems. The National Asthma Education and Prevention Program defined asthma as a chronic inflammatory disorder of the airways, in which many cells and cellular elements play a role. In susceptible individuals, inflammation may cause recurrent episodes of wheezing, breathlessness, chest tightness, and coughing. These episodes are usually associated with airflow obstruction that is often reversible, either spontaneously or with treatment. The inflammation also causes an increase in bronchial hyper responsiveness to a variety of stimuli. Studies have demonstrated the efficacy of inhaled corticosteroids in improving lung function, reducing symptoms, and reducing frequency and severity of exacerbations and improving the quality of life of patients with asthma. In the 2007 National Heart, Lung, and Blood Institute states that inhaled glucocorticoids are currently the most effective anti-inflammatory medication for the treatment of persistent asthma and the 2019 GINA full report advise that all patients with asthma should receive corticosteroid containing controller treatment to reduce the risk of serious exacerbations and to control symptoms. On the next slide, the GINA guidelines were also updated last year. They offer a control based management plan to adjust treatment in a continuous cycle of assessment, treatment, and review of the patient's response as it relates to symptom control, future risk of exacerbations, and side effects. Equally important in this process is identifying the patient's own goals regarding their asthma management to ensure improved outcomes. During this continuous cycle, a stepwise treatment approach is offered to achieve control using the patient's current level of control as the baseline. If the patient is not controlled on the current regimen, treatment should be stepped up until control is achieved. If control is maintained for at least three months on the current resident treatment can be stepped down to the lowest step and doses that maintain control. A combination ICS long acting beta agonist product is the preferred step up treatment for adults and adolescents 12 years of age or older, currently on a low dose ICS concurrently, who continued to have persistent symptoms and/or exacerbation. The risk of exacerbations can be reduced in adolescents and adults who are using other alternative therapies with treatment of a low dose ICS formoterol. And for children six to 11 years of age with persistent symptoms, an increased ICS dose is preferred over use of an ICS LABA agent. Notably, the 2019 guidelines no longer recommended SABA control treatment for step one patients. Rather, all adults and adolescents should

receive symptom-driven or regular low dose ICS containing controlled treatment. And the guidelines emphasize the impact of inhaler technique and adherence management of exacerbation in primary care using reliever medications is also discussed. This is a summary of the stepwise approach. If anyone in the committee wants to see the flow, it's in the appendix of the slides. On the next slide here, we have the national asthma education and prevention program 2020 update. Now as you can see, there's a lot of information here. And I'm just going to kind of summarize it. So the key recommendations for pharmacotherapy here, there's no recommended change in step one with intermittent asthma therapy as needed SABAs for rescue therapy. In row two, mild persistent asthma either daily low dose ICS plus as needed SABA therapy or as needed concomitant ICS and SABA therapy are recommended. Formoterol in combination with an ICS in a single inhaler is recommended as a preferred therapy for moderate persistent asthma. In step three, low dose ICS formoterol therapy and step four, medium dose ICS formoterol therapy for both daily and as needed therapy. A short term increase in the ICS dose alone for worsening of asthma symptoms is not recommended. Add on LAMAs are recommended in individuals whose asthma is not controlled by ICS formoterol therapy. This is in step five. Subcutaneous immunotherapy is recommended as an adjunct to standard pharmacotherapy for individuals with symptoms and sensitization to specific allergens. And lastly, sublingual immunotherapy is not recommended specifically for asthma. On the next slide here, we have first medication update for Breztri Aerosphere. So in July 2020, the FDA approved this combination of budesonide, which is an inhaled corticosteroid, glycopyrrolate, an anticholinergic, and formoterol, which is a LABA, indicated for the maintenance treatment of patients with COPD. There's a limitation of use. It is not indicated for the relief of acute bronchospasm or for the treatment of asthma. So as you can see, there's a little bit of overlap here. The precautions are similar. LABA monotherapy increases the risk of serious asthma related events and deterioration of disease and acute episodes do that initiate in acutely deteriorating patients. Dosage is maintenance therapy, two inhalations twice daily and the availability is an inhaled aerosol. The next and final slide for this class we have Trelegy Ellipta. Until September 2020, FDA approved expanded indication for this medication and it is now indicated for the maintenance treatment of asthma in patients 18 years of age or older. Previously, it was only indicated for the maintenance treatment of patients with COPD. And again, it is not indicated for the relief of acute bronchospasm. And just to remind the committee, when I have these classes where there's an expanded indication and new formulation, I bold the

relevant information just to avoid overwhelming you with information. And so there is a new dosage for the expanded indication of just one actuation once daily by oral inhalation. No changes to the precautions or availability here. That is the final slide for this class. I'll go ahead and pause there for the committee.

Ginni Buccola: Thanks, Umang. This is Virginia, committee chair. Are there any questions, committee members? Okay, we have three stakeholders. I see Jennifer Shear with Teva Pharmaceuticals, Vadim Gazarov with GSK, and Mark Maneval again with Boehringer Ingelheim Pharmaceuticals. So we'll go in that order. Jennifer, when you're ready, you'll have three minutes. And if you could just make sure that you share your affiliation that would be great. Thank you.

Jennifer Shear: Thank you. Good morning. My name is Jennifer Shear. I'm a medical outcomes liaison with Teva Pharmaceuticals and today I'm here to provide information on the Digihaler portfolio, specifically, for Armonair Digihaler and Air Duo Digihaler as well as to speak about the Digihaler technology. The Armonair Digihaler became available in September of last year. It's a drug product containing a corticosteroid fluticasone indicated for maintenance treatment of asthma as prophylactic therapy in patients 12 years of age and older. Armonair Digihaler is not indicated for the relief of acute bronchospasm. For air dual Digihaler, this also became available in September of last year. It is a drug product combination containing a corticosteroid fluticasone and long acting beta adrenergic agonist, Salmeterol. The Air Duo Digihaler is indicated for the treatment of asthma in patients of 12 years of age and older. Air Duo Digihaler should be used for patients not adequately controlled on a long term asthma control medication such as inhaled corticosteroids or whose disease warrants initiation of treatment with both inhaled corticosteroid and in LABA. The Air Duo Digihaler is not indicated for the relief of acute bronchospasm. The Armonair and Air Duo Digihaler each contain adult and electronic modules, which detects, records, and stores data on inhaler events. And this includes peak inspiratory flow rate for transmission to the mobile app through the Bluetooth wireless technology. The use of the app is not required for the administration of medication to the patient. There are several notifications, messages, and reports that are provided to users based on the Digihaler events. And these include inhalation events, twice daily reminders to take medication for maintenance inhalers, inhalation techniques modification, refills notification, and daily and weekly reports. These reports can be used to support consultations between patients and healthcare professionals. And

this concludes my statement. I respectfully request committee to consider allowing member access to the Digihaler family of products. And I'm happy to answer any questions.

Ginni Buccola: Thanks very much, Jennifer. Are there any questions from the committee? Okay, we'll move to Vadim Gazarov. You have three minutes to speak.

Vadim Gazarov: Thank you. Good morning. My name is Vadim Gazarov and I'm a pharmacist and a health outcomes liaison with GSK. Before joining GSK a little over a year ago, I spent over five years working for several managed care health plans. Many of those years were working with the Medicaid population, which included P and T committee, patient outreach, and provider programs. To speak a little bit on Trelegy Ellipta, which is a triple therapy that contains an ICS LABA/LAMA. Now Trelegy Ellipta is the only single inhaler triple therapy approved for both asthma and COPD. And like all the Ellipta devices, Trelegy Ellipta is always initiated with one inhalation once a day in a device shown in studies to be easy to use. Recalling my days as a community pharmacist, I quickly realized how many patients had poor inhaler technique or needed a lot of training and retraining to ensure proper use. Additionally, gold international treatment guidelines emphasize the importance of inhaler education, training, and assessment of techniques. Now, having previously worked on many med adherence programs and initiatives, I remember how challenging it was to get many patients to take a medication as prescribed. And intuitively, it always made sense to me that by streamlining and offering combination products could be one strategy to improve medication adherence. Now to confirm this point, a recent real world US claims based analysis found patients receiving Trelegy Ellipta had up to 2.5 times higher adherence when comparing it to multiple inhaler triple therapy. Patients in this study were also 91% more likely to remain on therapy. Lastly, I think many would agree that treating patients holistically is an ideal approach. On that note, in another claims based real world analysis, initiating Trelegy promptly after hospital discharge versus delayed initiation was associated with a reduction in the rate of moderate and severe exacerbations. Promptly initiating Trelegy also showed reduced hospital readmission rates, all contributing to lower overall medical costs. The most common adverse events with Trelegy are upper respiratory tract infection, pneumonia, and bronchitis. In conclusion, GSK would like to respectfully request the committee to add Trelegy to the Apple Health PDL without restrictions so patients can access triple therapy single inhaler without having to fail multiple inhalers. Thank you so much.

Ginni Buccola: Thank you Vadim. Committee, do you have any questions? Okay and we'll go then to Mark Maneval with Boehringer Ingelheim.

Mark Maneval: Great, good morning. Again, my name is Mark Maneval and I'm a pharmacist and health economics outcomes research liaison for Boehringer Ingelheim. I'm speaking with you today to draw your attention to some important changes to the guidelines and recommendations for the treatment of people with COPD that Dr. Patel mentioned in earlier slides. COPD is a heterogeneous condition with wide variation and clinical manifestations that require individualizing the pharmacologic treatment approach based upon exacerbation history, symptoms, side effects, and eosinophil count. In 2020, the Global Initiative for Chronic Obstructive Lung Disease, commonly referred to as GOLD, released a revision to their 2019 report that provides clinicians with a nonbiased review for the assessment, diagnosis, and treatment of COPD. Also in 2020, the American Thoracic Society and the European Respiratory Society issued official updated clinical practice guidelines for the pharmacologic treatment of COPD with the following core recommendations: LAMA and LAMA/LABAs remain the cornerstone of COPD maintenance treatment. Triple therapy is not recommended as initial maintenance treatment. Inhaled corticosteroid containing regimens require assessment of risk versus benefit, as regular treatment with inhaled corticosteroids increases the risk of pneumonia, especially in patients with severe disease. For initial therapy, GOLD recommends a threshold of EO count of 300 cells per microliter to initiate inhaled corticosteroids in patients in Group D. In follow up, GOLD recommends to consider the addition of an inhaled corticosteroid to long acting beta bronchodilators in patients with EO counts greater than 100 if they had two or more moderate exacerbations or one severe exacerbation and to avoid inhaled corticosteroids in patients with levels below this. Inhaled corticosteroid withdrawal or de-escalation should be considered in those with no exacerbations in the past year. Inappropriate use of inhaled corticosteroids may be associated with an increased risk of side effects, including pneumonia. Not all patients with COPD benefit from the use of inhaled corticosteroids. Several studies have shown extensive use of inhaled corticosteroids in patients for which they may not be recommended. GOLD, ATS, and ERS are unbiased collaborations to COPD experts reinforcing LAMAs and LAMA/LABAs as the preferred treatment for the majority of patients with COPD. Studies have shown that compliance to GOLD recommendations was associated with lower COPD related medical costs and lower risk of exacerbations. I hope you find this information helpful

as you work to align your formulary to guideline directed medication therapy. Our team is here to answer any questions you may have.

Ginni Buccola: Thank you, Mark. Committee, are there any questions? Okay, we're ready to move to the motion then.

Susan Flatebo: This is Susan Flatebo. I move that all products in the [audio dropout] necessity. All non-preferred products require a trial of two preferred product with the same indication before a non-preferred drug will be authorized unless contraindicated, not clinically appropriate, or only one product is preferred.

Diane Schwilke: This is Diane Schwilke. I second.

Ginni Buccola: This is Virginia Buccola, committee chair. All those in favor, please say aye.

All: Aye.

Ginni Buccola: Are there any opposed? The motion carries. And we'll go back to Umang for the next and last category of asthma and COPD agents.

Umang Patel: Thank you. Alrighty, so the next category here we have our asthma immunomodulators or monoclonal antibodies that are specifically for asthma and COPD. On the next slide here, a little bit of overview. I tried to underline more of the important information on this slide. Eosinophilic granulomatosis with polyangiitis, previously known as Churg-Strauss syndrome, is a systemic vasculitis of small to medium vessels characterized by allergic rhinitis, asthma, and hyper eosinophilia. It is a rare disease, affecting one to three out of 100,000 patients with a higher incidence of about one per 15,000 in patients with asthma. Onset may occur between 15 and 70 years of age, but diagnosis is typically made between 35 and 50 years. While the direct cause of the disease is unknown, HLA-DRB4 positivity may be a genetic risk factor. And symptoms can vary from mild to life threatening. In terms of diagnosis, a diagnosis may be confirmed if in addition to vasculitis, patients also have at least four of the following features: asthma, eosinophilia, neuropathy, pulmonary infiltrates, paranasal sinus abnormalities, and eosinophils vasculitis. Scoring systems to assess the severity of vasculitis and guide initial therapy in patients with EGPA include a five factor score and the Birmingham vasculitis activity score. In terms of guidelines, there are no US guidelines that are currently available for the treatment. As a consensus,

EGPA that is not severe in nature is often treated with oral corticosteroids alone and more than 90% of patients have achieved remission. Initial therapy may also include cyclophosphamide for patients with severe multi organ disease. Patients with severe EGPA may be transitioned to maintenance therapy with azathioprine, methotrexate, or leflunomide. And evidence supporting their use is limited. Other treatments including anti UL-5 antibodies, such as Nucala, immunoglobulins, interferon alpha with rituximab, or inhaled glucocorticoids can also be used. And notably Nucala is the only FDA approved medication for this disease state. On the next slide here, in October 2020, FDA approved a new indication for Nucala for the treatment of adult and pediatric patients 12 years of age or older with hypereosinophilic syndrome for six months or greater without an identifiable nonhematologic secondary cause. Again, the dosing is 300 mgs as three separate 100 milligram injections administered subcutaneously once every four weeks. For this medication, there are no adequate studies in the form of drug associated risk in patients who are pregnant and there are no clinical trials conducted in patients with hepatic and/or renal impairment. The next and final slide for this class is Xolair. And in December 2020, FDA approved a new indication for add on maintenance treatment of nasal polyps in adults with inadequate response to nasal corticosteroids. As you can see, it already has a litany of other indications. The dosing here is 75 to 600 mgs subcutaneously every two to four weeks. And it is recommended to determine the dose in milligrams and dosing frequency by serum total IVE levels. That is the end of this section. I'll go ahead and pause here for the committee.

Ginni Buccola: Thanks, Umang. Any questions from the committee? I don't see any listed stakeholders for this section. So it looks as if we can go right to the motion.

Leta Evaskus: Hi, Ginni. This is Leta Evaskus. We have two stakeholders who have raised their hands. First we have Craig Sexton.

Ginni Buccola: Alright, Craig, when you're unmuted and ready to go, you'll have three minutes to present. And if you could just state your name and affiliation.

[unrelated discussion]

Leta Evaskus: I see in the question/answer, he’s pointing to Vadim. So maybe he wants him to speak.

Ginni Buccola: You have three minutes Vadim.

Vadim Gazarov: Okay, thank you. Hello, everyone. This is Vadim Gazarov off with GSK medical affairs again. Having previous experiences participating in class reviews and health plans, I appreciate it is important to know the unique attributes and key differentiators of products within the class. Nucala mepolizumab is an anti-IL-5 monoclonal antibody and is differentiated from other biologics the following ways: one, Nucala is the only anti-IL-5 biologic indicated as an add on maintenance treatment for pediatric patients with severe eosinophilic asthma down to age six. Two, unlike other asthma biologic agents, Nucala is approved as a fixed dosing regimen every four weeks and is not dosed on weight and does not require a loading dose. This allows for more consistent and predictable dosing costs. Three, as noted in the Magellan review and report, Nucala is the only anti-IL-5 that is indicated for EGPA and HES, both eosinophilic diseases. Finally, Nucala is unique amongst the respiratory biologics having long term efficacy and safety data out to four and a half years. Now, if we take a look at some of the large phase three trials, Nucala when [indistinct] standard maintenance therapy has demonstrated consistent reductions in asthma exacerbations to include those requiring hospitalizations as well as reductions in oral corticosteroid dosing. The most common on treatment adverse events noted in the clinical trials with Nucala were fatigue, headache, back pain, and injection site reactions. Let's take a moment to highlight some flexibility in dosage forms that allows your patients and providers flexible treatment options. Nucala is available as a prefilled auto injector or prefilled syringe for at home self-administration and as a reconstituted lyophilized powder for health care provider administration. We ask that the current recognition of separate criteria for eosinophilic and allergic asthma products remain in place. Therapeutic interchange across different mechanisms of actions within this class is not supported by the guidelines or current Washington Health Care Authority PA criteria. In conclusion, GSK would like to request the committee recommend Nucala to be available as a preferred anti-IL-5 due to indications for multiple eosinophilic driven diseases, its simplified dosing schedule, and as long term efficacy and safety data. Thank you.

Ginni Buccola: Thank you Vadim. I heard Leta say there is a second stakeholder. I don't have their name.

Leta Evaskus: That was it.

Ginni Buccola: Okay, great. Then we can go to the motion.

Jordan Storhaug: This is Jordan Storhaug. I moved that all products in the asthma and COPD agents monoclonal antibodies drug class are considered safe and efficacious for their medically accepted indications and are eligible for preferred status and grandfathering at the discretion of HCA. Products in this class may require prior authorization to determine medical necessity. All non-preferred products require a trial of two preferred products with the same indication before a non-preferred drug will be authorized unless contraindicated, not clinically appropriate, or only one product is preferred.

Leah Marcotte: Leah Marcotte and I second that motion.

Ginni Buccola: This is Virginia Buccola, committee chair. All those in favor, please say aye.

All: Aye.

Ginni Buccola: Are there any opposed? The motion carries. And we will go back to Umang to discuss hematopoietic agents.

Umang Patel: We'll head and over to the next class, which is hematopoietic agents, specifically Gaucher Disease. And there are no significant clinical updates in the last 12 months in this class. So this and the next class will be a quick review. So I'll pause right there.

Leta Evaskus: This is Leta Evaskus. We do not have any stakeholders for this class so I'm going to bring up the motion.

Ginni Buccola: This is Virginia Buccola and I move that all products in Hematopoietic agents Gaucher Disease drug class are considered safe and efficacious for their medically accepted indication and are eligible for preferred status and grandfathering at the discretion of the HCA. Products in this class may require prior authorization to determine medical necessity. All non-preferred products require a trial of two preferred products with the same indication before a non-preferred drug will be authorized unless contraindicated, not clinically appropriate, or only one product is preferred.

Catherine Brown: This is Catherine Brown. I second.

Ginni Buccola: This is Virginia Buccola, committee chair. All those in favor please say aye.

All: Aye.

Ginni Buccola: Are there any opposed? And the motion carries. And we will go back to Umang for sickle cell anemia.

Umang Patel: Thank you. The next topic being sickle cell anemia. Again, there are no significant clinical updates in the last 12 minutes in this class. So similar to Gaucher, I'll pause right there.

Ginni Buccola: Okay, so we'll go right to stakeholders. I see three stakeholders listed: Foxy Davison from the Sickle Cell Task Force, Dr. Bender with Odessa Brown Children's Hospital and Fred Hutchinson, and Jamie Smutko with Global Blood Therapeutics. Foxy, when you're unmuted you'll have three minutes to present. We'll just ask that you share your name, affiliation, and if you have any affiliation with pharmaceutical company.

[unrelated discussion]

Foxy Davison: Yes, my name is Foxy. I am the community coordinator for the Sickle Cell Task Force. I'm also a mom of three kids, two of which have sickle cell disease. First, thanks for the opportunity to share. I had the privilege of sitting in and listening to the ones that you were sharing all the different folks who have been on before. And so I know it takes a skilled and compassionate listener to be present for each of these groups. So thank you. We are living in a very unique time, a time where black and brown folk voices, their joys and sorrows are center stage. And even in the sickle cell community, we finally have new treatments and more coming down the pipeline. Honestly, I'm so excited, and yet honestly can't help but feel a little bit skeptical. I have this deep fear that this is just a fad and at any moment the intermission will be over and the real show will begin again. That is my honest truth. Today, though, you have the opportunity to be sure that this is not just a fad. You have the power to put priorities in place that will help real people who have suffered and continue to suffer from a terrible disease. My son was prescribed a new sickle cell treatment that we finally decided after trying for a year to get approved, to just go to the local health store and get a product that was similar. This shouldn't be the reality for so many reasons. And especially not for a community who has been waiting far too long for new treatments. But today, I'm asking that you make all drugs approved for the treatment of sickle cell disease preferred so that there are no barriers in access to these much awaited treatments. I'm also asking that sickle cell care

and research remain a priority here in Washington State. Again, thank you for your time. And if there's anything we as the Sickle Cell Taskforce here in Washington can do to help in your efforts, please know we are here to work together as one team. Thank you.

Ginni Buccola: Thank you, Foxy. Committee, do you have any questions for Foxy? Okay, we'll move to Dr. Bender with Odessa Brown.

Dr. Bender: Hi, thank you for this opportunity. I'm Dr. Bender from Odessa Brown Children's Clinic in Seattle Children's. I run the largest sickle cell program in Washington and the Northwest. I'm a hematologist and researcher who's been doing sickle cell for over 30 years. I have no ties with any pharmaceutical. I just deeply care about the lives of our patients. Along these lines, I fully support and have gratitude for what Foxy shared. I want to support making all new agents for sickle cell, including voxelotor, glutamine, and crizanlizumab preferred. There's a few main points I want to make. First, hydroxyurea and these three new agents may have similar indications but each works by a different mechanism and act on a different pathway. So it's critical to provide easy access to these agents. Sickle cell pain results from not one pathway but the interaction of many pathways. I think many know the amazing advances in pediatric ALL, where survival increased from 10 to over 85%. This was accomplished by combining multiple drugs, all for the same indication, but each attacking a different pathway with a different mechanism of action. This is what has led to improve quality of life and survival. Similarly, in sickle cell, it can be addressed with a single helpful, imperfect drug but the combination of multiple drugs impacting different pathways are necessary to decrease the pain, organ damage, low quality of life, and shortened lifespan in sickle cell. Please don't make patients wait to fail a preferred agent before optimizing care with others. Second, if you're on hydroxyurea, adding any of these drugs provides additional benefit. This shouldn't be an either or situation. Patients deserve more support. Third, requiring two prefer drugs does not make sense in sickle cell. Hydroxyurea is the only preferred agent. So it's impossible to do trials of two preferred agents. And this makes prior authorizations really difficult. Related to this, the indication of voxelotor is completely different. It's to increase hemoglobin, not pain. And there's no other agents with the same indication. So again, it's an impossible situation. And finally, each agent has a different profile of benefits, risks and patients should be able to determine what profile best fits their goals and risk benefit profile and their family priorities. Not everyone wants to accept the potential risks of one agent and should

have the option for other drugs with the same indication but a different risk benefit profile. Thank you so much for the consideration here and I can answer any questions now or in the future.

Ginni Buccola: Thank you, Dr. Bender. Committee members, do you have any questions? Okay, we have one remaining stakeholder and that's Jamie Smutko with Global Blood Therapeutics.

Jamie Smutko: Good morning. My name is Jamie Smutko and I'm the West Region director of the medical science liaison team at Global Blood Therapeutics. The root cause of sickle cell disease is polymerization of hemoglobin S. And this results in red cell sickling that leads to hemolysis, anemia, base occlusion, and is associated with organ damage and reduced life expectancy. Oxbryta is the only drug that directly inhibits the polymerization of hemoglobin S. It is indicated for the treatment of sickle cell disease in patients 12 years of age and older and was approved under accelerated approval based on an increase in hemoglobin. Continued approval for this indication may be contingent upon verification and description of clinical benefit and confirmatory trials. We now have new data showing durable improvements in hemoglobin levels and markers of hemolysis out to 72 weeks where almost 90% of patients on expert achieved a hemoglobin increase of more than one gram per deciliter at one or more time points compared with 25% of placebo patients. Treatment remains well tolerated with no new safety signals and the most common adverse reactions were headache, diarrhea, abdominal pain, nausea, fatigue, rash, and pyrexia. You can refer to the full prescribing information for complete safety data. We also have seen in a post hoc analysis of patients with leg ulcers in the Hope study that 75% of patients had complete leg ulcer resolution when treated with 1500 milligrams of Oxbryta versus none in placebo. New real world evidence shows that Oxbryta's impact goes beyond hemoglobin and hemolysis. In a compassionate use case series of patients with severe sickle cell disease treated with Oxbryta, there was a 60% reduction in transfusions and a 67% reduction in [indistinct] crises hospitalizations in the 24 weeks after Oxbryta initiation. A new retrospective claims review of more than 1300 patients taking Oxbryta comparing the three months pre and post Oxbryta initiation, there was a 44% reduction in transfusions and a 23% reduction in BOCs in those with at least one of either in the past year. In an online retrospective chart review of 40 patients, 53% reported less fatigue and pain and 20% stopped or required fewer transfusion. Sickle cell disease impacts communities that are historically disadvantaged and progress has been slow

for the four treatments currently available to them. By adding Oxbryta to the preferred drug list, patients will have access to a treatment option that specifically targets the root cause of their disease. One that offers once daily oral dosing, requires no titration or monitoring and is well tolerated, one that not only improved hemoglobin and hemolysis, but also improves sickle cell disease symptoms and complications like jaundice, leg ulcers, anemia, transfusions, BOCs, pain, fatigue, and red blood cell health. I'd like to thank you for your time and I'm happy to take any questions.

Ginni Buccola: Thank you, Jamie. Committee, do you have any questions?

Leah Marcotte: Actually I have a question more related to Dr. Bender's comments. Are we reviewing the policy for sickle cell anemia at any time in the close future? He just brought up a few issues that seems like that might be helpful at some point.

Leta Evaskus: This is Leta Evaskus. Marissa, do you want to answer that?

Marissa Tabile: Hi, this is Marissa. So Dr. Marcotte, we're still working on that policy here internally. So I don't unfortunately have a set date on when we will be reviewing that policy. But it's definitely coming up in the future. So it is still on our radar. I just don't have it scheduled yet.

Leah Marcotte: Thank you so much. Appreciate it.

Ginni Buccola: Thank you, Leah. We can go ahead then and come on as a committee and look at the motion.

Kavita Chawla: This is Kavita Chawla. Can I ask a clarifying question about the motion? Regarding the sickle cell anemia drug class, does that include the three drugs? I'm just wondering which drugs are included as agents in this drug class.

Donna Sullivan: Hi, Kavita. This is Donna Sullivan, I can answer that. We have the hydroxyurea, the glutamine, and the voxelator. They're all three. And I'll just to clarify, we don't require a try and fail preferred in this particular class. The two nonpreferred agents are just requiring prior authorization. And we review them for medical necessity to FDA label until we can get the policies completed.

Kavita Chawla: Thank you. I move that all products in the Hematopoietic Agents: sickle cell anemia drug class are considered safe and efficacious for their medically accepted indications and are eligible for preferred status and grandfathering at the discretion of HCA. Products in this class may require prior authorization to determine medical necessity. All nonpreferred products require a trial of two preferred products with the same indication before a nonpreferred drug will be authorized unless contraindicated, not clinically appropriate, or only one product is preferred.

Susan Flatebo: This is Susan Flatebo. I second.

Woman: I'm sorry. A quick clarification. Donna, you had just said that in this class that all nonpreferred products do not necessarily require a trial of two preferred products. And I just wanted to check that language before we approve.

Donna Sullivan: That's true. This is our standard boilerplate language for nonpreferred. Not clinically appropriate would probably fall with the nonpreferred drugs. Obviously with Oxbryta having a different indication than hydroxyurea, it wouldn't be clinically appropriate to make somebody try hydroxyurea. So that's just the catch all. I confirmed online, our PDL, there is no try and fail status on any of these drugs.

Woman: Perfect. Thank you so much. Sorry for that interruption.

Ginni Buccola: This is Virginia. I think I heard it a second.

Susan Flatebo: This is Susan Flatebo. I second.

Ginni Buccola: Thank you, Susan. This is Virginia Buccola, committee chair. All those in favor, please say aye.

All: Aye.

Ginni Buccola: Are there any opposed? Okay, the motion carries. And going back to Umang to continue on hematopoietic agents.

Umang Patel: Okay, thank you. The next class we have here, the therapeutic class review that Magellan provides. They're labeled as colony stimulating factors. The subgroup in the Apple Health PDL is hematopoietic agents, specifically GCSF, so granulocyte colony stimulating factors. The next slide here, just to give a

little bit of background, myelosuppressive chemotherapy can induce neutropenia defined less than 500 neutrophils per microliter or less than 1000 neutrophils per microliter, and a predicted decline to less than or equal to 500 per microliter during the 48 hours after the dose, and febrile neutropenia, which is defined as 38.3 degrees Celsius, orally, or greater than 38 degrees Celsius sustained over an hour, which is a dose limiting toxicity of chemotherapy. Febrile neutropenia can cause increased diagnostic and treatment costs, prolonged hospitalizations, and broad spectrum antibiotic use, which may necessitate chemotherapy dose reductions, treatment delays and may ultimately compromise treatment outcomes. The risk of febrile neutropenia is dependent on treatment and dose intensity, which is often under reported. CSF and hematopoietic growth factors that have been shown to decrease the likelihood of neutropenic complications resulting from chemotherapy and to improve relative chemotherapy dose intensity. Colony stimulating factors are hematopoietic cells and stimulate proliferation, differentiation commitment and some end-cell functional activation. Prophylactic CSF can reduce the severity, risk, and duration of febrile neutropenia and decreased rates of infections and hospitalizations. Neupogen, Nivestym, Zarxio, Neulasta, Nyvepria, Udenyca, Fulphila, Ziextenzo, and Granix are granulocyte colony stimulating factors. Leukine is a granulocyte macrophage colony stimulating factor. On the next slide here the National Comprehensive Cancer Network practice guideline for Myeloid growth factors in 2020. Due to recent approval of pegfilgrastim, Nyvpria, it is not addressed by the NCCN since the approval of chimeric antigen receptor modified T cell of CAR-T therapies in the recent years, the guidelines advise against the use of GCSFs within 14 days after receipt of CAR-T therapy, due to concern for exacerbation of cytokine release syndrome or CRS. Use after this time period is considered for treatment of neutropenia. The guidelines state limited data suggests that patients can alternate between the originator product and the biosimilar without clinical meaningful differences regarding efficacy or safety. The next and final slide here, the new medication, Nyvpria in June 2020 was approved by the FDA, which is a biosimilar to Neulasta. The indications are a leukocyte growth factor indicated to decrease the incidence of infection as manifested by febrile neutropenia in patients with non-myeloid malignancies, receiving myelosuppressive anti-cancer drugs associated with a clinical significant incidents of febrile neutropenia, The limitations of use, it is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation. There are precautions for fatal splenic rupture and for acute respiratory distress syndrome. As you can see, the dosing for patients with cancer receiving

myelosuppressive chemotherapy are six milligrams sub Q once per chemo cycle. And the availability is an injection with a six mg per .6 mL solution and a single dose prefilled syringe. I'll go ahead and pause right there for the committee. This is the end of this section.

Ginni Buccola: Thanks, Umang. Any questions committee members? Okay, we have one stakeholder, Amy Stanford with Pfizer. Amy, as soon as you're unmuted, you'll have three minutes to speak. You'll just need to state your name and your affiliation.

Amy Stanford: Thank you. Good morning, everyone. My name is Amy Stanford. I am a pharmacist with Pfizer oncology medical affairs. Thank you for the opportunity to address the committee regarding Nivestym Filgrastim-AAFI, a biosimilar to Neupogen. I'm here today to provide the committee with efficacy and safety information for consideration. Nivestym is a leukocyte growth factor indicated to decrease the incidence of infection as manifested by febrile neutropenia in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever. It's also to reduce the time to neutrophil recovery and the duration of fever following induction or consolidation chemotherapy. Treatment in patients with AML reduce the duration of neutropenia and mobilize autologous hematopoietic progenitor cells into the peripheral blood for collection by Leukapheresis, as well as reduce the incidence in duration of [indistinct] severe neutropenia in symptomatic patients with congenital neutropenia, [indistinct] neutropenia, or idiopathic neutropenia. For dosage and administration similar to the originator patients with cancer receiving myelosuppressive chemotherapy or induction and/or consolidation chemotherapy for AML. The starting dose is five micrograms per kilogram per day. Patients with cancer undergoing bone marrow transplant is ten micrograms per kilogram per day, given us an intravenous infusion no longer than 24 hours. In patients undergoing autologous peripheral blood progenitor cell collection and therapy is ten micrograms per kilogram per day, subcutaneous injection. Patients with congenital neutropenia, the starting dose is six micrograms per kilogram, subcutaneous injection twice daily, and then patients with cyclic or idiopathic neutropenia, the recommended dose is five micrograms per kilogram subcutaneous injection daily. For additional details, please see the full prescribing details for recommended dosage adjustments and timing of administration. For the clinical safety profile, the most common adverse reactions in patients are pyrexia, pain, rash, epistaxis, bone pain, anemia, diarrhea, hypoesthesia,

alopecia, headache, cough, and dyspnea. Nivestym has warnings and precautions for fatal splenic rupture, acute respiratory distress syndrome, serious allergic reactions, including anaphylaxis, fatal sickle cell crisis [indistinct] nephritis. See again, the full prescribing information for suggested evaluations and actions. And in closing, adding Nivestym, an FDA approved biosimilar to Neupogen will offer additional treatment options for patients requiring treatment with a leukocyte growth factor in the state of Washington Medicaid population. So based on the efficacy and safety of Nivestym, I request the committee to provide availability for Nivestym for your patients. Thank you for your time and consideration.

Ginni Buccola: Thank you. Committee, do you have any questions? Okay, let's go ahead and move to the motion.

Catherine Brown: This is Catherine Brown. I move that all products in the Hematopoietic agents: granulocyte colony stimulating factors, GCSF drug class are considered safe and efficacious for their medically accepted indications and are eligible for preferred status and grandfathering at the discretion of HCA. Products in this class may require prior authorization to determine medical necessity. All non-preferred products require a trial of one preferred product with the same indication before a non-preferred drug will be authorized unless contraindicated or not clinically appropriate.

Alex Park: This is Alex Park. I second that motion.

Ginni Buccola: This is Virginia Buccola, committee chair All those in favor please say aye.

All: Aye.

Ginni Buccola: Are there any opposed? The motion carries. Back to you, Umang to continue the Hematopoietic agents.

Umang Patel: Next we have Erythropoiesis stimulating agents. On the next slide here, a little bit of background. So Anemia and Erythropoietin. Anemia is a frequent complication affecting over three million Americans. It is associated with a number of serious diseases such as CKD, diabetes, heart disease, and cancer, as well as chronic inflammatory conditions like rheumatoid arthritis and IBD. These conditions can cause anemia by interfering with the production of oxygen carrying red blood cells. And sometimes, as is the case of cancer chemotherapy, anemia can be caused by the treatment itself. In terms of

Erythropoietin, it is a glycoprotein produced by the kidneys that stimulate red blood cell production from the bone marrow. It acts on the progenitor cells in the bone marrow to cause late differentiation and maturity into red blood cells. Endogenous production of Erythropoietin by the kidney is normally regulated by the level of tissue oxygenation. Hypoxia and anemia generally increase the production of erythropoietin, which in turn stimulates Erythropoiesis. In normal subjects, plasma erythropoietin levels range from .01 to .03 units per milliliter and may increase 100 to 1000 fold during hypoxia or anemia. In contrast, patients with CKD have impaired production of erythropoietin which is a primary cause of their anemia. And anemia in cancer patients may be related to the disease itself or the effects of concomitantly administered chemotherapeutic agents. On the next slide here, we'll pivot over to beta thalassemia. It is a rare inherited blood disorder marked by a reduction of functional hemoglobin levels and has an incidence of approximately one in 100,000 individuals in the general population. There are three subtypes, which are characterized by the severity of symptoms: minor, intermediate, and major. Individuals with major, require blood cell transfusion as often as once every two to four weeks and are dependent on medical care. Treatment for beta thalassemia is highly dependent on the type, progression, and severity of disease and the presence or absence of certain symptoms. Treatment options may include regular blood transfusion, chelation therapy, folic acid treatment, removal of spleen and/or gallbladder, and bone marrow transplant. Reblozyl is the first FDA approved erythroid maturation agent which reduces patient transfusion burden by regulating red blood cell maturation. It is approved for the treatment of anemia in adult patients with beta thalassemia who require regular red blood cell transfusion. On the next slide here, we have some updates on guidelines, first being the NCCN guidelines in 2020. I tried to underlining some of the more relevant information. Physicians are advised to use the lowest ESA dose possible to maintain hemoglobin levels sufficient to avoid blood transfusions. ESAs should be discontinued once the course of chemotherapy has been completed and anemia resolves. And there's not enough evidence to support the use of ESAs for the treatment of anemia related to myelosuppressive chemotherapy with curative intent, patients receiving non-myelosuppressive therapy, or patients with cancer not receiving therapy. For the American Society of Clinical Oncology and the American Society of Hematology, they updated their 2010 recommendations for the use of ESAs in patients with cancer. Guidelines emphasize the intent of treatment be considered when weighing the benefits and risks of these agents, including thromboembolism. ESAs may be offered to patients with chemotherapy associated anemia

whose cancer treatment is not curative in intent and whose hemoglobin level is less than ten grams per deciliter. It can also be used for low risk myelodysplastic syndrome. The goal hemoglobin should be lowest value that prevents need for transfusion. And ESA should be discontinued if there's a lack of hemoglobin increased by one to two grams per deciliter by six to eight weeks. On the next and final slide, I alluded to Reblozyl a second ago in the background section. But April 2020, FDA approved a new indication for the treatment of anemia failing an erythropoiesis stimulating agents and requiring two or more red blood cell units over eight weeks in adult patients with a very low to intermediate risk myelodysplastic syndromes with ring sideroblasts or MDS-RS or with myelodysplastic/ myeloproliferative neoplasms with ring sideroblasts and thrombocytosis. Again, the bold is to indicate the new information here. The warnings and precautions stay the same along with formulations. And the dosage there is starting as one mg per kg once every three weeks by sub q injection. In terms of special populations such as pediatrics and geriatrics, safety and efficacy for this medication has not been studied yet. I'll go ahead and pause there for the committee.

Ginni Buccola: Thanks, Umang. Committee, any questions? Okay, we have two stakeholders. We have Wendy Bibeau with Bristol Myers Squibb and then Amy Stanford again with Pfizer. So Wendy, as soon as you're unmuted, just let me know and you'll have three minutes to present.

Wendy Bibeau: Thank you for inviting me. My name is Wendy Bibeau. I'm an epidemiologist and currently a field health economics and outcomes research scientist with Bristol Myers Squibb. Today I'll be presenting Reblozyl or luspatercept, which is the first FDA approved erythron maturation agent. Reblozyl is indicated for the treatment of anemia in adult patients with beta thalassemia who require red blood cell transfusions. Reblozyl also indicated for the treatment of anemia failing an ESA and requiring two or more red blood cell units over eight weeks. In adult patients with very low to intermediate MDS risk with ring sideroblasts or with myelodysplastic or myeloproliferative neoplasm with rings sideroblasts and thrombocytosis. Reblozyl is not indicated for use as a substitute for red blood cell transfusions in patients who require immediate correction of anemia. For the MDS indication, Reblozyl gained indication based on the results of Medalist, a phase three multicenter, randomized, double blind, placebo controlled study that evaluate the efficacy and safety of Reblozyl versus placebo in patients with very low to intermediate risk, ring sideroblasts, positive MDS requiring regular red blood cell transfusions. Eligible patients had an inadequate

response to prior treatment with an ESA or were ineligible or intolerant to ESAs. The primary endpoint metals was a proportion of patients achieving red blood cell transfusion independence, defined as the absence of red blood cell transfusions during any consecutive eight week period during weeks one through 24. More Reblozyl treated patients than placebo treated patients achieved this red blood cell transfusion independence by greater than eight weeks. There's also additional data on reducing blood cell transfusion independence at other specified time periods and the prescribing information. The safety of Reblozyl was evaluated in 242 patients. The most common all great adverse events included fatigue, muscular skeletal pain, dizziness, diarrhea, nausea. The most common grade three event or higher included fatigue, hypertension, syncope, and muscular skeletal pain. The incidence of serious treatment emergent adverse events was similar across treatment groups. NCCN guidelines currently recommend Reblozyl for anemia and very low to intermediate risk MDS with ring sideroblasts after two months of no response to ESAs. And that's a category 2A recommendation. Based on the clinical evidence provided, we respectfully request that the committee keeps Reblozyl on the PDL in accordance with FDA label. Thank you for your time and the opportunity to speak. I'm happy to answer any questions.

Ginni Buccola: Thanks very much. Committee, do you have any questions for Wendy? Okay, Amy, are you ready to go?

Amy Stanford: Yes, good morning again. My name is Amy Stanford. I'm a pharmacist with Pfizer oncology medical affairs. I'm here to provide the committee with another summary of efficacy and safety data for Retacrit, a biosimilar to Epogen. Retacrit is an [indistinct] stimulating agent indicated for the treatment of anemia due to CKD in patients on dialysis and not on dialysis versus [indistinct] in patients with HIV infection. The effects of concomitant myelosuppressive chemotherapy and upon initiation, there's a minimum of two additional months planned chemotherapy and the reduction of allergenic RBC transfusions in patients undergoing elective noncardiac non vascular surgery. For the dosage and administration consistent with the originator evaluate iron status before and during treatment and maintain iron repletion, correct or exclude other causes of anemia before initiating treatment. Patients with CKD, the dose for initiating is 50 to 100 units per kilogram three times weekly in adults and 50 units per kilogram three times weekly for the pediatric population. Individualized maintenance doses, intravenous route is recommended for patients on hemodialysis. For patients

and zidovudine due to HIV infection, the dose is 100 units per kilogram three times weekly. And for patients with cancer and chemotherapy, the dose is 40,000 units weekly or 150 units per kilogram three times weekly in adults, and 600 units per kilogram intravenous weekly for pediatric patients. Surgery patients, the dose is 300 units per kilogram per day daily for 15 days or 600 units per kilogram weekly. And then for the clinical safety profile, the most common adverse reactions which are also consistent with the originator are the hypertension, arthralgia, muscle spasms, pyrexia, dizziness, medical device malfunction, vascular occlusion, upper respiratory tract infection, cough, rash, injection site irritation, injection site pain, nausea, vomiting, myalgia, dermatitis, weight decrease, leukopenia, bone pain, hyperglycemia, insomnia, depression, dysphasia, hyperkalemia thrombosis pruritis, headache, chills, DVT, cough, and hypertension. Retacrit also has the warnings and precautions for increased mortality, myocardial infarction, stroke, thromboembolism, thrombosis of vascular access, increased mortality, and/or increased risk of tumor progression or recurrence in patients with cancer, hypertension, seizure, PRCA, serious allergic reactions, severe cutaneous reactions, and phenylketonuria. People prescribing information for suggested evaluation and actions. So in conclusion for the summary, adding Retacrit, an FDA approved biosimilar to Epogen will offer additional treatment options for patients requiring treatment with an ESA or erythropoiesis stimulating agents for the HCA population. And based on the efficacy and safety presented for Retacrit, I request the committee to provide availability to your patients. Thank you for your time and consideration again.

Ginni Buccola: Thank you very much. Committee members, do you have any questions? Okay, let's look at this motion then.

Susan Flatebo: This is Susan Flatebo. I move that all products in the hematopoietic agents, erythropoiesis stimulating agents drug class are considered safe and efficacious for their medically accepted indications and are eligible for preferred status and grandfathering at the discretion of HCA. Products in this class may require prior authorization to determine medical necessity. All nonpreferred products require a trial of two preferred products with the same indication before a nonpreferred drug will be authorized unless contraindicated, not clinically appropriate, or only one product is preferred.

Leah Marcotte: Leah Marcotte. I second that.

Ginni Buccola: This is Virginia Buccola, committee chair. All those in favor?

All: Aye.

Ginni Buccola: Are there any opposed? And the motion carries. That brings us to a morning break. Looks like 10:28. Leta, are we good to come back at 10:40?

Leta Evaskus: Yeah, 10:40 works.

Ginni Buccola: Okay, let's see everybody then.

[break]

Ginni Buccola: Hi, everybody. This is Virginia, committee chair. Welcome back from break. Umang, when you're ready to go on immune modulators, I will turn it over to you.

Umang Patel: Okay, so with the oral immunomodulators classes, there is usually an issue with the classes lining up. And just for mechanism of the action sake, I went ahead and broke these up between hematologic, oncology agents, and breast cancer oncology agents. And I will specify which subclasses this falls under on the Apple Health PDL. So I hope that makes sense for the committee and if there are any questions, please let me know. So we have on the next slide here, just to give a little bit of an overview, the specific disease states that go in correlation with the Apple Health PDL subclasses, first thing, marginal zone lymphoma. This is MZLs account for approximately 10% of all NHLs and are generally divided into three subtypes: nodal, splenic, and the most common subtype mucosal associated lymphoid tissue or MALT lymphoma. Lenalidomide plus rituximab is an NCCN category 2B recommendation for first line therapy for elderly or infirm patients, chlorambucil with or without rituximab may also be utilized in the first line setting. Both lenalidomide with or without rituximab and rituximab as a single agent are NCCN V4 2020 category 2A preferred recommendations for second and subsequent line therapy. Idelalisib or duvelisib may be used in second and subsequent line of marginal zone lymphoma in patients who are relapsed/refractory after two prior therapies. Acute myeloid leukemia is the most common form of acute leukemia among adults estimated 5930 cases diagnosed and 1500 deaths in the US in 2019. In a patient who obtained a CR, three years survival is 25% and remission rates are inversely proportional to age. Cytogenetics plays a large role in determining prognosis and treatment options as well. Acute

myelocytic leukemia is a subtype of AML with distinct features and treatments. For diffuse large B cell lymphoma, it is the most common type of lymphoma and accounts for about 30% of all NHL. There are several subtypes including DLBCL arising from follicular lymphoma. Some patients with follicular lymphoma may undergo conversion to more aggressive lymphoma such as DLBCL and this risk increases over time. About 30% of SL patients convert to a more aggressive lymphoma at ten years post FL diagnosis. The B cell lymphoma guidelines list Xpovio as an option for DLBCL not otherwise specified, including DLBCL arising from follicular lymphoma after at least two prior systemic therapies. On the next slide, here we have our fourth disease states that falls into this class review and that is Kaposi sarcoma. It is a malignancy of the endothelial cells and is characterized by cutaneous red or brown papules often seen on the lower extremities. There are four types: classic presents with cutaneous lesions but follows an indolent course. It is the most common in elderly patients of Mediterranean, Eastern European, Middle Eastern, and/or Jewish descent. Endemics Kaposi sarcoma tends to be more aggressive than classic and occurs in younger patients less than 40 years of age, as well as in children in Equatorial Africa. The third type is lateral genic and it occurs in the setting of patients taking immunosuppressive therapy, such as organ transplant recipients. The fourth type is seen in patients infected with HIV. In these patients, it is considered to be AIDS defining cancer. The risk of developing Kaposi sarcoma is estimated to be approximately 498 fold higher in HIV positive population compared to the general US population. Due to the improved treatment options available to AIDS patients, the incidence of this cancer has been declining. And the NCCN v 32020 guidelines for AIDS related Kaposi sarcoma lists Pomalyst as a preferred systemic therapy option for patients with relapsed refractory disease. And know that Pomalyst has been FDA approved for treatment of adult patients with AIDS related Kaposi's sarcoma after failure of highly active antiretroviral therapy. On the next slide here, in terms of guidelines, we have the American Society of Hematology in 2020. They published guidelines for the treatment of newly diagnosed AML in older adults. The guidelines examined questions around the role of treatment for older adults with AML and the intensity and length of treatment in this population. The general conclusion of the panel of experts was that for older adults, treatment is recommended over best supportive care and more intensive therapy is recommended over less intensive therapy when it is tolerable. Specific recommendations pertaining to patients who are not appropriate for intensive antileukemic therapy but who are able to receive treatment include recommendation of monotherapy over combination therapy. Lastly, the

guidelines further note that when these patients choose combination therapy, there is evidence to support the use of LDAC in combination with venetoclax. On the next slide, here's a breakdown of this class in comparison with the Apple Health PDL. And so the medications that are bolded are the ones that do have clinical updates that I will be providing. So an overview of all the subclasses by the Apple Health Organization consists of alkylating agents, thalidomide analogues, anti-neoplastic miscellaneous, BCL2 inhibitors, histone deacetylase inhibitors, IDH1 and IDH2 inhibitors, JAK Janus Associated Kinase inhibitors, proteasome inhibitors, XPO1 inhibitors, antimetabolites. And I just want the committee to note that these are found in both metalogic and breast cancer. So, I've broken them down a little bit further. Then we have the PI3K inhibitors. On to the next slide. The first medication I have here is Ukoniq. And for this medication, in February 2021, the FDA granted accelerated approval to this kinase inhibitor for the treatment of adults with relapsed or refractory marginal zone lymphoma. They've received one or more prior anti-CD 20 based regimen or relapsed or refractory follicular lymphoma, whoever sees three or more prior lines of systemic therapy. These indications were approved under accelerated approval based on the overall response rate. Continued approval for these indications may be contingent upon verification and description of clinical benefits in the confirmatory trial. There are some warnings and precautions primarily infections, neutropenia, diarrhea, or noninfectious colitis, and hepatic toxicity. In terms of those things, as you can see, the recommended dosage is 800 mgs once daily with food and is ideally recommended to manage toxicity using treatment interruption dose reduction for discontinuation. The availability are tablets of 200 milligrams strength. In terms of special population, pediatric patients, safety and efficacy has not been established yet. And for renal and hepatic impairment, there is no adjustment needed in mild or moderate. It is not studied in severe but I do circle back to hepatic toxicity being a warning and precaution. Next slide. Here we have Onureg. In September 20, FDA approved this medication for continued treatment of adults with acute myeloid leukemia who achieved first complete remission or complete remission with incomplete blood count recovery following intensive induction chemotherapy and are not able to complete in terms of curative therapy. In terms of warnings and precautions, there are risks of substitution with other Azacytidine products of do not substitute, myelosuppression, and embryo fetal toxicity. In terms of dosage, it is recommended to be administered 300 mgs once daily on days one through 14 of each 28-day cycle and it is recommended to administer an antiemetic before each dose for at least the first two cycles. And this is available in 200

and 300 milligram strength tablets. Similar to the previous slide, there are no safety and efficacy studied in pediatrics and mild to severe renal and hepatic impairment does not require a dose adjustment. On the next slide we have Pomalyst. So there are two updates here. In November 2020, the approval of shared Pomalyst REMS include brand Pomalyst, original REMS was approved in 2013 and generic pomalidomide. In December 2020, FDA approved Pomalyst for the treatment of adults with AIDS related Kaposi sarcoma after failure of highly active antiretroviral therapy or in patients with Kaposi sarcoma who are HIV negative. Again, bold indicates the new updated information. No updates to warnings and precautions. Dosage for Kaposi sarcoma indication show five mgs per day taken orally on days one through 21 of repeated 28 day cycles until disease progression or an acceptable toxicity. And it is available in one, two, three, and four milligram capsules. On the next and final slide, we have Xpovio. And in December 2020, accelerated approval for the new indication of treatment of adults with relapsed or refractory diffuse large B cell lymphomas, not otherwise specified, including DLBCL arising from follicular lymphoma after at least two lines of systemic therapy. It was already indicated for the use in combination with dexamethasone for the treatment of adults with relapsed or refractory multiple myeloma who have received at least four prior therapies and has diseases refractory to at least two proteasome inhibitors, at least two immunomodulatory agents, and an anti CD38 monoclonal antibody. Again, no updates to warnings and precautions. The dosage for the updated indication is 60 milligrams taking daily, orally on days one and three of each week. The availability is 20 milligram tablets. In terms of pediatric safety and efficacy is not established. For renal impairment, no specific dosing recommendations are provided. No clinically significant differences in the PK were observed in patients with mild to severe renal impairment. For hepatic impairment, no specific dosing adjustment recommendations were provided. Mild hepatic impairment had no clinically significant effects on the pharmacokinetics and the effects of moderate and severe hepatic impairment is unknown. I'll go ahead and pause right there before for the committee.

Ginni Buccola: Thank you again, Umang. Any questions, committee members? I see two stakeholders listed. Margaret Olmon with AbbVie and Wendy Bibeau with Bristol Myers Squibb. Margaret, when you're unmuted, you can start your three minutes.

Margaret Olmon: Thank you. Good morning. My name is Dr. Margaret Olmon with medical affairs at AbbVie. I am here to provide any information that you need about

Venclexta, which is the only BCL2 inhibitor that's among the treatments that you've reviewed today. Dr. Patel, thank you for your review of this area and talk about Venclexta. I appreciate it. I'm happy to answer any questions that you have. I don't have any new clinical data to provide. And I'm happy to give my time back to the committee.

Ginni Buccola: Thank you, Margaret. I appreciate it. Wendy, we will move to you. When you are unmuted let me know and we'll start your three minutes.

Wendy Bibeau: Great. Thank you. And thanks again for letting me speak on behalf of Idhifa. And my name is Wendy Bibeau and I'm a field health economics and outcomes research scientist with Bristol Myers Squibb. Today I'll be presenting on Idhifa isocitrate dehydrogenase two inhibitor, which was improved in August 2017. Idhifa is a once daily oral inhibitor of the ADH2 enzyme and it is indicated for the treatment of patients with relapsed refractory acute myeloid leukemia with an IDH2 mutation detected by an FDA approved test. The efficacy of Idhifa was approved for use in patients based on results of an open label single arm multicenter clinical trial. Efficacy was established on the basis of the rate of complete response with partial hematologic recovery, duration of complete response or partial hematologic recovery, and the rate of conversion from transfusion dependence to transfusion independence. For patients on the 100 milligram dose, the overall response rate was 38.8% and the complete response rate was 19.6%. Among the 157 patients who are dependent on red blood cell transfusion or platelet transfusions at baseline, 34% became independent of red blood cell and platelet transfusions during any 56 day post baseline period. Serious adverse events were reported in 77.1% of patients and 43% recorded dose interruption due to an adverse event. A real world analysis of Idhifa was recently conducted to access real world outcomes of using Idhifa versus other first line therapies in the treatment of relapsed refractory acute myeloid leukemia patients. For both progression free survival and overall survival endpoints, Idhifa patients had statistically lower hazard ratios where the reductions were 64 and 63%, respectively over other first line treatments. Relating to safety, patients on Idhifa versus other therapies had statistically significant lower rates of hospitalizations. So based on the clinical and real world evidence provided, we respectfully request that the committee keeps Idhifa on the PDL in accordance with FDA label. So thank you again for the opportunity to speak and I'm happy to answer any questions.

Ginni Buccola: Thanks very much, Wendy. Are there any questions? Okay, committee, we can go ahead and look at the motion.

Leah Marcotte: This is Leah Marcotte. I move that all products in the drug classes listed on slides 18 and 19, are considered safe and efficacious for their medically accepted indications and are eligible for preferred status and grandfathering at the discretion of HCA. Products in this class may require prior authorization to determine medical necessity. All non-preferred products require trial of two preferred products with the same indication before non-preferred drug will be authorized unless contraindicated, not clinically appropriate, or only one product is preferred.

Marissa Tabile: Hey, Ginni, this is Marissa Sorry to interrupt. I think the intention was to actually have all of the oncology agents be in one motion. Correct me if I'm wrong, Umang. I think you have cancer after right? And then that's it? So yeah, I lumped everything together so they could all be in one motion, because I think there's some other classes that are listed on this slide that haven't been reviewed yet, because he hasn't gotten there yet.

Ginni Buccola: Thank you for letting us know, Marissa. So we'll hold off then. And I'm sorry. We'll go back to Umang to continue. And then we'll return to the motion. Thanks, everybody.

Umang Patel: Great. So there are no updates in this class. But on the next slide, I just wanted to show the breakdown. So for this breast cancer class, you can see that it is comprised of antimetabolites and PI3Kinhibitors as well. And again, you're seeing these classes again because some of the medications fall under breast cancer, not illogical cancer treatments. Again, no updates in these subclasses. So I'll pause right there and hand it right back to the committee.

Ginni Buccola: Okay, great. Thanks. So Leta, if we can go back to where we were in the motion and Leah can finish, or maybe Leah had already finished supporting the motion.

Nancy Lee: And this is [indistinct]. I second the motion.

Ginni Buccola: This is Virginia Buccola, committee chair. All those in favor, please say aye.

All: Aye.

Ginni Buccola: Are there any opposed? And the motion carries. Okay. And then back to Umang again to continue this category.

Susan Flatebo: This is Susan Flatebo. I'm sorry to interrupt. But if you go back to the drugs from the breast cancer slide. It says PI3K but it's actually [nonsense] PIK3CA.

Marissa Tabile: Hi, Susan. This is Marissa. So the reason why that is labeled the way it is, is because we get our drug name classes from [indistinct]. So that's the way that they had it classified. Are you recommending to rename this class?

Susan Flatebo: Well, technically, Piqray drug is a PIK3 CA inhibitor drug. It targets that mutation. So I don't know. In my mind, that's really not correct for that particular drug. It's PIK3CA inhibitor. I've never seen a PI3K abbreviation before. But if that's how they're labeling it, I guess. But I know that particular drug is considered a PIK3CA.

Marissa Tabile: Okay, I can actually take that back and consider if we want to rename that. So thank you for the feedback on that name. Yeah, I'll take that back and see if we want to rename it. Thank you.

Umang Patel: I will go ahead and start in our next and final therapeutic class review for thrombopoiesis stimulating factors. To give a little background, first, platelets are small circulating cell particles that do not contain a nucleus and are released into the bloodstream by megakaryocytes that reside in the bone marrow and function to maintain hemostasis by aggregating and forming platelet plugs at sites of injury to limit blood loss. Thrombocytopenia is generally defined as a platelet count of less than 100 times 10 to the ninth per liter. It can result in bruising, bleeding, and fatal hemorrhaging. The causes of thrombocytopenia include decreased bone marrow production of megakaryocyte, splenic sequestration of platelets, and increased destruction of platelets. Immune thrombocytopenia, previously known as immune thrombocytopenia purpura or idiopathic thrombocytopenia. It is defined as a platelet count of less than 100 times 10 to the ninth per liter. And is an immune mediated disorder in which platelets are opsonized by autoreactive antibodies and prematurely destroyed by the reticular endothelial system. The next slide here for ITP, immune thrombocytopenia in children. It is an acute self-limiting disease that often occurs two to three weeks after a viral infection or immunization. Spontaneous remission in children typically occurs within two to eight weeks. In adults, it has an insidious onset with no preceding viral or other illness and typically has a chronic course. Many adult

cases of ITP are diagnosed incidentally after routine complete blood count. Signs and symptoms of ITP are highly variable and range from asymptomatic with mild bruising or mucosal bleeding to frank hemorrhage from any site. Severity of ITP in adults is dependent on the presence of active bleeding, platelet count, patient age, a patient's lifestyle related to risk of bleeding, and presence of additional risk factors for bleeding such as uremia or chronic liver diseases. Primary ITP is defined as an autoimmune disorder with an isolated thrombocytopenia of less than 100 times 10 to the ninth per liter in the absence of other causes or disorders that might cause harm to cytopenia. Diagnosis remains one of exclusion. No robust clinical or laboratory parameters are currently available to establish this diagnosis with accuracy. Primary ITP is also defined by the length of time since diagnosis. Newly diagnosed less than three months, persistent between three and 12 months, and chronic 12 months or more. The main clinical problem of primary ITP is an increased risk of bleeding, although bleeding symptoms may not always be present. Secondary causes of ICP include drug induced autoimmune diseases such as systemic lupus, erythematosus, and viral infections, such as HIV and Hep C. Severe ITP occurring at any time indicates bleeding which requires treatment for the occurrence of new bleeding symptoms which requires additional treatment or increased dose to control the bleeding. On the next and final slide here we have a medication Nplate where in February 2021, FDA approved new indication for Nplate to increase survival in adult and pediatric patients including term neonate acutely exposed to myelosuppressive doses of radiation. Since this was an expanded indication, there was no changes to warnings and precautions. The dosing as you can see is 10 micrograms per kilogram administered once as a sub q injection. It is recommended to administer the dose as soon as possible after suspected or confirmed exposure to the myelosuppressive dose of radiation. No changes in warnings and precautions or availability here. I'll go ahead and pause there for the committee.

Ginni Buccola: Excellent. Any questions? Okay, I don't see any stakeholders listed unless there are any present. If there are, go ahead and raise your hand. And if not, we can go ahead and look at the motion.

Donna Sullivan: Ginni, this is Donna. I'd like to clarify Susan's question from earlier just for the record. The mechanism of action of the one drug, Piqray is actually the phosphatidylinositol 3 kinase inhibitor, which shows activity to the PIK3CA mutation. So the drug class is named after its mechanism of action, so it was correct the way that it was originally written.

Ginni Buccola: Thanks, Donna.

Diane Schwilke: This is Diane Schwilke. I move that all products in the Hematopoietic agents: thrombopoiesis TPO stimulating proteins drug class are considered safe and efficacious for their medically accepted indications and are eligible for preferred status and grandfathering at the discretion of HCA. Products in this class may require prior authorization to determine medical necessity. All non-preferred products require a trial of two preferred products with the same indication before a non-preferred drug will be authorized unless contra indicated, not clinically appropriate, or only one product is preferred.

Jordan Storhaug: This is Jordan Storhaug. I second.

Ginni Buccola: This is Virginia Buccola, committee chair. All those in favor, please say aye.

All: Aye.

Ginni Buccola: Are there any opposed? And the motion carries. And we're going to move to Marissa for Apple health policies.

[unrelated discussion]

Marissa Tabile: This is Marissa from HCA. I will be presenting today the rilpivirine Edurant HIV policy that we created. So just to give the board some background, what really triggered us to make this policy was there's a new product called Cabenuva that was released to the market and just recently FDA approved, which is a cabotegravir, which is a new active ingredient and rilpivirine injection. And really how that medication works just to give a little bit more background is patients would have to take oral lead in therapy over rilpivirine and cabotegravir first for one month before they would get the injections, which are every month. So right now we have rilpivirine on the PDL. It's preferred. But to help with management of this drug and also for us to really monitor for safety and any drug interactions, we did create criteria for this product. Cabotegravir, just for background, also will be distributed by the manufacturer pretty much free of cost to all patients. And so we really don't have any way of checking if someone is taking cabotegravir because we wouldn't be able to see those claims. So having a prior authorization policy or clinical policy in place would really allow us just to make sure that everything is right, it's safe for the patient, we can see any drug interactions that could

possibly be happening for this patient. So that's why we put this criteria together. So just to give you some background I'll go through the policy. So rilpivirine - and the brand name is Edurant - may be considered medically necessary for the following indications. So for the treatment of HIV-1 infection in patients and then the new indication now for Edurant is also in combination with cabotegravir for short term treatment to replace their current stable antiviral regimen. So for the HIV-1 infection criteria, it's pretty basic criteria, it's nothing too complex. Rilpivirine may be authorized when all the following are met. So the patient is treatment naive and meets all of the following, and it would be A through D. So for treatment naive patients that would have a confirmed diagnosis of HIV-1, HIV-1 RNA less than 100,000 copies per ml, and CD4 cell count greater than or equal to 200 cells per millimeter cube. And it's prescribed in combination with other appropriate antiretroviral agents. So we would want to see what the whole regimen would be just to make sure that it is appropriate for the patient. Or if the patient is treatment experienced, the patient is ART experienced with virologic suppression for at least six months, and the patient is 12 years of age or older, their body weight is 35 kilograms or greater. And it won't be co-administered with any of these contra indicated products. I won't go through all of them. You can see them listed here. And if all the criteria are met, the request will be approved for 12 months. We also have our boilerplate statement here about the products. If they don't meet all the criteria, it can still be approved on a case by case basis if it is clinically appropriate by the medical reviewer. So that statement is here. And then for reauthorization, Rilpivirine may be reauthorized if the patient shows previous history of medication use within the last six months. And the reauthorization will be good for 12 months. And then the next indication here is the in combination with cabotegravir for short term treatment to replace current stable antiviral regimen. And they would just have to meet all of the following. So we would want to make sure because in order to be on cabotegravir and rilpivirine, you have to already be established on an HIV regimen before you can switch and it would have to be at least for six months. So that criteria is listed here. It's pretty much the same as above. The patient is 18 years of age or older. So cabotegravir, you have to be 18 or older in order to use it. So that's a little bit different with this criteria compared to above that would be 12 years of age, which is listed above for treatment naive. And then for three, their body weight is greater than or equal to 35 kilograms. And then we have their boilerplate statement as well. And then dosage in quantity limits is 30 for 30 day supply. And that's pretty much it for the policy. I'll go ahead and switch over to the form. And this form, like all the other forms that we reviewed are

just to help guide providers, when they are doing prior authorization requests for medications. This is just kind of what they would fill out. So basic demographic information up at the top, medication and strength directions, quantity and day supply. Is this request for a continuation of therapy? Is it for HIV-1 treatment? Are they going to be using it in combination with cabotegravir? Is the patient treatment naive? What's their HIV-1 RNA? Have they been adherent to an ART regimen in the last six months? What's the patient's weight? And then checking off if they will be taking it with any of these medications. And then of course, chart notes, labs, and tests are required, as always with this request. So I will go ahead and pause here for any questions or feedback from the board.

Ginni Buccola: Thanks, Marissa.

Kavita Chawla: Kavita Chawla here. I have a language clarifying question regarding the policy. So clinical criteria for HIV-1 infection, I'm trying to understand how point one and point two can be accurate for the same patient and whether it's either point one or point two. Does that question makes sense? It's either they are treatment naive or they've been on ART.

Marissa Tabile: Yeah, this is Marissa. That's correct, Dr. Chawla. It would either be one or two. So either they're treatment naive or they're treatment experienced. It was these two right here that I have highlighted that you put the question on, right?

Kavita Chawla: That's correct. Yes.

Donna Sullivan: Marissa, I think what you need to do is after the "and" on D, it should say "or".

Kavita Chawla: I would agree with that. Thank you.

Marissa Tabile: Sorry, the Zoom controls at the top get in the way of my Word document. I will make that there. Thank you.

Ginni Buccola: Any other questions?

Alex Park: Marissa, Alex part here. I was reading about this drug. It looks like it's an injection and a pill. So the policy is coverage regardless of form?

Marissa Tabile: The policy is really just for the coverage of the rilpivirine and then we have a separate Cabanuva policy that's pretty much live already.

Alex Park: So this is just for the oral [indistinct]. Okay.

Marissa Tabile: Yeah, it's just for the oral therapy, Dr. Park.

Alex Park: Thank you.

Donna Sullivan: Dr. Park, this is Donna Sullivan. One of the challenges that we have is that Vive is providing one of the oral products without -- they are circumventing the payer and sending it directly to the client at no charge. And so one of the concerns that we have is that patients are going to start on these medications without any authorization. And we won't have a claim. So when we're doing prospective DUR, we're not able to look at drug interactions, which is one of the reasons why we put this one on prior authorization so that we can find out when providers and patients are starting on these medications with the intent to convert to the injectable.

Alex Park: That makes sense. My understanding is that you have to be on the oral first for tolerance.

Donna Sullivan: That is correct. For four weeks, I believe.

Alex Park: That's a good opportunity for me to do that quality utilization assessment. Okay, thank you.

Ginni Buccola: This is Virginia. Do we feel like we're ready to look at the motion? Are there any other things to discuss? And just to clarify, if I didn't already say, we don't have any stakeholders listed. Thanks, Martha.

Kavita Chawla: This is Kavita Chawla. I move the Apple Health Medicaid program implement the clinical criteria listed on policy 12.10.90.AA-1 as recommended. Update criteria 1d to have or at the end.

Alex Park: This is Alex Park. I'll second but just looking at the copy of the policy I have, there's no dash on it. Did we do an updated version of that, Marissa?

Marissa Tabile: I have it on this one. So I think that's why mine isn't current. But I'll make sure I have the dash on there to reflect version one.

Alex Park: Sounds great. Thank you. So yes, this is Alex Park and I second the motion.

Ginni Buccola: And this is Virginia Buccola, committee chair. All those in favor, please say aye.

All: Aye.

Ginni Buccola: Are there any opposed? And the motion carries. And when we'll go to Ryan Taketomo, who will cover Isotretinoin.

[unrelated discussion]

Ryan Taketomo: This is Ryan Taketomo. Good morning, committee. Today I'll be presenting the clinical policy for oral isotretinoin products. Isotretinoin a systemic analog of vitamin A and is FDA indicated for the treatment of severe recalcitrant nodular cystic acne. Isotretinoin is teratogenic which requires wholesalers, patient, providers, and pharmacies to participate in the I pledge risk evaluation and mitigation strategy, also called the REMS program to better ensure safe use of medication. And so just moving to the clinical policy criteria, starting with the one we're going to be reviewing. This policy includes indications for moderate to severe acne and will be considered medically necessary when all of the criteria are met. Criteria one is a diagnosis of moderate or severe acne. Criteria two is client is 12 years of age or older, which matches the FDA labeling. Criteria three is for nonpreferred isotretinoin products requiring a greater than or equal to two preferred products. Each product must be taken for at least 15 weeks, which is a course of isotretinoin therapy, unless that preferred product is not tolerated. And for criteria four, we have a trial and failure with one of the following therapies listed in A, B, or C in combination with either topical benzoyl peroxide or a topical retinoid, such as topical tretinoin for at least one month. The three therapies to use in combination include either oral anti biotics for females, oral contraceptives, or for females spironolactone. And the last criteria is that the client has not been treated with the full course of isotretinoin for the past two months. If all the criteria are met, they'll be approved for 20 weeks, which is the maximum duration for a course of therapy. For the reauthorization criteria, isotretinoin will be reauthorized all of the following are met. Criteria one is that the client continues to experience recurrent or persistent moderate to severe acne. Criteria two is that there's clinical documentation demonstrating that the client has had a

positive response to treatment. And criteria three is that the client has not been treated with isotretinoin for the past two months. And so if they meet all those, they'll be authorized for an additional 20 weeks. Below that, we have the dosage and quantity limits which reflect the labeling of the medication, followed by references. So we can move on to the pen form. So the pen form is used to facilitate the prior authorization process and to help make that more efficient. So I'll pause and give a few minutes for the committee to read over the form and open it up for questions and discussion. Thank you.

Ginni Buccola: Thanks, Ryan. Committee, do you have any questions about the form for Ryan or anything else before we get ready to consider the motion? Okay, it looks like we're ready to look at the motion then.

Nancy Lee: This is Nancy, I move that the Apple Health Medicaid program implement the clinical criteria listed on policy 90.05.00.AA-1 as recommended.

Kavita Chawla: Do you do the primary risk of the teratogenic side effects? I was trying to look real quick on the FDA page. Is there any requirement to document occurrent pregnancy test status before prescribing? Or is that just for clinical documentation? Not for med approval documentation?

Ryan Taketomo: Great question. And so as part of the REMS program, a female client is required to have at least two pregnancy tests that are negative and they have to be done from a certified lab. I believe that the REMS program also requires monthly tests as well. And unless those are accrued, a pharmacy will not be authorized to provide a prescription to the client.

Kavita Chawla: Thank you. I second the motion.

Ginni Buccola: This is Virginia Buccola, committee chair. All those in favor, please say aye.

All: Aye.

Ginni Buccola: Are there any opposed? Okay, the motion carries. And we'll go to Marissa to review Eucrisa.

Marissa Tabile: This is Marissa. So I will be going through the Eucrisa policy. So right now we do have a Eucrisa policy that is implemented and on our website. So this is really just an annual update to our current policy that we have. So just to give

some background, Eucrisa is used for the treatment of -- [unrelated discussion]. Eucrisa is used for the treatment of atopic dermatitis. And just to give you a little bit of background, atopic dermatitis is a chronic non contagious inflammatory disease of the skin resulting from a combination of genetic and environmental factors. It is often known as the common name as eczema. And Eucrisa is a topical treatment for atopic dermatitis. And it is a PDE4 inhibitor. This actually right here needs to be updated. Because I believe this doesn't match right here that it's three months of age and older. So I will make sure that this gets updated right here. So like I said, this is just an annual update to our current policy that we have right now. So I didn't really make any big changes to this policy. Everything as far as criteria has largely stayed the same as what it is currently. I'll just run through it very quickly. So the patient one, must be three months of age or older. They must have a diagnosis of a topic dermatitis with the documentation of baseline evaluation including severity of symptoms. They have to have a trial and failure of two topical corticosteroids, either medium or high potency. And what's really changed in this particular criteria is the days for treatment. So right now it's 14 days. But now we've changed that to be a 28 day trial. So now it would be a trial and failure of two topical corticosteroids for daily treatment for a minimum of 28 days within the previous six months, unless, of course, that steroid is contra indicated or not tolerated. And then these are the Contra indications that we've noted. And then we have also added number four, that is the new criteria for this. And it would be a trial of at least one topical calcineurin inhibitor. So that would be either pimecrolimus or tacrolimus. And that would be for a minimum of 28 days unless it's contra indicated, and the contra indications are listed here. And that would be if they're between three months and three years old. If they meet all the criteria, the request may be approved for six months. We added the boilerplate case by case basis approval statement here. And then for the reauthorization, it would just show that they have clinical documentation of disease stability or improvement from baseline. So just seeing that their condition has been approved through the clinic notes. And then if they meet all that criteria, then the request will be approved for 12 months. And then here are the quantity limits and the references. And then I'll go ahead and move over to the form. And I don't think anything really has changed too much on this form, besides the days, the trial, changing that from 14 to 28 days. And then adding this criteria number four for trial and failure of one topical calcineurin inhibitor. And those are pretty much the updates to this policy. So I'll stop and take any questions or feedback from the board.

Ginni Buccola: Thanks, Marissa. I will leave time for any questions.

Alex Park: This is Alex Park. I'm just curious, Marissa. I don't disagree with any of the changes that you made. And I'm just curious for the impetus behind them. Was there a utilization overrun on the drug or some new data that came out about the drug?

Marissa Tabile: Was it in reference to changing the amount of days for the trial or just in general for the update?

Alex Park: No, no, the 14 to 28 days in addition to the [indistinct].

Marissa Tabile: Yeah, it's really just more for utilization management. So now I believe we're making a change where I think we're going to be having some of these calcineurin inhibitors preferred just based off of some of the rebates that we've been able to negotiate. So some of them will become preferred with no PA. So that's one of the reasons why now it just made sense to have them try and fail a preferred agent that we have that'll be changing. And I think that change, if it's not already happened, I think it's going to be happening pretty soon within the next six months.

Donna Sullivan: Dr. Park, this is Donna Sullivan. Another reason we were specific to the 28 days is so there's not a claim that is filled. If you do it looking at it automatic, it could be like a one or two day, I tried it and it didn't -- and then they would allow for Eucrisa to be used. So we want to make sure that they're using the drugs for a reasonable amount of time before there's a determination that it's ineffective.

Alex Park: Makes sense. Thank you. Marissa, the copy I have of the policy has the effective date of -- it must be the last time we looked at the policy last year. You probably just have to change that.

Marissa Tabile: Hi, Dr. Park. Yes. So this is Marissa. So for the effective date, we keep the original date but the first version was ever implemented. So this date, even though it goes through DUR for review, we probably won't be changing it, just so you know even when just a policy for this product at all was implemented. Did that make sense? We keep the original implementation date for the policies as the effective date instead of the new current -- so if this third version gets passed at the DUR meeting and we choose to implement it, we don't usually update this effective date to reflect the new

date. It's always just the very first original date that the policy was ever implemented.

Alex Park: I see. Okay.

Marissa Tabile: Yeah. Any updates that we do make, we do list them at the bottom here. So if this does get approved at DUR today, there'll be a little column here with the date 6/16 saying it's been approved by DUR. And then they'll have any other updated information here at the bottom in the history.

Alex Park: As long as there's some way to know.

Marissa Tabile: Sorry for the confusion.

Nancy Lee: This is Nancy. I had a quick question about -- so I'm fine with that change of 14 to 28 days. But I was wondering, is the previous six months, was that there before or is it a new addition?

Marissa Tabile: This is Marissa. I believe that was there before and I think it's in the policy that we have published right now.

Kavita Chawla: Kavita Chawla here. Is there anything in the drug information that tells us that if there's a persistent staph infection, which can be quite common for severe atopic dermatitis, that a shorter course of the topical steroid might be adequate to move on to Eucrisa, because it is not as immunosuppressive?

Marissa Tabile: Can you repeat that one more time?

Kavita Chawla: Yes. So because severe atopic dermatitis often has the complication of superimposed cutaneous staph infections, sometimes medium or high potency steroids can actually limit the ability for the skin to heal. And I'm not as familiar with crisaborol, whether that is not as immunosuppressive and hence a shorter than 28 day and that exceptional case would be appropriate.

Marissa Tabile: I think if that was the case for a patient, we do have this boilerplate statement right here. So if the clinical reviewer thinks that maybe the 28 days, or if the patient's only tried it for 14 days and they are having recurrent staph infections, they can definitely, by all means, approve this product for that patient. That's why we have that statement here because it is on a case

by case basis. So I think this statement can cover situations like that, that you've brought up.

Kavita Chawla: Thank you.

Alex Park: Marissa, could they also use point numbers three. So if they have infections or other reasons that they would not want to be continuing steroids they could use that? In other words, steroids being contraindicated or not tolerated.

Marissa Tabile: Yes. Yeah. I think that covers that as well, Dr. Park.

Ginni Buccola: This is Virginia. Any other questions? Everybody feeling ready to look at the motion? Okay, let's go ahead and pull that up, Marissa, when you're able to. Great, thanks.

Nancy Lee: This is Nancy. I move that the Apple Health Medicaid program implement the clinical criteria listed in policy, 90.23.00.AA-3 as recommended. \

Catherine Brown: Catherine Brown. I second.

Ginni Buccola: And this is Virginia. All those in favor, please say aye.

All: Aye.

Ginni Buccola: Are there any opposed? And the motion carries. And we'll go back to Marisa for our final motion or a final review on Dupixent.

Marissa Tabile: So this clinical policy I'll be presenting is on Dupixent. And this one is like the Eucrisa, just an annual update based off of some of the changes that we'll be making on the PDL. And also some label updates regarding Dupixent. There's been some age changes for some of the different indications. So make sure to include that here in the policy. So here are the different indications that -- we currently have this policy implemented. So these are the four that we've had and they are pretty on par with the labeling for the product. So I'll go ahead and get into the atopic dermatitis and just note the changes that have really just been made. One and two, there hasn't been any updates to this clinical criteria here for one and two. What's really changed for this criteria for atopic dermatitis is changing the trial duration, like Eucrisa, from 14 to 28 days. And for patients to get Dupixent, they would have to have a history of

failure or trial and failure of all of the following. So it would be a trial of two topical corticosteroids. Now I've added in the trial of one topical calcineurin inhibitor for daily treatment for at least 28 days. A trial of crisaborole for a daily treatment for at least 28 days. This is the new criteria that we've added for this product. So in order for someone to get just an overview of Dupixent for atopic dermatitis, they would have to try two topical corticosteroids, one calcineurin inhibitor and crisaborole and then have at least one of the following. So it would be trial and failure of phototherapy, systemic steroids, or any of the following systemic immunosuppressants. And then I have updated number four to reflect the age indication. So for atopic dermatitis, Dupixent is indicated for patients six years of age and older. So I've added that in. It has to be prescribed by or in consultation with a specialist. That's not new. Nothing has changed. If all criteria are met, the request will be approved for six months and then added the boilerplate statement here. And then the reauthorization criteria, I didn't really change anything. It's still the same as what it currently is, just added this statement right here for approving things on a case by case basis. So moving on to asthma with an eosinophilic phenotype. I didn't change any of the criteria in number one and number two. That's still the same as what we currently have for our criteria right now. History of failure contraindication to a high dose inhaled corticosteroid in combination with conditional controllers. That's still the same. What's really changed in this criteria, because I've added number four, so it would be a history of failure, contraindication, or intolerance to a preferred asthma monoclonal antibody, which is listed on the AH PDL. So those would be things like, and I might be wrong on what's preferred right now, but like Nucala, some of those other asthma monoclonal antibodies, they would have to try a preferred one first before they could get Dupixent. And then number five is still the same. They would have to be used in combination with additional asthma controller medications. I did change this number six statement a little bit compared to what we have now. I think what we had before was it would not be used in combination with -- we have other monoclonal antibodies, and we listed these. But then Dupixent was listed too, but it just didn't really make sense to have Dupixent listed in the list if it was a request for that particular medication. So I removed that and kept the other monoclonal antibodies listed for the indication. And then I did also update the age indication for this. So the patient is 12 years of age or older. So for eosinophilic asthma, Dupixent is indicated for patients 12 years of age and older. I haven't changed anything else besides adding these statements here. The reauthorization criteria is still the same For asthma with oral corticosteroid dependent asthma, I didn't really change anything

here as well. The only thing I changed was number four. So I took Dupixent off of this list just because it didn't really make sense, like the other reason I just stated before. But the criteria is still very much largely the same as what it was or what it currently is. And then reauthorization criteria is the same. And then for chronic rhinosinusitis with nasal polyposis. The only thing that I really have changed in this particular section is just adding the age. So for Dupixent in this particular indication, it's only indicated for patients 18 years of age and older. I haven't added or changed any of the criteria really, besides number six for this indication. And then just added these statements here. Here are the dosage and quantity limits for different indications. The references and then I'll go ahead and move over to the form. And the form just reflects the updates that I've made within 20 days right here for the trials, adding in the trial of Eucrisa right here. And then I don't think the ages are on here. But those are the two that should reflect the changes on the criteria. So I'll go ahead and stop here if anyone has any questions. I'll pause so you can look over the form.

Ginni Buccola: Thanks, Marissa, we'll just hold for questions. This is this is Virginia. I just always want to make sure I give people enough time to read and formulate questions. I don't hear anything yet. So I'm wondering if we're okay to move to the motion. Or do people need more time?

Donna Sullivan: This is Donna. Marissa, I do have a question. I'm just wondering, if it's on the face, is there a criteria to skip the steroids due to the requirement for medium or high potency?

Marissa Tabile: This is Marissa. Let me scroll up. So this is the atopic dermatitis. I don't think there is, Donna, unless I am missing something. You said to skip the steroids, right?

Donna Sullivan: Yes. So I'm just thinking there should be a criteria. If it's not just a contraindication to all the preferreds. But if there's a reason for not using high or medium potency steroids based on the location of the eczema or the atopic dermatitis. And one of the providers can chime in if I'm wrong, but I recall that that used to be one of our criteria to get to the [indistinct] inhibitors.

Alex Park: This is Alex Park. I appreciate that suggestion though. I'm trying to pull up the other atopic dermatitis policy we just looked at. I think there was

something about what you're bringing up on that policy. We could try to bring over that language.

Marissa Tabile: Dr. Park. I believe the Eucrisa policy does have language about if it's contraindicated in the different areas. I'm opening it right now so then we can compare it. So this is what we have for Eucrisa. And right here we have the contraindications listed and then the treatment of sensitive areas.

Donna Sullivan: Is that included in the one that we were just reviewing and I just missed it?

Marissa Tabile: No, for Dupixent, that's not in here. Would you like me to include it?

Donna Sullivan: I think we need to. Yeah.

[unrelated discussion]

Donna Sullivan: And then Marissa, just make a note that we need to make this change on the form and we'll do that offline. We don't need to do it in the meeting.

Kavita Chawla: Kavita Chawla here. When providers receive these forms to fill out, do they also have the policy available with the form to review? Or is that something they have to seek out on their own?

Marissa Tabile: So I believe the policy should be available. At least for fee for service, we do have them published online, so the providers can reference it through our website. And the forms, I'm not sure about, exactly - and Donna, correct me if I'm wrong - if the MCOs have theirs published. They might do it a little bit differently. I think some of them might have them published online and some of them might not. But if you're ever in doubt, I would definitely reference the fee for service website because all MCOs MP for service follow the same policy.

Donna Sullivan: We do not send the form with the policy. So they would have to go online to find the actual policy.

Kavita Chawla: I see. The reason that I'm asking is from a provider perspective, as I'm looking at the form, so we can take the example of chronic rhinosinusitis with nasal polyposis. And question 17, is the patient continuing to use intranasal corticosteroids while using dupilumab. And our policy says that that's required. And maybe from a provider standpoint, we and the patient

themselves are ambivalent on continuing it. So they would be fine continuing it if we knew that that was actually a required part of the policy. And that's just one example. I'm just wondering whether something about the language can be made so that it is more indicative of what is required by policy and hence, there's less back and forth of like, oh, they'll say, No. It's not approved because you're not using concurrent intranasal corticosteroid. And then we send a form back saying, okay, fine, we will use it. Do you see what I'm saying? I'm just trying to figure out if there's a way we can skip those unnecessary steps for approval.

Donna Sullivan: I think we can take that away and try to make some improvements.

Woman: On the top of the form, is there a guidance to please refer to the policies available at this link.

Marissa Tabile: This is Marissa. For the forms, it doesn't look like there is any link to the actual policies on here. But we don't actually publish these forms online.

Donna Sullivan: I think we could maybe put our web address on here so that it makes it easier for a provider to find the policy. I don't think that we can embed hyperlinks as these are usually faxed and that's not a function once it's been faxed.

Alex Park: That's a good point, Kavita because as I look at this again, I think if I was filling this out for a patient, I would read question 17 and think I'm supposed to check no in order to get the drug approved. But now it is part of the policy that they want to support the intranasal steroids to continue.

Kavita Chawal: I suppose the overarching question is just what are the absolute necessary parts of the form that are more informative that a provider, if you're going to prescribe this, then these are the requirements that need to be satisfied rather than a yes, no. So it can be these things all need to be satisfied. Do you agree? Some version of that that's more binding, rather than a yes/no, yes/no for each individual policy requirement.

Alex Park: What do you think Donna? Should we wordsmith number 17 so that it's more obvious that that's part of the policy? Or should we just put a link to the policy? We want to be consistent with what HCA is doing with the rest of these policies too.

Amy Irwin: Hi, this is Amy Irwin. And I apologize. I don't mean to speak for Donna. But the intent of the forms are really to capture, what are you doing with the patient right now? So when we're sending out that form, we're really trying to see if the client or the patient meets the criteria to have Dupixent approved. Our intent is not to tell you what to answer so that you can get approval. It's really kind of partnering with you to ensure, is this what you're doing? And would we then take that into consideration and the client meets the criteria for us to approve the drug and pay for the drug?

Alex Park: That makes a lot of sense. If that's the case, then when I look at question 17, it's weird because it says is - present tense - the patient continuing to use the steroids while using the dupilumab. But I think the assumption is dupilumab would not have been used at the point that you're filling this form out, right? You're trying to get first approval for it.

Donna Sullivan: This is Donna. We can maybe wordsmith this and say, will patient continue to use intranasal corticosteroids?

Amy Irwin: Yeah, I think that would be better wording.

Marissa Tabile: And this is Marissa. Sorry, can you repeat that one more time, Donna, so I can document it?

Donna Sullivan: I think just delete the "is".

Kavita Chawal: And my purpose was not to just spotlight question 17. I was in general trying to understand the intent of the form and how to streamline the approval process, of course, without binding the individual clinical decision making by each individual provider.

Donna Sullivan: Kavita, this is Donna. Part of the problem is, these are not supposed to be trick questions. And we do find that providers will check the box that they think will get them to an approval. So we don't really want to lead them to just say what we want to hear to get approval, which is also why chart notes are required. And so it's a lot more difficult for us when the form I think is kind of designed the way I think you're recommending, because it leads the provider to approval, and then the chart notes don't support what they've checked. And so it gets really challenging from a reviewer standpoint when we're looking at these.

Kavita Chawla: I agree. Yeah, as long as these policies are readily searchable online and we can make a reference maybe at the top of the form about that, as you suggested earlier with just the website, I think between those two things that would help a provider along.

Leah Marcotte: This is Leah. I'll also add just from a primary care perspective, I wouldn't be prescribing these medications in primary care. And so I also would hope that the specialists who are prescribing these medications will have a lot more context in terms of the guideline directed therapy. That's just kind of a general comment. And then Marissa, I think just to make it grammatically correct, number 17 should probably say "will patient continue".

Woman: Marissa, will you stop on number 17? Will you cross out "while using"? Yeah, perfect. And I apologize. Did you capture the note to add at the top, the link to the website? Perfect. Thank you so much.

Marissa Tabile: No problem.

Alex Park: Are we doing this for all our policies now?

Amy Irwin: Hi, this is Amy. I think it's great feedback that we take back and start updating our forms moving forward with that link to the policies. I think it would be a better support more than just Dupixent.

Alex Park: Great, thank you.

Ginni Buccola: This is Virginia. Thanks, everyone for the good discussion. Any more questions? Are we ready to look at the motion?

[unrelated discussion]

Nancy Lee: This is Nancy, I moved that the Apple Health Medicaid program implement the clinical criteria listed on policy 90.27.30.AA-4 as recommended, with the addition of the link to the website on the form.

Alex Park: This is Alex Park. I second that motion.

Ginni Buccola: And this Virginia, committee chair. All those in favor, please say aye.

All: Aye.

Ginni Buccola: Are there any opposed? And the motion carries. So that's it for our work today, committee. I'll go ahead and adjourn the DUR board. Welcome again to our new committee members. Thanks for jumping in on the Zoom platform. And hopefully we get to meet you in person someday. Soon.

Nancy Lee: I had a question. Sorry, I wasn't sure if I was a minute or two late, what the status or plan was for in person? I'm just curious.

Ginni Buccola: That's a good question. I don't know.

Leta Evaskus: This is Leta Evaskus. We have looked at options of maybe going back to a hybrid. The conference center at SEATAC isn't set up for that yet in terms of having cameras for those who are not in the room. So right now we're going to stay with webinars. And we're just monitoring the recommendations from the state as far as going back and then also the rules for open public meetings. So I'll keep you posted.

Donna Sullivan: And this is Donna Sullivan. So Virginia, as state employees, we haven't received instruction about us even returning to the office to go to work. So I'm assuming that the open public meetings and the work that we conduct will have to wait until there's a decision made about numbers of people within a meeting room and rules around how that might work.

Ginni Buccola: Thanks for the update. Leta, any other things we should be aware of before we sign off?

Leta Evaskus: This is Leta, I do not have any other announcements for today. Thank you all.

Ginni Buccola: Thanks, everybody.

[end of file]