Members present: Alissa Aylward, Melinda Carroll, Hoo Feng Choo, Evan Crump, Paul Johnson, Scott Johnston, Kristen Lovas, Chris Mosier, Garry Needham, Danae Stampfli, Patrick Yost

Ex-officio: Cori Cooper, Melissa Hunter, James Bush

Guests: Melissa Eames, Sandra Deaver, Patrick Johnson, Matt Robison (CHC), Corwyn Moss (CHC), Melissa Mehle (CHC), Nikki Yost (CHC), Laken Mitchell (UW Student), Mike Donabedian (Sarepta), Aimee Redhair (Biogen), Tami Sova (Biogen), Laura Hill (Abbvie), David Block (Corium), Lance Lewis (Corium), Jane Stephen (Amgen), Tressa Diebes (Takeda), David Cram (Takeda), Donna Parker (Stemline), Michele Sabados (Alkermes), Amy Rodenberg (Abbvie)

Dr. Johnson called the meeting to order at 10:00 a.m.

Introductions were made.

Approval of Minutes:
The minutes of the November 4, 2021 meeting were approved.

Department of Health:

A. Pharmacy Program Manager Report: The PBM contract with Change Healthcare has been extended with an expiration of 12/31/2024. The RFP will go out this year. This includes claims processing, pharmacy prior authorizations, physician administered drug prior authorizations, preferred drug list, rebate services, and state maximum allowable cost services. The medical claims system (CNSI) went live in October. They are working through some bumps, as expected.

Teri Green has retired from her position as Medicaid Director. She was the longest standing Medicaid Director in the nation. Jan Stall has been named interim Director during the hiring process.

B. Medical Director Report: The National Association of Medicaid Medical Directors have published a paper outlining their concerns on accelerated approval drugs. Medicaid is required to cover all medications approved by the FDA but cannot cover experimental drugs which creates an issue with these medications.

C. DUR Manager Report: The RFP for the DUR Contract will also go out this year or early next year as the current contract expires 6/30/2023.

Old Business:
New Business

A. PA Criteria

1. Review existing criteria
   i. The use of albuterol inhalers was reviewed. The current criteria allows for up to two inhalers per month or a total of 24 inhalers per year. 145 patients are receiving 12 or more inhalers per year. It is not clear how many of these may be lost inhalers or inhalers kept in different locations. There was a motion, second and all were in favor of requiring prior authorization after a total of 12 inhalers per year. Additional data will be brought back in 6 months, or sooner as warranted.
   
   ii. The upper age limits were added to those ADHD medications that have clear limits in their product labeling. No vote is necessary on this item.

2. New Drugs
   i. Livmarli is indicated for the treatment of cholestatic pruritus with Alagille syndrome in patients aged 1 year and older. There was a motion, second and all were in favor of limiting to indication.
   
   ii. Qulipta is a new CGRP receptor agonist approved for the preventive treatment of episodic migraine in adults. Laura Hill (Abbvie) provided public comment. She asked the Committee to consider allowing Qulipta in a step 2 position for prophylaxis with clinical criteria. Qulipta levels peak within 1 – 2 hours with benefits seen after 24 hours of therapy. The medication is cleared within 3 days of discontinuation. The Committee noted there was no evidence of a benefit in safety or efficacy over existing medications. There was a motion, second and all were in favor of referring Qulipta to the Department of Health for cost analysis and PDL placement.
   
   iii. Skytrofa is a long-acting somatropin product approved for pediatric patients over age 1 who have growth failure due to inadequate secretion of endogenous growth hormone. The Committee noted no evidence of a significant benefit in safety or efficacy over existing medications. There was a motion, second and all were in favor of referring Skytrofa to the Department of Health for cost analysis and PDL placement.
   
   iv. Tyrvaya is a nasal spray approved for the treatment of signs and symptoms of dry eye disease. The Committee noted no evidence of a benefit in safety or efficacy over existing medications. There was a motion, second and all were in favor of referring Tyrvaya to the Department of Health for cost analysis and PDL placement.
   
   v. Vuity is a pilocarpine formulation approved for treatment of presbyopia in adults. The Committee noted that it is simply a different strength of other existing pilocarpine eye drop products. They noted no evidence of a benefit in safety or efficacy over existing products. There was a motion, second and all were in favor of referring to the Department of Health for cost analysis and PDL placement.
   
   vi. Elyxyb is an oral solution of celecoxib approved for treatment
of migraine with or without aura in adults. Several black box warnings are listed in the label. Due to safety concerns compared to the other medications approved for migraine, there was a motion, second and all were in favor of making Elyxyb non-preferred.

vii. Voxzogo is indicated to increase linear growth in pediatric patients with achondroplasia who are 5 years of age and older with open epiphyses. There was a motion, second and all were in favor of limiting Voxzogo to indication.

viii. Livtencity is a new antiviral indicated for treatment of post-transplant cytomegalovirus infection/disease that is refractory to treatment (with or without genotypic resistance) with ganciclovir, valganciclovir, cidofovir, or foscarnet in adults and pediatric patients 12 years of age and older. David Cram (Takeda) provided public comment. There was a motion, second and all were in favor of limiting Livtencity to indication.

ix. Paxlovid is approved under an emergency use authorization for treatment of mild to moderate COVID-19 in outpatients with high risk of progression to severe illness. Currently the product itself is paid for by the federal government. Medicaid would be responsible for the dispensing fee if provided by an enrolled pharmacy. Currently, County Health Officers are evaluating where drugs should be sent in their counties. At this time, most of this product is at hospitals. There was a motion, second and all were in favor of limiting to indication.

x. Molnupravir is another medication approved under an emergency use authorization for mild to moderate COVID-19 in outpatients with high risk of progression to severe illness. The data with this product is not as clear. There is concern regarding fetal adverse events, requiring contraception use for 3 months after therapy. There is no contraindication for use with ritonavir as there is with Paxlovid. It was also noted that there was a high pill burden compared with Paxlovid. Due to safety concerns, there was a motion, second and all were in favor of making molnupravir non-preferred.

3. Determine need for criteria
   i. Zavesca is approved for adults with Gaucher disease. There are no current limits on this medication; however, claims have been for very young children without the approved indication. There was a motion, second and all were in favor of limiting Zavesca to indication.

4. Physician Administered Drugs
   i. Aduhelm was discussed with respect to the proposed Medicare rule that would only cover the product for patients enrolled in a clinical trial. Aduhelm is approved for treatment of Alzheimer’s disease and was approved under the accelerated approval process. Additional data is expected to be published. The Committee deferred the discussion until after Medicare makes their final decision. Additional information will be brought back in May. Tami Sova (Biogen) noted that Biogen has provided their comments on the proposed rule. Those comments are available on the CMS website.

Other

There being no further business, the open portion of the meeting adjourned at 11:40 am and the Committee met in closed session. During closed session, the Committee unanimously elected Dr. Paul Bongat to the open Committee position.
Respectfully Submitted,

Aimee Lewis
WYDUR Manager