Meeting Agenda			
Division	Iowa Medicaid Quality Improvement Organization (QIO)		
Meeting Title	Clinical Advisory Committee (CAC)	
CAC Chair	Bill Jagiello, DO		
Facilitator	Heidi Weaver		
Date	July 18, 2025	TIME	1:00pm - 4:00pm
Location	Virtual: Via Zoom https://telligen.zoom.us/meeting/register/Ut3hGQowRJC4VzGv03lDjQ In-Person: Lucas Building Capitol Complex, 321 E 12th St, Des Moines, Conference Room L221		

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 decisions to the Department of Health and Human Services (HHS) for the Iowa Medicaid program.

HIPAA Reminder: As a reminder to all members of the public who are presenting during the CAC meeting: Do not provide any personal health information (PHI) regarding a member covered by Iowa Medicaid Insurance that would constitute a violation of Federal HIPAA standards.

Meeting Participants		
Iowa Medicaid	 □ Rebecca Curtiss, HHS Deputy Director of Operations □ Jenny Erdman, HHS Quality, Innovation & Medical Policy Bureau Chief □ Andrea Maher, HHS LTSS Bureau Chief ☑ Tami Lichtenberg, QIO Director ☑ Bill Jagiello, DO ☑ Else Umbreit, PharmD 	
Committee Members	 ☑ Dr. Dana Danley-Family Practice ☑ Diana Smith, ARNP-Family Practice ☑ Dr. Polly Ferguson-Pediatric Rheumatology ☑ Dr. Chitra Reddy-Endocrinology ☑ Dr. Geetanjali Sahu-Child and Adolescent Psychiatrist ☑ Wendy Sanders, ARNP-Family Practice ☑ Dawn Schwartz, ARNP- Neonatology/Pediatrics ☑ Dr. Kelli Roenfanz-Family Medicine, OB/Gyn ☐ Dr. Kartik Anand-Hematology/Oncology 	



Managed Care Organizations	□ Dr. Paul Mulhausen, Iowa Total Care□ Dr. Timothy Gutshall, Molina Healthcare of Iowa
	☐ Dr. Jason Kessler, Wellpoint
	☐ Dr. James Elliot, Managed Care of North America
	☐ Dr. Jeff Chaffin, Delta Dental of Iowa

Agenda Topic

Public Comment Period

- A maximum of 5 minutes will be allotted to each public guest who has submitted a completed <u>Conflict of Interest Disclosure</u>. Submissions must be received no later than one week prior to the meeting date.
- To be respectful of the meeting time if you find your topic will exceed the maximum 5-minute allotment we welcome you to submit your detailed information to <u>CAC@hhs.iowa.gov</u> prior to and/or post meeting.

Approval of April 18, 2025, Meeting Minutes

Old Business

1. Lung Transplant

New Business

Consent Agenda

Durable Medical Equipment (5):

- 1. Custom Knee Orthotics
- 2. Enteral Products and Supplies
- 3. High Frequency Chest Wall Oscillation
- 4. Medical Foods
- 5. Strollers and Wheelchairs for Safety

Lab (3):

- 6. Gene Expression Profiling for the Management of Breast Cancer Archive
- 7. Genetic Testing for Lynch Syndrome Archive
- 8. Serum Iron Studies Archive

Surgical Procedures (6):

- 9. Heart Transplant Archive
- 10. Laser Linear Accelerator Based Stereotactic Radiosurgery
- 11. Left Ventricular Assist Device
- 12. Liver Transplant Archive
- 13. Reduction Mammoplasty Mastopexy
- 14. Risk Reduction Mastectomy

Radiology (1):

15. Functional Fraction Reserve

Physician Administered Medications (12):

- 16. Adakveo (crizanlizumab-tmca)
- 17. Columvi (glofitamab-gxbm)
- 18. Elrexfio (elranatamab-bcmm)
- 19. Fyarro (sirolimus protein-bound particles)



- 20. Monjuvi (tafasitamab-cxix)
- 21. Namenda (memantine) for Autism Spectrum Disorder
- 22. Opdualag (nivolumab and relatlimab-rmbw)
- 23. Rylaze [asparaginase erwinia chrysanthemi (recombinant)-rywn]
- 24. Talvey (talquetamab-tgvs)
- 25. Tecvayli (teclistamab-cqyv)
- 26. Tezspire (tezepelumab-ekko)
- 27. Zynlonta (loncastuximab tesirine-lpyl)

Criteria Review

Surgical Procedures (1):

1. Bone Marrow and/or Peripheral Blood Stem Cell Transplant

Physician Administered Medications – Review (5):

- 2. Epkinly (epcoritamab-bysp)
- 3. Fasenra (benralizumab)
- 4. Jemperli (dostarlimab-gxly)
- 5. Sarclisa (isatuximab-irfc)
- 6. Uplizna (inebilizumab-cdon)

Upcoming Meetings

- Friday, October 17, 2025
 - Virtual Meeting Link: https://telligen.zoom.us/meeting/register/LBFFkAvCRrqMX8mCVzbdrw
- Friday, January 16, 2026
 - Virtual Meeting Link: https://telligen.zoom.us/meeting/register/_9baOMgVRhm6tyLZ9s8sZA

Adjournment

Additional Information

- Iowa Medicaid CAC contact: CAC@hhs.iowa.gov
- **lowa Medicaid CAC webpage**: https://hhs.iowa.gov/about/advisory-groups/clinical-advisory-committee-cac
- lowa Medicaid Fee Schedules webpage: https://hhs.iowa.gov/programs/welcome-iowa-medicaid/policies-rules-and-regulations/covered-services-rates-and-payments/fee-schedules
- Guests wanting to speak during the public comment period must complete a
 <u>CAC Disclosure Form</u> and email it to <u>CAC@hhs.iowa.gov</u>. Submissions must be received no
 later than one week prior to the meeting date.



Meeting Minutes

Meeting Minutes (Q3 2025)

Opening: Heidi Weaver, Iowa Medicaid QIO, welcomed everyone to the quarterly Iowa Medicaid Clinical Advisory Committee (CAC) Meeting for 2025, and provided an overview of the house rules.

Verbal roll call of the Committee Members: Quorum was confirmed with 8 of 9 members.

Introduction: Heidi introduced Committee Chairman, Dr. Jagiello, who is the Medical Director for Iowa Medicaid, QIO. Heidi presented the Meeting Objectives and the instructions for the Public Comment period presentations, with the use of a visible timer for each Public Guest Speaker and allotment of 5 minutes to present.

Approval of the April 18, 2025, Minutes: Dr. Jagiello opened for a vote to approve the minutes, with no requests for any changes or corrections from the Committee.

Dr. Jagiello asked for motion to approve from the Committee.

- First motion to approve by Dr. Ferguson
- Second motion to approve by Diana Smith

Committee Member by toll call vote for approval:

- ☑ Dr. Dana Danley-Family Practice
- ☑ Diana Smith, ARNP-Family Practice
- ☑ Dr. Polly Ferguson-Pediatric Rheumatology
- ☑ Dr. Chitra Reddy-Endocrinology
- ☑ Dr. Geetanjali Sahu-Child and Adolescent Psychiatrist
- ☑ Dawn Schwartz, ARNP- Neonatology/Pediatrics
- ☑ Dr. Kelli Roenfanz-Family Medicine, OB/Gyn
- ☐ Dr. Kartik Anand-Hematology/Oncology

Old Business:

1. Lung Transplant

Dr. Jagiello communicated that at the last meeting Lung Transplant was requested to be moved to the July 2025 meeting. Clarification was requested on contraindication number 10, acute coronary syndrome. The Committee requested clarification regarding how long after a heart attack is a transplant contraindicated.

• Dr. Jagiello explained the criterion was reviewed along with Committee feedback by our subject matter expert. His comments were that each institution would have their own guidelines or would follow the national standard guidelines; therefore, he was reluctant



to specify a specific time. He felt that the criterion was appropriate and recommended leaving it untimed and to the discretion of the institution submitting the request.

Dr. Jagiello opened for Committee Member comments. Agreeing comments were heard from Committee Members.

Dr. Jagiello asked for motion for approval as amended from the Committee.

- First motion to approve by Diana Smith
- Second motion to approve by Dawn Schwartz

Committee Member by roll call vote for approval:

- ☑ Dr. Dana Danley-Family Practice
- ☑ Diana Smith, ARNP-Family Practice
- ☑ Dr. Polly Ferguson-Pediatric Rheumatology
- ☑ Dr. Chitra Reddy-Endocrinology
- ☑ Dr. Geetanjali Sahu-Child and Adolescent Psychiatrist
- ☑ Dawn Schwartz, ARNP- Neonatology/Pediatrics
- ☑ Dr. Kelli Roenfanz-Family Medicine, OB/Gyn
- ☐ Dr. Kartik Anand-Hematology/Oncology

Heidi Weaver announced the next order of business.

Consent Agenda:

Heidi Weaver provided the purpose of the Consent Agenda and explained the procedure for archiving criteria. Archival of criteria means that the prior authorization requirements for these test or procedures are not going away, rather the criteria are being replaced by the MCG Guidelines.

Dr. Jagiello explained that nationally there are two standards or two companies that produce medical policy guidelines that are evidence based and accredited by national organizations of quality. The organizations are InterQual and MCG and are widely used sets of clinical guidelines and criteria that health insurance companies and other payers rely on to determine medical necessity for healthcare services, particularly for hospital admissions, prior authorizations, and other forms of care. These guidelines help to ensure appropriate and cost-effective utilization of healthcare resources.

Heidi Weaver asked if any members of the Committee wanted to pull an agenda item from the Consent Agenda for discussion. No responses were received from the Committee.

Dr. Jagiello asked for motion for approval of the Consent Agenda from the Committee.

- First motion to approve by Dawn Schwartz
- Second motion to approve by Wendy Sanders

Committee Member by roll call vote for approval:



- ☑ Dr. Dana Danley-Family Practice
- ☑ Diana Smith, ARNP-Family Practice
- ☑ Dr. Polly Ferguson-Pediatric Rheumatology
- ☑ Dr. Chitra Reddy-Endocrinology
- ☑ Dr. Geetanjali Sahu-Child and Adolescent Psychiatrist
- ☑ Dawn Schwartz, ARNP- Neonatology/Pediatrics
- ☑ Dr. Kelli Roenfanz-Family Medicine, OB/Gyn
- ☐ Dr. Kartik Anand-Hematology/Oncology

Criteria Review:

1. Bone Marrow and/or Peripheral Blood Stem Cell Transplant

Dr. Jagiello presented Bone Marrow and/or Peripheral Blood Stem Cell Transplant as amended. He explained that historically dental clearance has always been a criterion due to the higher risk of infection from immunosuppressant medication. The subject matter expert reviewer recommended removing the dental clearance from the criterion, because it is already being done as standard of care among transplant institutions.

Dr. Jagiello opened for Committee Member comments.

- Diana Smith agreed that this is the standard of care.
- Dr. Ferguson also agreed to remove this, adding that having to go to a dentist could delay treatment for the patient.
- Dawn Schwartz shared she had no concerns and agreed with the recommendation.

Dr. Jagiello asked for motion for approval as amended from the Committee.

- First motion to approve by Dr. Dana Danley
- Second motion to approve by Diana Smith

Committee Member by roll call vote for approval:

- ☑ Dr. Dana Danley-Family Practice
- ☑ Diana Smith, ARNP-Family Practice
- ☑ Dr. Polly Ferguson-Pediatric Rheumatology
- ☑ Dr. Chitra Reddy-Endocrinology
- ☑ Dr. Geetanjali Sahu-Child and Adolescent Psychiatrist
- ☑ Dawn Schwartz, ARNP- Neonatology/Pediatrics
- ☑ Dr. Kelli Roenfanz-Family Medicine, OB/Gyn
- ☐ Dr. Kartik Anand-Hematology/Oncology



Heidi Weaver introduced Dr. Umbreit with the Iowa Medicaid Quality Improvement Organization to present Physician Administered Medications.

2. Epkinly (epcoritamab-bysp)

Dr. Umbreit presented a complete review for Epkinly (epcoritamab-bysp) as amended. Epkinly was approved by the U.S. Food and Drug Administration (FDA) on June 26, 2024, for treatment of adult patients with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy. Common to the original indication for the diffuse large B-cell lymphoma and high-grade B-cell lymphoma, this is also an accelerated approval, indicating that the approval is based on response and durability of that response. Continued approval may be contingent upon verification and description of clinical benefit. Updates were made to the Descriptive Narrative and Criteria sections to include the new indication. NCCN Guidelines were also updated.

Dr. Jagiello opened for Committee Member comments. No comments were offered.

Dr. Jagiello motioned for approval as amended from the Committee.

- First motion to approve by Dr. Polly Ferguson
- Second motion to approve by Dr. Dana Danley

Committee Member by roll call vote for approval:

- ☑ Dr. Dana Danley-Family Practice
- ☑ Diana Smith, ARNP-Family Practice
- ☑ Dr. Polly Ferguson-Pediatric Rheumatology
- ☑ Dr. Chitra Reddy-Endocrinology
- ☑ Dr. Geetanjali Sahu-Child and Adolescent Psychiatrist
- ☐ Dawn Schwartz, ARNP- Neonatology/Pediatrics
- ☑ Dr. Kelli Roenfanz-Family Medicine, OB/Gyn
- ☐ Dr. Kartik Anand-Hematology/Oncology

3. Fasenra (benralizumab)

Dr. Umbreit presented a complete review of Fasenra (benralizumab) as amended. On September 17, 2024, Fasenra was approved for a new indication for eosinophilic granulomatosis with polyangiitis (EGPA). Updates were made to the Overview, Descriptive Narrative, and Criteria sections to include the new indication. The Guidelines section was added along with current recommendations for treatment of asthma and EGPA. The Approval Duration and Quantity Limits, Coding and Product Information, and References were also updated.

Dr. Jagiello opened for Committee Member comments.

 Dr. Jagiello recognized Dr. Ferguson who acknowledged a conflict in the criteria as written under EGPA. Dr. Ferguson indicated for criteria number two it states you must have nonsevere disease; however, in the Guidelines section it states when you have a severe disease you should be treated with cyclophosphamide or rituximab and should start this as



soon as possible. Dr. Umbreit agreed with Dr. Ferguson's comments. Updates were made to the EGPA criteria as suggested by Dr. Ferguson.

Dr. Jagiello asked the Committee for any further questions or comments. No comments were offered.

Dr. Jagiello motioned for approval as amended from the Committee.

- First motion to approve by Dr. Polly Ferguson
- Second motion to approve by Dr. Chitra Reddy

Committee Member by roll call vote for approval:

- ☑ Dr. Dana Danley-Family Practice
- ☑ Diana Smith, ARNP-Family Practice
- ☑ Dr. Polly Ferguson-Pediatric Rheumatology
- ☑ Dr. Chitra Reddy-Endocrinology
- ☑ Dr. Geetanjali Sahu-Child and Adolescent Psychiatrist
- ☐ Wendy Sanders, ARNP-Family Practice
- ☑ Dawn Schwartz, ARNP- Neonatology/Pediatrics
- ☑ Dr. Kelli Roenfanz-Family Medicine, OB/Gyn
- ☐ Dr. Kartik Anand-Hematology/Oncology

4. Jemperli (dostarlimab-gxly)

Dr. Umbreit presented a complete review of Jemperli (dostarlimab-gxly) as amended. A revised indication for endometrial cancer was approved by the FDA on August 1, 2024, to include all adult patients with endometrial cancer, regardless of mismatch repair status. Updates were made to the initial and continuation criteria for endometrial cancer to align with the new indication. Dosage and administration guidelines were also updated.

Dr. Jagiello opened for Committee Member comments. No comments were offered.

Dr. Jagiello motioned for approval as amended from the Committee.

- First motion to approve by Dr. Ferguson
- Second motion to approve by Dawn Schwarz

Committee Member by roll call vote for approval:

- ☑ Dr. Dana Danley-Family Practice
- ☑ Diana Smith, ARNP-Family Practice
- ☑ Dr. Polly Ferguson-Pediatric Rheumatology
- ☑ Dr. Chitra Reddy-Endocrinology
- ☑ Dr. Geetanjali Sahu-Child and Adolescent Psychiatrist
- ☑ Dawn Schwartz, ARNP- Neonatology/Pediatrics



☑ Dr. Kelli Roenfanz-Family Medicine, OB/Gyn

☐ Dr. Kartik Anand-Hematology/Oncology

5. Sarclisa (isatuximab-irfc)

Dr. Umbreit presented a complete review of Sarclisa (isatuximab-irfc) as amended. A new indication was approved by the FDA on September 20, 2024. The approval was for use in combination with bortezomib, lenalidomide and dexamethasone, for the treatment of adult patients with newly diagnosed multiple myeloma who are not eligible for autologous stem cell transplant. Updates were made to the Overview, Criteria, and Approval Duration/ Quantity Limits sections to accommodate the new indication.

Dr. Jagiello opened for Committee Member comments. No comments were offered.

Dr. Jagiello motioned for approval as amended from the Committee.

- First motion to approve by Dr. Danley
- Second motion to approve by Dr. Ferguson.

Committee Member by roll call vote for approval:

- ☑ Dr. Dana Danley-Family Practice
- ☑ Diana Smith, ARNP-Family Practice
- ☑ Dr. Polly Ferguson-Pediatric Rheumatology
- ☑ Dr. Chitra Reddy-Endocrinology
- ☑ Dr. Geetanjali Sahu-Child and Adolescent Psychiatrist
- ☑ Dawn Schwartz, ARNP- Neonatology/Pediatrics
- ☑ Dr. Kelli Roenfanz-Family Medicine, OB/Gyn
- ☐ Dr. Kartik Anand-Hematology/Oncology

6. Uplizna (inebilizumab-cdon)

Dr. Umbreit presented a complete review of Uplizna (inebilizumab-cdon) as amended. A new indication was approved by the FDA on April 3, 2025, for treatment of immunoglobulin G4-related disease (IgG4-RD) in adult patients. Immunoglobulin G4-related disease (IgG4-RD) is an immune-mediated fibroinflammatory condition that can affect multiple organs. Early recognition and treatment are important because of the indolent nature of the condition and the risk of progression from a typically treatment-responsive proliferative and inflammatory stage to poorly responsive fibrotic disease and serious organ damage. Updates were made to the Overview. Descriptive Narrative. Guidelines. and Criteria sections to include the new indication.

Dr. Jagiello opened for Committee Member comments. No comments were offered.

Dr. Jagiello motioned for approval as amended from the Committee.

First Motion to approve by Diana Smith



Second Motion to approve by Dawn Schwartz

Committee Member by roll call vote for approval:

- ☑ Dr. Dana Danley-Family Practice
- ☑ Diana Smith, ARNP-Family Practice
- ☑ Dr. Polly Ferguson-Pediatric Rheumatology
- ☑ Dr. Chitra Reddy-Endocrinology
- ☑ Dr. Geetanjali Sahu-Child and Adolescent Psychiatrist
- ☑ Dawn Schwartz, ARNP- Neonatology/Pediatrics
- ☑ Dr. Kelli Roenfanz-Family Medicine, OB/Gyn
- ☐ Dr. Kartik Anand-Hematology/Oncology

Closing Remarks:

Heidi Weaver presented closing announcements. She also included in the chat a reminder to send any questions or comments to the CAC email: CAC@hhs.iowa.gov and to visit the lowa HHS Fee Schedules webpage: https://hhs.iowa.gov/programs/welcome-iowa-medicaid/policies-rules-and-regulations/covered-services-rates-and-payments/fee-schedules for code related questions.

Heidi Weaver announced the upcoming meeting and thanked all Committee Members.

Upcoming Meeting:

Friday, October 17, 2025 Friday, January 16, 2026

Dr. Jagiello thanked everyone for their participation.

Motion for Adjournment:

Dr. Jagiello asked for motion for approval to adjourn the meeting from the Committee.

- First motion: Dr. Dana Danley
- Second motion: Dawn Schwartz

Dr. Jagiello adjourned the meeting.