Department of HUMAN SERVICES

Meeting Agenda			
Division:	Iowa Medicaid Enterprise Quality Improvement Organization (QIO)		
Meeting Title:	Clinical Advisory Committee (CAC)		
Facilitator:	Bill Jagiello, D.O.		
Location:	Go To Webinar and conference call: (914) 614-3221, access code: 786-770-377		
Date:	October 15, 2021	**Time:**	1:00 p.m. – 4:00 p.m.

Meeting Objectives

The purpose of the CAC is to increase the efficiency, quality and effectiveness of the Medicaid healthcare system. The CAC provides a process for physician and other healthcare provider contributions to promote quality care, member safety, cost effectiveness and positive physician and provider relations through discussion about Medicaid benefits and healthcare services.

The CAC is charged with recommending clinically appropriate healthcare utilization management and coverage decision to the Department of Human Services (DHS) for the Iowa Medicaid program.

Meeting Participants

Name	Organization
Bill Jagiello, D.O.	IME
Tami Lichtenberg	IME
Cassie Reece	IME
Becky Carter	IME
Carrie McFarland	IME
Diane Morrill	IME
Else Umbreit, PharmD	IME
Paula Motsinger, DHS Bureau Chief, LTSS and Medical Policy	IME
Liz Matney, Medicaid Director	IME
Dr. Alexandra Hubbell – Family Practice	
Clarice Blanchard, PA-C, Family Practice/Emergency Medicine	

Dr. Dana Danley – Family Practice	
Dr. Dennis Zachary – Family Practice	
Diana Smith, ARNP – Family Practice	
Dr. Polly Ferguson – Pediatric Rheumatology	
Dr. Stephen Mandler – Psychiatry	
Dr. Chitra Reddy – Endocrinology	
Dr. Kathleen Lange – Family Practice	
Dr. Leslie Schechtman	Amerigroup
Dr. Paul Mulhausen	Iowa Total Care
Leland Ward, DSL	Bristol Myers Squibb
Sara Hovland, PharmD	Bristol Myers Squibb
Jill Frauenheim, MS, CGC	Takeda

Agenda Topics	Responsible Party
New Business: **1. Introduction of new member – Dr. Chitra Reddy** **2. Open Comment – Guidelines for Persons with Disabilities (Informational Only)** The American Psychological Association (APA) is seeking comments on the attached **Guidelines for Assessment and Intervention for Persons with Disabilities**, due 11/14/21. It's 118 pages of material (rest are references). Sharing in case you/yours are interested in reviewing. I will not be reviewing as I provided feedback back in February 2020 as part of APA's Committee on Legal Issues (COLI). Feel free to share with other stakeholders who may be interested. **Call for Comments: Guidelines for Assessment and Intervention with Persons with Disabilities** APA boards and committees, divisions, affiliated psychological associations, and other stakeholders are invited to review and provide comments on the revision of the 2011 Guidelines for Assessment and Intervention with Persons with Disabilities. The Guidelines were initially available for a sixty (60) day period of public review and comment. Following this period, information received was reviewed by a Task Force and a draft containing revisions to the Guidelines, considering these comments, has been prepared. A second sixty (60) day comment period on the Guidelines is required by Association Rule 30-8, allowing for broad public review of the proposed revisions. ***Comments are due by November 14, 2021.*** **Link to comment:** https://apps.apa.org/CommentCentral2/default.aspx?site=79	Dr. Jagiello Liz Matney, Medicaid Director

Deadline for comments (60-day public comment period): November 14, 2021. **3. Update on MFP supplemental funding and our draft ARPA spending plan**	Paula Motsinger, DHS Bureau Chief, LTSS and Medical Policy
Public Comment Period	Guests
Consent agenda- Approval of the minutes from our July meeting 1. DEN.Orthodontic Procedures 2. DME.Ceiling Track Lifts and-or Electric Patient Lifts 3. DME.Continuous Glucose Monitoring 4. OPH.Retisert, Iluvien, and Yutiq (fluocinolone acetate intravitreal implant) ARCHIVE 5. OPH.Visual Aids and Vision Therapy 6. PAM.Vivitrol (extended-release injection naltrexone) ARCHIVE 7. SRG.Panniculectomy 8. THR.Transcranial Magnetic Stimulation	Dr. Jagiello
Criteria Review 1. PAM.Abecma (idecabtagene vicleucel) 2. PAM.Bavencio (avelumab) 3. PAM.Breyanzi (lisocabtagene maraleucel) 4. PAM.Danyelza (naxitamab-gqgk) 5. PAM.Elaprase (idursulfase) 6. PAM.Kadcyla (ado-trastuzumab emtansine) 7. PAM.Padcev (enfortumab vedotin-efjv) 8. PAM.Zulresso (brexanolone)	Dr. Jagiello
Upcoming Meetings January 21, 2022 April 15, 2022 July 15, 2022	Dr. Jagiello
Adjournment	Dr. Jagiello

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Guests wanting to speak during the public comment period should contact Wendy Lathrop and complete a disclosure form which is available on our website:
https://dhs.iowa.gov/ime/about/advisory_groups/clinical-advisory-group

New Business

1) **Introduction of new member – Dr. Chitra Reddy**

   Dr. Jagiello introduced Dr. Chitra Reddy the newest CAC committee member. Dr. Reddy practices Endocrinology in Cedar Falls, Iowa. She has been with UnityPoint Health for over 16 years.

2) **Open Comment – Guidelines for Persons with Disabilities (Informational Only)**

   See notes above regarding this topic.

3) **Update on MFP supplemental funding and our draft ARPA spending plan**

   Funding has become available for LTSS and HCBS. In early March, President Biden signed the American Rescue Plan Act (ARPA) which included a temporary 10 percentage point increase and federal medical assistance percentage (FMAP) for certain Medicaid expenditures for HCBS programs. This funding is intended to supplement HCBS programs which will enhance, expand or strengthen HCBS under the Medicaid program. This will allow for a little over $100 million to supplement this program. A proposed spending plan has been submitted for approval. Areas of focus include increased training and support, expanding access and workforce support, provider training platform, HCBS employee training and scholarship grant program, sustainability plan, crisis response, provider training related to members with ID diagnosis or developmental disability. It will also focus on resources and services for parents/caregivers and children with those disabilities. Another focus will be Health IT infrastructure. Behavioral health will be a focus to look at systems and identify gaps in services for members served. Will have assistance from TCM under mental health and disability services to provide assistance to those applying for Medicaid and HCBS services to ensure focus is on the appropriate waiver. This will include a developmental grant for neuro-rehabilitative services. CRNS is currently available for adults to bring BI members back into state. The hope is to work with CNRS on a pilot for children. There has been difficulty in finding providers to manage behavioral health for the ID population with co-occurring behavioral health issues. A residential pilot for that program, as well as a pilot for adults transitioning out of correctional environment. is being worked on as well. Also looking to expand remote support for HCBS provider technology grants. Looking at bringing other providers in-state to look at smart homes and other technology to support those who do not require 24-hour care. Paula asked that committee members reach out to her with any feedback or suggestions for pilot programs. A stakeholder group will be developed, and Dr. Mandler indicated he would like to be involved.

The following is the link to the DHS website with ARPA information:
https://web.cvent.com/event/e85c22f0-a87f-4aef-a959-18b2d7a63617/websitePage:81c7d618-4dc8-4c0f-b881-33af6a9ff125

Consent Agenda

There was a request to approve agenda items and approval of the July 2021 meeting minutes, and all approved.

Criteria Review

1) **PAM.Abecma (idecabtagene vicleucel)**

Else presented this policy. All approved.

Sara Hovland commented that she was not aware the study allowed 1.5 percent of patients with ECOG score of 2, and she was not sure whether that is based on anything specific. She also asked that if written comments can be submitted for consideration and whether that would be taken into consideration for the next review of the cycle or just the actual next review. Dr. Jagiello directed her to his contact information. Sarah will include Else in this correspondence.

Follow up information from Else is as follows:

> *If you look at the inclusion criteria for the study, it indicates an ECOG performance status of 0 or 1 was required. However, if you look at the population demographics from the phase II trial, it indicates that 3 patients had an ECOG score of 2.*
>
> *After reviewing the study protocol versions, the ECOG requirement has not changed from the very 1st study version to the most recent version on 8/2/21, it has always been ECOG of 0 or 1.*
>
> *So I reviewed the FDA clinical review memo and found the following information:* ***"Three patients had ECOG scores of < 2 at screening for eligibility, but subsequently deteriorated to ECOG scores of ≥ 2 at baseline prior to the start of lymphodepleting chemotherapy."***
>
> *This same review details one of the study subjects who died on study day 5 due to cytokine release syndrome. Due to development of multiple medical complications with this patient, there was a 2-month delay between the time of enrollment and initiation of lymphodepletion. This death prompted changes to study design implemented in Protocol amendment 3.0 requiring that subjects complete baseline assessments 72 hours prior to receiving bb2121 (aka Abecma) or on the day of lymphodepletion to ensure that study subjects have no intercurrent illness or toxicity that may place them at safety risk from the investigational therapy.*

2) **PAM.Bavencio (avelumab)**
   Else presented this policy. Dr. Blanchard motioned to approve, Dr. Hubbell seconded the motion. All approved and the motion carried.
3) **PAM.Breyanzi (lisocabtagene maraleucel)**
   Else presented this policy. Dr. Ferguson motioned to approve, Dr. Zachary seconded the motion. All approved and the motion carried.
4) **PAM.Danyelza (naxitamab-gqgk)**
   Else presented this policy. Dr. Lange motioned to approve, Dr. Ferguson seconded the motion. All approved and the motion carried.
5) **PAM.Elaprase (idursulfase)**
   Elaprase is up for annual revision and moved from Claims Pre-pay to Prior Authorization. Jill Frauenheim, MS, CGC from Takeda had questions regarding the

determination of 18 months as the age and the background surrounding that. Else stated the age should be 16 months rather than 18 months of age and that this change would be made. Dr. Ferguson discussed a comment from the Delphi study where the criteria showed only people who are 16 months or older with symptoms meet criteria. Else stated she will look at study criteria to see how that was developed. If that's the case, FDA approved indications would be followed. Dr. Ferguson will send questions and concerns to Dr. Jagiello who will share with Else. This policy will be removed from today's agenda for further research and will be brought to the January meeting. There is an existing policy in place so members will not be kept from getting this treatment. Also, it is a rare condition so there will not likely be any requests before that time.

The following is additional information provided by Dr. Ferguson:

Delphi states:

1. *All individuals with severe MPS II or predicted to have severe MPS II based on genotype warrant starting ERT, prior to showing signs or symptoms.*

Yet criteria doesn't include these patients with genotype predicted to have severe MPS II so doesn't allow for starting ERT prior to signs and symptoms and if you start prior to signs and symptoms, you might not develop symptoms that would allow the medication to be continued even if it was allowed to start.

- *There is a link below to an NIH information sheet (from Stat Pearls updated August 2021) that says that 60% have severe phenotype and they typically develop normally until 3 to 4 years of age. The two approved treatment ERT and HSCT are both maximally effective in relieving somatic symptoms when administered to patients earlier in their clinical course. Both treatments are ineffective in improving musculoskeletal symptoms if they are given after the appearance of skeletal symptoms.*

  https://www.ncbi.nlm.nih.gov/books/NBK560829/

6) **PAM.Kadcyla (ado-trastuzumab emtansine)**
   Else presented this policy. Dr. Zachary motioned to approve, Dr. Ferguson seconded the motion. All approved and the motion carried.
7) **PAM.Padcev (enfortumab vedotin-efjv)**
   Else presented this policy. Dr. Blanchard motioned to approve, Dr. Lange seconded the motion. All approved and the motion carried.
8) **PAM.Zulresso (brexanolone)**
   This was brought back for reconsideration by the committee. Dr. Mandler commented on how these criteria are set up in policy and shown to be beneficial and helpful. Dr. Ferguson stated she just sent email to Pharmacy for the status in Iowa and was surprised it is not on the list. Dr. Hubbell stated she was in agreement with Dr. Randleman that the inability to access Zulresso in Iowa makes this fairly unattainable for patients. As someone that does OB for a large Medicaid population, she stated she does not feel most members would have the resources to leave the

state for care. Dr. Hubbell also stated the most common tool she is familiar with for postpartum depression is the Edinburg postpartum depression scale. She asked if that tool could be looked at as an additional option. The Edinburg is meant to mirror the PHQ9 but to take into account the postpartum period such as exhaustion and poor or excessive appetite. The Edinburgh Postnatal Depression Scale will be added to the scores. Dr. Danley stated she was not sure if this should be added but it appears to not be recommended during pregnancy or breastfeeding. It can be given in the third trimester or within four weeks of delivery, but it does not mention breastfeeding, risk, etc. Else stated the onset symptoms has to be in the third trimester or within four weeks of delivery but medication is administered after delivery. Dr. Jagiello asked Dr. Mandler about any changes that should be made. Dr. Mandler stated his only question is about overdependence in certain circumstances. The diagnosis of moderate to severe depression is a behavioral assessment based on a psychiatric interview. This should not be the only way to access this Dr. Mandler suggested that we are relying strictly on tests for the diagnosis, and that the psychiatrist can make the diagnosis in a clinical assessment as an alternative to these tests. Criteria was updated with suggested language to take this into consideration. Dr. Mulhausen stated that the first criteria, diagnosis with major depression, should not supersede the DSM-5 criteria for diagnosis of major depression. It is intended to help the prescriber show they have major depressive disorder but met level of severity that is consistent with the clinical trials. Another area to get around this or for the committee to consider is that PHQ-9 is in alignment with the DSM 5 criteria and can be used to grade severity of illness and guide through DSM criteria. The criteria was updated based on feedback from committee members. Dr. Jagiello shared that Dr. Lindberg, head of Psychiatric Unit at Broadlawns, shared at the Maternal Health Taskforce meeting that an oral form or oral counterpart of Zulresso is under development by the same company and close to FDA approval in near future. The likelihood of this policy being needed is low unless the member is willing or able to travel to a contiguous state to receive treatment. Else stated it is currently covered on the fee schedule. If the request came now it would go to the Medical Director for review. Dr. Zachary motioned to approve, Dr. Danley seconded the motion. All approved and the motion carried.

Upcoming Meetings: January 21, 2022

Meeting was adjourned.