

**MEETING AGENDA**

DIVISION	Iowa Medicaid Quality Improvement Organization (QIO)		
MEETING TITLE	Clinical Advisory Committee (CAC)		
FACILITATOR	Bill Jagiello, DO		
DATE	October 21, 2022	TIME	1:00pm-4:00pm
LOCATION	Zoom Meeting Register in advance for this meeting: <a href="https://telligen.zoom.us/join/https://telligen.zoom.us/meeting/register/tZcpd-uhqjgtHNeJooYa0xHPbhhJaAHLEMPX">https://telligen.zoom.us/meeting/register/tZcpd-uhqjgtHNeJooYa0xHPbhhJaAHLEMPX</a> After registering, you will receive a confirmation email containing information about joining the meeting via Zoom.		

**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**

<b>Name</b>	<b>Organization</b>
<input type="checkbox"/> Elizabeth Matney, Medicaid Director	Iowa Medicaid
<input type="checkbox"/> Rebecca Curtiss, DHHS Bureau Chief, Quality, Innovation and Medical Policy	Iowa Medicaid
<input type="checkbox"/> Paula Motsinger, DHHS Bureau Chief, LTSS	Iowa Medicaid
<input checked="" type="checkbox"/> Bill Jagiello, DO	Iowa Medicaid
<input type="checkbox"/> Mark Randleman, DO	Iowa Medicaid
<input checked="" type="checkbox"/> Tami Lichtenberg	Iowa Medicaid
<input checked="" type="checkbox"/> Carrie Ortega	Iowa Medicaid
<input checked="" type="checkbox"/> Else Umbreit, PharmD	Iowa Medicaid
<input checked="" type="checkbox"/> Becky Carter	Iowa Medicaid
<input type="checkbox"/> Cassie Reece	Iowa Medicaid
<input checked="" type="checkbox"/> Barb Cox	Iowa Medicaid
<input checked="" type="checkbox"/> Jennifer Ober	Iowa Medicaid

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<input checked="" type="checkbox"/> Diane Morrill <input checked="" type="checkbox"/> Carrie McFarland <input checked="" type="checkbox"/> Wendy Lathrop <input checked="" type="checkbox"/> Charissa Blinkmann <input checked="" type="checkbox"/> Dr. Paul Mulhausen <input checked="" type="checkbox"/> Dr. Nivedita Krishnan <input checked="" type="checkbox"/> Dr. Timothy Gutshall <input checked="" type="checkbox"/> Dr. Alexandra Hubbell-Family Practice <input checked="" type="checkbox"/> Clarice Blanchard, PA-C, Family Practice/ Emergency Medicine <input type="checkbox"/> Dr. Dana Danley-Family Practice <input checked="" type="checkbox"/> Dr. Dennis Zachary-Family Practice <input checked="" type="checkbox"/> Diana Smith, ARNP-Family Practice <input checked="" type="checkbox"/> Dr. Polly Ferguson-Pediatric- Rheumatology <input checked="" type="checkbox"/> Dr. Stephen Mandler-Psychiatry <input type="checkbox"/> Dr. Chitra Reddy-Endocrinology <input checked="" type="checkbox"/> Dr. Kathleen Lange-Family Practice	Iowa Medicaid Iowa Medicaid Iowa Medicaid Iowa Medicaid Iowa Total Care Amerigroup Molina Healthcare of Iowa
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AGENDA TOPIC	RESPONSIBLE PARTY
<b>New Business</b>	Dr. Jagiello
<b>Public Comment Period</b>	Guests
<b>Approval of July 15, 2022 Meeting Minutes</b>	Dr. Jagiello
<b>Old Business</b> Continuous Glucose Monitoring Aduhelm	Dr. Jagiello
<b>Consent Agenda</b> 1. PAM Abecma (idecabtagene vicleucel) 2. PAM Bavencio (avelumab) 3. PAM Breyanzi (lisocabtagene maraleucel) 4. PAM Danyelza (naxitamab-gqgk) 5. PAM Kadcyla (ado-trastuzumab emtansine) 6. PAM Padcev (enfortumab vedotin-efjv) 7. PAM Zulresso (brexanolone) 8. DME. Percussors 9. SRG. Panniculectomy 10. SRG. Cochlear Implant	Dr. Jagiello
<b>Criteria Review</b> 1. DME.Negative Pressure Wound Therapy 2. THR.Repetitive Transcranial Magnetic Stimulation	Dr. Jagiello

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3. MED-Off-Label Drug Use <b>**NEW**</b> 4. PAM-Aduhelm (aducanumab-avwa) <b>**NEW**</b> 5. PAM-Zolgensma (onasemnogene abeparvovec-xioi)	
<b>Upcoming Meetings</b> January 20, 2023 April 21, 2023 July 21, 2023	Dr. Jagiello
<b>Adjournment</b>	Dr. Jagiello

NEW ACTION ITEMS				
ITEM #	DESCRIPTION	OWNER	DUE DATE	STATUS

Contacts:

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 Medical Director  
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Charissa Blinkmann  
 Review Assistant  
 (515)256-4659  
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Guests wanting to speak during the public comment period should contact Charissa Blinkmann and complete a disclosure form, which is available on our website:  
[https://dhs.iowa.gov/ime/about/advisory\\_groups/clinical-advisory-group](https://dhs.iowa.gov/ime/about/advisory_groups/clinical-advisory-group)

**Introduction**

Dr. Jagiello, Medical Director for IME/QIO & Committee Chair, offered the introduction for the quarterly CAC Iowa Medicaid meeting. Roll call proceeded with quorum confirmation.

**Public Comment Period**

Registered speaker acknowledgements with the opportunity to speak as policy is presented.

- Christina Trout, RN, MSN, Univ of Iowa Stead Family Children’s Hospital, Neuromuscular Clinic, *Zolgensma*
- Rachel Kinn, Clinical Pharmacist, Pediatric Neurology, University of Iowa Stead Children’s Hospital, *Zolgensma*
- Jaclyn Smith, Clinical Specialist of Diabetes, Mercy Medical Center, *Continuous Glucose Monitors*
- Dr. Phillip Masters, Clinical Pharmacist, Lucas County Medical Center, *Continuous Glucose Monitors*
- Heidi York, Diabetes Educator, Unity Point, emailed letter, *Continuous Glucose Monitors*

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- Brian Howell, Regional Medical Director, *Novartis*
- Dr. Richard Carano, McFarland Clinic, Endocrinology, *Continuous Glucose Monitors*
- Tami Sova, Clinical Representative, Biogen, *Aduhelm*
- Brent Lundsten, Regional Account, Dexcom, *Continuous Glucose Monitors*

### **Announcements**

Introduction for Tim Gutshall, Chief Medical Officer, for Molina the new Managed Care Organization for Iowa (Beginning July 2023)

### **Approval of the July 15, 2022 Meeting Minutes**

Opportunity for additions, corrections, or comments: none. Motion to approve by Dr. Ferguson, Clarice Blanchard seconded. All approved and the motion carried.

**New Business:** No new business presented at this time.

### **Old Business:**

#### **Physician Administered Medication (Aduhelm)**

Will be presented during the Criteria Review agenda later in the meeting.

#### **Continuous Glucose Monitoring**

- Email review from Heidi York, Diabetes Educator, Unity Point. Concerns: Diagnosis type for Type I or Type II, Required 4 sticks/per day, Submission of 30 days of glucose logs.

Dr. Jagiello led discussion on policy criteria, which is inclusive for members with a diagnosis of either Type I & Type II Diabetes, with “multiple glucose tests, meaning 2 or more”, no age restriction, confidence that the member has cognitive ability to use the device, make use of the data, and be able to make necessary adjustments. The new policy is available on the website.

- Jaclyn Smith states her questions were answered in the review and request it will be helpful for the Policy links to posted.
- Dr. Phillip Masters provided comments and concerns on the number of tests requiring 4/per day, 30 days of blood glucose logs. Presents that during Covid-19, Medicare expanded their access to CGM’s to patients who have one insulin dose per day, with a consideration at this time to continue that long term and notes improved outcomes, and he’d like to see this benefit for Medicaid patients. He would like to see a standardization of access to CGM’s across all payers of Medicaid, since as a provider it’s more difficult ensure the patient has met all criteria due to plan variations. He would access provided for members with the requirement for insulin use from 3x/day to 1x/day.

Dr. Jagiello opened the conversation opportunity to Dr. Mulhausen, ITC and Dr. Krishnan, AGP to provide insight into their respective current policies and areas of alignment. Dr. Jagiello closed with the shared common interest in putting the right tools in the hands of providers and members to achieve adequate control and reduce the risk of adverse outcomes. The opportunity to review the Policies, which will be posted on the Dept. of Health and Human Services website. Wendy Lathrop provided a link in the chat. There is no action required by the committee at this time.

### **Consent Agenda**

Dr. Jagiello and Else Umbreit, PharmD, presented information on the Consent Agenda items and advised of the changes that were made. They gave the committee the opportunity to pull any of the Consent Agenda items for discussion. No concerns were mentioned. The first motion to Approve by Diana Smith, Dr. Kathleen Lange seconded. All approved and the motion carried.

### **Criteria Review Agenda**

- 1. Negative Pressure Wound Therapy:** Dr. Jagiello presented the policy. Dr. Krishnan, AGP and Dr. Mulhausen, ITC provided their respective policy standings and agreed on the alignment of this policy criteria with the standards of care. Dr. Jagiello added the older language in the Provider Manual is in the process of being updated. First motion to approve by Dr. Zachary. Seconded by Dr. Lange. All approved and the motion carried.
- 2. Transcranial Magnetic Stimulation:** Dr. Jagiello presented the policy. New change was to remove the outdated criteria of offering ECT therapy to the member under medical necessity, which had been reviewed as a barrier to treatment by the network. Dr. Mulhausen, ITC, provided feedback on policy alignment and the implementation of the identical policy. Dr. Krishnan, AGP, provided feedback on policy alignment of this criteria is also followed. Dr. Jagiello clarified that coverage isn't being extended to iTBS (intermittent theta burst repetitive TMS) at this time. First motion to approve revised criteria, by Dr. Zachary. Seconded by Dr. Mandler. All Approved and the motion carried.
- 3. Off-Label Drug Use:** Else Umbreit, PharmD, presented this as a new policy that has been in the works for a while, with the three requirements for Off-Label indication. Emily Rogers, Pharmacist, offered feedback of appreciation for thoroughness. Dr. Ferguson and Dr. Mandler spoke to their concerns with the policy as written because of the restrictions it could introduce for children due to the lack of studies done on children, even though they see effectiveness with their patients. Rachel Kinn, Clinical Pharmacist commented in support that due to the low number of these patients, no FDA approved medications, and without having adequate trials, she supports carving out an exception for rare diseases or for diseases with no FDA approved medications or guidelines for treatment. Dr. Jagiello offered the opportunity to have those concerns, barriers to treatment and additional information to be sent over for review and made

the decision to table this policy until the next meeting, Q1-January 2023. First approval of motion to table the policy by Dr. Ferguson. Seconded by Diana Smith. All approved to table this policy until the next meeting to allow further review.

4. **Aduhelm:** Else, PharmD, presented this policy. This indication is approved under an accelerated approval based on a reduction of amyloid beta plaques, to slow the progression of Alzheimer's Disease. Tami Sova, Clinical Representative, Biogen, present to answer any questions. There were no questions at this time. First motion to approve by Dr. Ferguson. Seconded by Dr. Zachary. All approved and the motion carried.
5. **Zolgensma:** Else, PharmD, presented this policy. This is a revision, to have as close alignment in criteria and benchmark the criteria against standards for large insurance companies. She went through changes made to the criteria. She provided the July 2020 group study literature on labs testing discrepancies in accuracy for higher copies and the efforts for making improvements in that. Christina Trout, RN, MSN, is present to review this policy. She spoke to their concerns on the rendition, with a new restriction being included limiting treatment, and that with 2, 3, & 4 copies they should receive immediate treatment to prevent loss of motor neurons, which are permanently gone if they aren't rescued by receiving the treatment that provides the protein. Rachel Kinn, Pediatric Neurology, Clinical Pharmacist spoke to advocate for adjusted guideline to move it to 4 copies, and to eliminate a requirement of onset of symptoms age (prior to six months). Christina Trout includes the goal is to prevent death and disability and that treatment for this needs to be initiated as early as possible (by 3 weeks of age) and wouldn't want to wait for onset of symptoms. She outlined the personal benefit to members with this severe disease on Iowa Medicaid as well as the cost comparison of administering this drug treatment at \$2 million dollars, verse a lifetime of treatment at \$29 million dollars. Dr. Ferguson provided comment in agreement with the Specialists from the U of I hospital on not delaying therapy for this severe disease that causes motor neuron death, because there isn't a treatment to regenerate motor neurons. Christina Trout and Rachel Kinn will send their literature and information for further review to Else and Dr. Jagiello. They will also discuss this with their team at the U of I colleagues, Dr. Matthews and Dr. Saudi. Dr. Jagiello moves for the policy to be tabled for further review and brought back at the next meeting. First motion by Dr. Lange. Seconded by Clarice Blanchard. Christina Trout requested information on a question included in the letter they sent, that is regarding the execution of benefits. She states that their interpretation of the Iowa Administrative Code indicates that the MCO managers are not to be more restrictive than the Iowa Medicaid policy and if there is a conflict between the MCO policy and an Iowa Medicaid policy, that the Iowa Medicaid plan is to take precedence. This question is sought for clarity affecting an active appeal for a member who qualifies for this treatment under the current Iowa Medicaid policy. Dr. Jagiello clarifies due to an open active appeal, and to protect integrity of that process, the committee can't answer on how discrepancies are resolved but affirms she submitted her information to the correct process in which it will be reviewed. All

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approved and the motion carried for policy to be tabled for further review and brought back at the next meeting in January 2023.

Dr. Jagiello and Else Umbreit reminded the committee that the Exon Skipping policies will again be reviewed in accordance with their annual review in April 2023 and that will ensure they are all back under the same month.

Rachel Kinn, Clinical Pharmacist, requested further information also on questions from their letter, within a non-patient specific manner, and to clarify the execution of benefits. Tami Lichtenberg, QIO/IME Director, states since it was only received today, before the meeting, she would like to take the opportunity to take it back to the policy folks and leadership to provide a thoughtful response to the questions submitted.

Dr. Jagiello provided the next meeting date for the Clinical Advisory Committee, QI is on January 20, 2023 and adjourned the meeting.