

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: (213)929-4212, access code: 545-151-649		
Date:	July 16, 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	IME
Dr. Alexandra Hubbell – Family Practice	
Clarice Blanchard, PA-C, Family Practice/Emergency Medicine	
Dr. Dana Danley – Family Practice	
Dr. Dennis Zachary – Family Practice	
Dr. Diana Smith, ARNP – Family Practice	

Dr. Polly Ferguson – Pediatric Rheumatology	
Dr. Stephen Mandler – Psychiatry	
Dr. Leslie Schechtman	Amerigroup
Dr. Paul Mulhausen	Iowa Total Care
Jomy Joseph	Sanofi Genzyme
Janet Ritter	Sanofi Genzyme
Susie Moroney	Novartis
John Ford	NS Pharma
Leo Pratt, PharmD	NS Pharma
Dale Edberg, Ph.D.	Viela Bio/Horizon Therapeutics
Tami Sova	Biogen

Agenda Topics	Responsible Party
New Business: <ol style="list-style-type: none"> 1. Introduction of new member 2. Update on MFP supplemental funding and our draft ARPA spending plan 	Dr. Jagiello Paula Motsinger, DHS Bureau Chief, LTSS and Medical Policy
Public Comment Period	Guests
Consent agenda- Approval of the minutes from our April meeting <ol style="list-style-type: none"> 1. Back-up ventilators 2. Enteral Products and Supplies 3. Percussors 4. Pneumatic Compression Devices 5. Strollers and Wheelchairs for Safety 6. Wearable Automated External Defibrillator 7. CMH LOC 8. Habilitation Level of Care 9. Namenda (memantine) for Autism Spectrum Disorder 10. Crysvita (Burosumab-twza) 11. Spinraza (nusinersen) 12. Zolgensma (onasemnogene abeparvovec-xioi) 13. Laser Linear Accelerator Based Stereotactic Radiosurgery 14. Reduction Mammoplasty/Mastopexy 15. Risk Reduction Mastectomy 	Dr. Jagiello

<p>Criteria Review</p> <ol style="list-style-type: none"> 1. Adakveo (crizanlizumab-tmca) 2. Elaprase (idursulfase) 3. Fasenra (benralizumab) **NEW** 4. Kadcyra (ado-trastuzumab emutansine) 5. Orphan Drug (Rare Disease) Policy **NEW** 6. Sarclisa (isatuximab-irfc) **NEW 7. Trodelvy (sacituzumab govitecan-hziy) 8. Uplizna (inebilizumab-cdon) **NEW** 9. Viltepso (viltolarsen) **NEW** 10. Yescarta (axicabtagene ciloleucel) 11. Gene Expression Profiling for the Management of Breast Cancer 12. Genetic Testing for Lynch Syndrome **NEW 13. Artificial Disc Replacement **NEW** 14. Left Ventricular Assist Device **NEW 	<p>Dr. Jagiello</p> <p style="text-align: center;"></p> <p style="text-align: center;">Support for Addition of Inebilizu</p>
<p>Upcoming Meetings</p> <p>October 15, 2021</p> <p>January 21, 2022</p> <p>April 15, 2022</p>	<p>Dr. Jagiello</p>
<p>Adjournment</p>	<p>Dr. Jagiello</p>

New Business

1. Dr. Jagiello introduced Diana Smith as a new committee member. Diana is a Family Nurse Practitioner in rural west central Iowa.
2. Paula Motsinger was on the agenda to provide an update on MFP supplemental funding and our draft of ARPA spending; however, she had a conflict and was not able to attend. (please reach out to Paula and see if she wants to present this info at the October 2021 CAC)

Consent agenda

Request to approve agenda items and approval of the April 2021 meeting minutes. Motion to approve by Dr. Hubbell, Dr. Blanchard seconded. All approved and the motion carried.

Guest Speakers

1. Leo Pratt, PharmD with NS Pharma spoke about Viltepso and was available for questions.
2. Dale Edberg, Ph.D. with Viela Bio/Horizon Therapeutics spoke about Uplizna.

Criteria Review

1. **Adakveo (crizanlizumab-tmca)** – This policy was originally brought to the CAC meeting in January 2021. There were some recommendations made because of rural areas in Iowa. The policy was originally worded to require a hematologist with expertise in diagnosis and management of sickle cell disease. The criteria was amended to require a hematologist and to remove “with expertise in sickle cell disease.” The new criteria now states “prescribed by or consultation with a hematologist.” The initial authorization will be for six months and for continuation requests that we criteria, those could be reviewed for up to a year at a time. Both recommendations were accepted. Ferguson motioned to approve as amended, Dr. Zachary seconded the motion. All approved and the motion carried.
2. **Elaprase (idursulfase)** – This was added as a late addition from the consent agenda and was already approved.
3. **Fasenra (benralizumab)**NEW** – This is a self-injected pen and is covered under the pharmacy benefit. For clarification, this is for the physician-administered benefit, not self-administered. Dr. Zachary motioned to approve, Dr. Hubbell seconded the motion. All approved and the motion carried.
4. **Orphan Drug (Rare Disease) Policy (Cabliivi and Givlaari)** – Else presented this policy. Dr. Ferguson motioned to approve, Dr. Smith seconded the motion. All approved and the motion carried.
5. **Sarclisa (isatuximab-irfc)**NEW** – Else presented this policy. Dr. Ferguson motioned to approve, Dr. Smith seconded the motion. All approved and the motion carried.
6. **Trodelvy** – Else presented this policy. Dr. Hubbell motioned to approve, Dr. Blanchard seconded the motion. All approved and the motion carried.
7. **Uplizna** – Else presented this policy. Dr. Jagiello shared a letter from UIHC Neuroimmunology that was written in support of approval of Uplizna and that referenced neuromyelitis optica spectrum disorder. There was a paragraph on the disease itself and how Uplizna is administered. There are no conflicts of interest to disclose for this therapy. It is felt to be an excellent option for many of their patients and they advocate that the drug be covered by Iowa Medicaid. Dr. Ferguson stated that it is also used to treat children with neuroinflammatory processes and the group that wrote the letter is very expert. Dr. Ferguson motioned to approve, Dr. Danley seconded the motion. All approved and the motion carried.
8. **Viltepso** – Else presented this policy. Dr. Zachary motioned to approve, Dr. Hubbell seconded the motion. All approved and the motion carried.
9. **Yescarta** – Dr. Ferguson pointed out the Black Box Warning that states Yescarta should not be administered to patients with inflammatory disorders. This is very broad and vague language that would include a lot of people. Dr. Zachary motioned to approve, Dr. Blanchard seconded the motion. All approved and the motion carried.
10. **Gene Expression Profiling for the Management of Breast Cancer** – Dr. Jagiello presented this policy. These are a set of tests that are used to identify or distinguish patients with a low risk for recurrence of breast cancer versus those who are high risk and would benefit from additional chemotherapy treatment. This was brought back due to a new indication of patients with one to three axillary lymph nodes. This expands the number of patients who would be eligible. Dr. Blanchard motioned to approve, Dr. Ferguson seconded the motion. All approved and the motion carried.

11. **Genetic Testing for Lynch Syndrome** – Dr. Jagiello presented this policy. Dr. Zachary motioned to approve, Dr. Danley seconded the motion. All approved and the motion carried.
12. **Artificial Disc Replacement** – Dr. Jagiello presented this policy. Dr. Zachary questioned why the maximum age is 60 rather than age 70. Dr. Jagiello stated he chose that because it was either an FDA limitation or he mirrored commercial bench marking in terms of most of the studies being done on younger patients and data becomes thinner at age over 60. Discretion can be used on this to go over age 60. Dr. Mandler stated that other factors should be included aside from age, as there are some 60-year-olds that are decrepit, and some are very fit and a good candidate for this. Age should not be limiting factor that is set so arbitrarily. Dr. Schechtman indicated that Amerigroup’s policy does not have the age limit criteria in their policy. Dr. Jagiello will re-review the evidence and provide additional information in October. Dr. Jagiello could either support the age 60 criteria or remove it. This will be removed from the voting agenda since the committee had questions and it will be brought back. This policy was not voted on during this meeting.
13. **Left Ventricular Assist Device** – Dr. Jagiello presented this policy. Dr. Zachary motioned to approve, Dr. Blanchard seconded the motion. All approved and the motion carried.

Follow up email sent to members on 7/19/2021

Dear CAC member,

At last Friday’s meeting, Dr. Zachary raised a very relevant question about the source of the following criterion in the portion of the policy addressing Lumbar Disc Arthroplasty:

Member is between 18 and 60 years of age

After reviewing my research, I found the following sources that supported the upper age limit of 60 years:

- FDA approval
- Amerigroup medical policy
- Iowa Total Care medical policy
- Wellmark BCBS medical policy
- UpToDate

Based on these sources, I am recommending that we retain the age limit criterion in the policy. In order to keep this policy in a reasonable time cycle (this was a network provider request), I would like to know if any Committee members have reservations about approving the policy as is, so that it can continue to move through the IME process.

As an aside, the Cervical Disc Arthroplasty criteria did not have an age restriction.

No committee members expressed any objection to retaining the language in the policy that was originally presented in the July 16 meeting. Therefore, the policy is approved.

Upcoming Meetings: October 15, 2021

Meeting was adjourned.