

MEETING AGENDA

DIVISION	Iowa Medicaid Quality Improvement Organization (QIO)		
MEETING TITLE	Clinical Advisory Committee (CAC)		
FACILITATOR	Bill Jagiello, DO		
DATE	January 20, 2023	TIME	1:00pm-4:00pm
LOCATION	Zoom Meeting Register in advance for this meeting: https://telligen.zoom.us/join/91134214810 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

<u>Name</u>	<u>Organization</u>
<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 checked="" 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 checked="" type="checkbox"/> Cassie Reece	Iowa Medicaid
<input checked="" type="checkbox"/> Barb Cox	Iowa Medicaid

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<input checked="" type="checkbox"/> Jennifer Ober <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 Medicaid Iowa Total Care Amerigroup Molina Healthcare of Iowa Committee Member Committee Member Committee Member Committee Member Committee Member Committee Member Committee Member Committee Member
AGENDA TOPIC	RESPONSIBLE PARTY
New Business	Dr. Jagiello
Public Comment Period	Guests
Approval of October 21, 2022 Meeting Minutes	Dr. Jagiello
Old Business 1. MED.Off-Label Drug Use (review evaluation process) 2. PAM.Zolgensma (onasemnogene abeparvovec-xioi)	Dr. Jagiello
Consent Agenda 1. DEN.Orthodontic Procedures 2. DEN.Periodontic Procedures 3. DME.Ceiling Track Lifts and/or Electric Patient Lifts 4. DME.Mobility Related Device Purchase 5. DME.Myoelectric Prosthesis Upper Extremity 6. DME.Power Seat Elevation for Power Wheelchairs 7. DME.Power Wheelchair Attendant Controls	Dr. Jagiello

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8. DME.ReliZORB (immobilized lipase)
Cartridge
 9. LAB.Chromosomal Microarray Analysis
 10. LAB.Gene Expression Profiling for the
Management of Breast Cancer
 11. LAB.Genetic Testing for Hereditary
Breast and Ovarian Cancer Syndrome
(BRCA1-BRCA2)
 12. LAB.Non-Invasive Prenatal Testing for
Aneuploidy Using Cell Free DNA
 13. LAB.Whole exome sequencing-XomeDX
 14. LOC.Intermediate Care Facility for
Intellectual Disability Level of Care
 15. LOC.Pediatric SNF Level of Care
 16. OPH.Visual Aids and Vision Therapy
 17. RAD.CT Colonography
 18. SRG.Ablative Laser Treatment of Burns
and Traumatic Scars
 19. SRG.Bariatric Surgery
 20. SRG.Bone Marrow/Peripheral Blood Stem
Cell Transplant
 21. SRG.Cochlear Implant
 22. SRG.Fecal Microbiota Transplantation
 23. SRG.Heart Transplant
 24. SRG.Liver Transplant
 25. SRG.Lung Transplant
 26. SRG.Nipple Tattooing
 27. SRG.Pancreas Transplant
 28. SRG.Varicose Vein Treatment
 29. WPA.Environmental Modification-
Adaptive Devices
 30. WPA.Home and Vehicle Modification
 31. WPA.Pre-Vocational Services
 32. MED.Vitamin, Mineral, Amino Acid
Supplements
 33. PAM.Elaprase (idursulfase)
 34. PAM.Lutathera (lutetium Lu 177
dotatate)
 35. PAM.Orphan Drug (Rare Disease) Policy
 36. PAM.Tecartus (brexucabtagene
autoleucel)
 37. PAM.Vyepti (eptinezumab-jjmr)
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<p>Criteria Review</p> <ol style="list-style-type: none"> 1. DME.Cranial Orthotics 2. LAB.Testing for Hereditary Cancer Susceptibility Syndromes Using Multi-Gene Panels 3. PAM.Carvykti (ciltacabtagene autoleucel)**NEW** 4. PAM.Enhertu (fam-trastuzumab deruxtecan-nxki) 5. PAM.Imfinzi (durvalumab) 6. PAM.Injectafer (ferric carboxymaltose)**NEW** 7. PAM.Intravenous Immune Globulins 8. PAM.Kimmtrak (tebentafusp-tebn)**NEW** 9. PAM.Pluvicto (lutetium Lu 177 vipivotide tetraxetan)**NEW** 10. PAM.Vyvgart (efgartigimod alfa-fcab)**NEW** 	<p>Dr. Jagiello</p>
<p>Upcoming Meetings April 21, 2023 July 21, 2023 October 20, 2023</p>	<p>Dr. Jagiello</p>
<p>Adjournment</p>	<p>Dr. Jagiello</p>



Contacts:

Dr. Bill Jagiello, D.O.
 Medical Director
 (515)974-3057
wjagiel@dhs.state.ia.us

Charissa Blinkmann
 Review Assistant
 (515)256-4659
cblinkm@dhs.state.ia.us

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

Please note our new website is <https://hhs.iowa.gov/>

Below is the link to our new webpage:
https://hhs.iowa.gov/ime/about/advisory_groups/clinical-advisory-group

Introduction

Dr. Jagiello, Medical Director for IME/QIO & Committee Chair, offers an introduction for the quarterly Iowa Medicaid Clinical Advisory Committee meeting. Silent roll call proceeded with quorum confirmation.

Public Comment Period

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

- *Brian Howell, PharmD, Regional Medical Director, Novartis Gene Therapies, Zolgensma*
- *Susie Moroney, PharmD, MS, BCOP, Director, Oncology Clinical Values & Evidence Liaison, Novartis. Pluvicto*
- *Doug McCann, PharmD, MBA, Account Medical Lead, Medical Affairs, US Region, Takeda Pharmaceuticals USA, Inc., Eleprase, Intravenous Immune Globulins*
- *Dr. Richard Deming, American Cancer Society-Cancer Action Network, Biomarkers*
- *Jackie Cale, Government Relations Director, Iowa for American Cancer Society-Cancer Action Network, Biomarkers, she presented the letter "Expanding access to biomarkers testing-the key to unlocking precision medicine".*
- *Dr. Anthony Snow, American Cancer Society-Cancer Action Network, Biomarkers*
- *Rachel Kinn, PharmD, BCPPS, Clinical Pharmacy Specialist, Pediatric Neurology, Pharmaceutical Care, University of Iowa Health Care, Zolgensma*

Announcements

Approval of the October 21, 2022 Meeting Minutes

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

New Business: No new business presented at this time.

Old Business:

- I. **MED.Off-Label Drug Use-** (review evaluation process), reviewed and presented by Dr. Jagiello and Else Umbreit, PharmD. Comments: Dr. Ferguson offered comment on the obstacles encountered for this drug use authorization, for members with *rare disorders*. Rachel Kinn, PharmD, agrees with Dr. Ferguson's comment on the barriers faced when seeking authorization for this drug usage for members with *rare diseases or disorders* and for those without diagnoses. Dr. Mandler offered comment and expressed concerns with the policy and the specific concern of over-regulating the physician's determination on optimal care. Dr. Ferguson offered further comment that she would want to have criteria included by some other standards for *rare disorders* where there isn't the evidence available that is currently being required. Dr. Jagiello expanded the Additional Requirements/Comments #4. Rachel Kinn, PharmD, supports the change. First motion to approve the modified policy was requested and made by Dr. Zachary. A request for a second approval was proposed. Dr. Hubbell deferred for further review by her

colleagues who still had concerns. Dr. Lange offered comments on her concerns about having rebuttal options to a decision made when *rare disorders* are presented. Clarice Blanchard offered comment on suggestion for addressing the time constraint concerns under the current process. Diana Smith offered comment with support to vote on a second of the motion. Three committee members voted “yes”; Four committee members voted “no”. The policy is not passed.

- **PAM.Zolgensma (onasemnogene abeparvovec-xioi)**- updated policy presented by Else Umbreit, PharmD. She expressed appreciation for all the updated literature and references sent to her for review, along with all the input and information that was provided. Comments: Brian Howell, PharmD, offered comment of support for the changes made. Rachel Kinn, PharmD, BCPPS, Clinical Pharmacy Specialist, Pediatric Neurology, offered comment of support for the updated policy. First motion to approve by Dr. Zachary; Dr. Ferguson, seconded. All approved and the motion carried.

Consent Agenda

Dr. Zachary-Cochlear Implant commented about the literature on using the PCV20. Else Umbreit, PharmD, offered comment that codes are both open on the fee schedule now for the PCV20 and PCV15. Dr. Jagiello advised on pulling the policy for revision and bring it back at the next meeting. Dr. McCann, PharmD, offered comment on the Elaprase policy regarding the 5-year time frame, and the benefits for time frame of 16 months to 5 years. Else Umbreit, PharmD, responded with the current policy does include that guideline now. First motion to approve as Amended (one policy was pulled back at this time) by Dr. Zachary; seconded by Dr. Hubbell. All approved and the motion carried.

Criteria Review Agenda

1. Cranial Orthotics

Dr. Jagiello presented the policy. No comments or concerns. First motion to approve by Dr. Lange; seconded by Dr. Hubbell. All approved and the motion carried.

2. Testing for Hereditary Cancer Susceptibility Syndromes Using Multi-Gene Panels

Dr. Jagiello presented the policy. Dr. Ferguson offered comment with concern on the age criteria and believes it should be open for members under the age of 18, since these are likely to be rare disorders. Dr. Mulhausen, ITC, offered comment that they would be open to reviewing for members under the age of 18 with clear documentation, with a parent involved, with a clinically relevant decision to be made with the parent helping the child, they would consider it for potentially meeting medical necessity. Dr. Krishnan, AGP, offered comment that the overall approach to these types of reviews is to the validity of the tests and the outcomes, when those questions are answered adequately age wouldn't stop them from reviewing. Dr. Ferguson, commented further, that she thinks that if it's for prognostication, for example when the pediatric patient doesn't have disease but perhaps the mother does, then it would be appropriate to wait until 18

years of age, but if there was an unusual occurrence of rare disease presenting in childhood, that they would be able to get the appropriate genetic testing that they are worried falls within the spectrum. No further comments or concerns. First motion to approve by Dr. Zachary; seconded by Diana Smith. All approved and the motion carried.

3. Carvykti

Else Umbreit, PharmD, presented the policy. No questions or comments. First motion to approved by Dr. Ferguson; seconded by Dr. Zachary. All approved and the motion carried.

4. Enhertu

Else Umbreit, PharmD, presented the policy. This is not a new drug or new policy but a review since there are two new indications, for approval for HER2-low breast cancer (08/05/22) and Non-Small Cell Lung Cancer (08/11/22 per accelerated approval). The criteria for HER2-positive Breast Cancer are now at regular approval because it has fulfilled post-marketing requirements. She provided a review of the criteria for HER2-Positive Breast Cancer, HER2-Low Breast Cancer, Non-Small Cell Lung Cancer, HER2-Positive Gastric or Gastroesophageal Junction Adenocarcinoma and the Continuation Criteria (all indications). No questions or comments. First motion to approve by Dr. Ferguson; seconded by Dr. Lange. All approved and the motion carried.

5. Imfinzi

Else Umbreit, PharmD, presented the policy. This policy is already in place. She reviewed the new indications updated on 09/02/22, 10/21/22 and 11/10/22. Introduction of Imjudo (tremelimumab-actl) that was approved by the FDA on 10/21/22 to use in combination with Imfinzi. Imjudo does not have an individual HCPCS code available yet. She reviewed the criteria for each indication. No questions or comments. First motion to approved by Dr. Ferguson; seconded by Dr. Hubbell. All approved and the motion carried.

6. Injectafer

Else Umbreit, PharmD, presented the policy. This is not a new drug but wasn't open previously on the fee schedule. Prior Authorization is required. No questions or comments. First motion to approve by Clarice Blanchard; seconded by Diana Smith. All approved and the motion carried.

7. Intravenous Immune Globulins

This policy was not presented today and under review yet. Public Speaker, Doug McCann, present to speak on this, withdrew for comment at this time.

8. Kimmtrak

Else Umbreit, PharmD, presented the policy. Prior Authorization is required. Dr. Gutshall, Molina, offered comment for clarification on the Dosage and Administration. Else clarified. First motion to approve by Dr. Zachary; seconded by Dr. Lange. All approved and the motion carried.

9. Pluvicto

Else Umbreit, PharmD, presented the policy. Recently FDA approved. Prior Authorization is required. Susie Moroney, PharmD, offered comment on the policy with review of Criteria #5. Else will review further to determine if modification is needed. The code is currently open. This policy will be brought back at the next meeting. First motion to bring the policy back in April by Dr. Ferguson; seconded by Dr. Lange. All approved this motion, and it will be brought back in April.

10. Vyvgart

Else Umbreit, PharmD, presented the policy. Prior Authorization is required. No questions or comments. First motion to approve by Dr. Ferguson; seconded by Diana Smith. All approved and the motion carried.

Closing Comments: No further comments or questions.

Next Meeting: April 21, 2023

Meeting was adjourned.