IOWA | Health and Human Services

Meeting Agenda

Division	Iowa Medicaid Quality Improvement Organization (QIO)		
Meeting Title	Clinical Advisory Committee (CAC)		
CAC Chair	Bill Jagiello, DO		
Facilitator	Heidi Weaver		
Date	October 17, 2025	TIME	1:00pm - 4:00pm
Location	Virtual: Via Zoom: https://telligen.zoom.us/meeting/register/9cLUmPM4SqKO2OqwU6aPsg 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

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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 Conflict of Interest Disclosure. 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 CAC@hhs.iowa.gov prior to and/or post meeting.

Announcements

- **Recognition of Service:**
  - Polly Ferguson, MD

Approval of July 18, 2025, Meeting Minutes

New Business

Consent Agenda

Durable Medical Equipment (3):

1. Negative Pressure Wound Therapy
2. Pneumatic Compression Devices - *Archive*
3. Wearable Automatic External Defibrillator

Level of Care (1):

4. Habilitation Eligibility (Non-Financial)

Surgical Procedures (2):

5. Autologous Chondrocyte Implantation
6. Panniculectomy - *Archive*

Physician Administered Medications (14):

7. Amondys 45 (casimersen)
8. Bavencio (avelumab)
9. Danyelza (naxitamab-gqgk)
10. Elahere (mirvetuximab soravtansine-gynx)
11. Exondys 51 (eteplirsen)
12. Kadcyla (ado-trastuzumab emtansine)
13. Loqtorzi (toripalimab-tpzi)
14. Margenza (margetuximab-cmkb) - *Archive*
15. Padcev (enfortumab vedotin-ejfv)
16. Phesgo (pertuzumab, trastuzumab, and hyaluronidase-zzxf)
17. Spevigo (spesolimab-sbzo)
18. Viltepso (viltolarsen)
19. Vyondys 53 (golodirsen)
20. Ycanth (cantharidin)

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Criteria Review

Level of Care (1):
1. Children's Mental Health Waiver Level of Care

Waiver Prior Authorization (1):
2. Medical Day Care for Children

Physician Administered Medications – Review (5):
3. Abecma (idecabtagene vicleucel)
4. Breyanzi (lisocabtagene maraleucel)
5. Carvykti (ciltacabtagene autoleucel)
6. Vyjuvek (beremagene geperpavec-svdt)
7. Yescarta (axicabtagene ciloleucel)

Upcoming Meetings

- Friday, January 16, 2026
  - Virtual Meeting Link: https://telligen.zoom.us/meeting/register/_9baOMgVRhm6tyLZ9s8sZA
- Friday, April 17, 2026
  - Virtual Meting Link: https://telligen.zoom.us/meeting/register/s6lQqY7lTTuEoR92nF2rlA

Adjournment

Additional Information

- **Iowa Medicaid CAC contact**: CAC@hhs.iowa.gov
- **Iowa Medicaid CAC webpage**: https://hhs.iowa.gov/about/advisory-groups/clinical-advisory-committee-cac
- **Iowa 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** CAC Disclosure Form **and email it to** CAC@hhs.iowa.gov**.** Submissions must be received no later than one week prior to the meeting date.

Meeting Minutes (Q4 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 6 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.

Recognition of Service: Dr. Jagiello announced that Dr. Polly Ferguson's tenure was ending as a CAC Committee member due to the 2 term appointment criteria.

Approval of the July 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 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
☒ Wendy Sanders, ARNP-Family Practice
☒ Dawn Schwartz, ARNP- Neonatology/Pediatrics
☐ Dr. Kelli Roenfanz, Family Medicine, OB/Gyn
☐ Dr. Kartik Anand-Hematology/Oncology

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 Umbreit added a slight correction to the definition by explaining that there was a physician administered medication, Margenza (margetuximab-cmkb), on the list that was being archived because the medication is no longer rebate eligible and was being removed from the fee schedule.

Dr. Jagiello asked the committee if there were any comments or questions about an item on the consent agenda, adding that a committee member may, at their request, take an item off the

consent agenda and open it up for discussion. With no comments or questions heard, Dr. Jagiello asked for a motion to approve the consent agenda as presented.

- First motion to approve by Dawn Schwartz.
- 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
☒ Wendy Sanders, ARNP-Family Practice
☒ Dawn Schwartz, ARNP- Neonatology/Pediatrics
☐ Dr. Kelli Roenfanz, Family Medicine, OB/Gyn
☐ Dr. Kartik Anand-Hematology/Oncology

Criteria Review:

1. **Children's Mental Health Waiver Level of Care.**

   Cindy Palmer, Quality Improvement Organization, presented Children's Mental Health Waiver Level of Care as amended. Cindy explained the changes in the criteria as follows:

   - A change defining the person or group responsible for completing the reviews.
   - A change in the wording to clarify what was needed for needed to be documented for a SED (serious emotional disturbance.) and not the need for a completely new assessment.
   - A change to the requirements in terms of participating in the intervention. It is required that there is proof that the member and the family members are participating. In terms of making progress towards goals, it decided there was some subjectivity, and it would be difficult to always make a determination if a child is making progress.

Dr Jagiello asked the committee if there were any questions or comments on the revisions of the policy.

- Dr. Ferguson asked to review the criteria on page 3 regarding the requirements of experience for a mental health provider, asking if we are asking for the provider to have at least 2 years' post decree experience or after their fellowship or are the requirements 2 years practice before they can provide this.
- Cindy explained that she didn't believe there to be any delineation between the two. This information is defined in the Iowa Code and sometimes there is research done and connections with providers to determine what their experience is to ensure that they're a qualifying as a mental health provider.
- Dr Ferguson expressed that if a provider had practice mental health providing services for 2 years, because that would remove many providers, from the mix.
- Cindy agreed that this does happen with this definition from the Iowa Code.

Dr. Jagiello thanks Dr. Ferguson and asked the committee if there were any other questions or comments. Hearing no further comments or questions, he asked the committee for a motion to approve the policy as revised.

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

2. Medical Day Care for Children

Lisa Roush, Quality Improvement Organization, presented Medical Day Care for Children as amended. Cindy explained the changes in the criteria as follows:

- Clarification: The services, are to be, rendered when the, as long as the member is, in school. School being defined, refers to brick or mortar building, where students attend class in person during school hours set by the school district, or participation in home schooling and private educational instruction occurring inside and outside the home
- Clarification: To define, the medical daycare for children, is expected that the services will be used while the primary caregivers are absent due to working, attending school. Participating in vocational training or otherwise regularly absent and unavailable to provide the specialized exceptional care to the child.
- There will be a rate change, the upper rate limit will be changed on the fee schedule and will be published on the HHS Fee website.

Dr Jagiello asked the committee if there were any questions or comments on the revisions of the policy. Hearing none he asked for a motion and a second to approve the revised criteria.

- First motion to approve by Wendy Sanders
- Second motion to approve by Dr. 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

☒ Wendy Sanders, ARNP-Family Practice
☒ 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.

Dr Umbreit explained that there were 5 medications on the Criteria Review to review. 4 of the 5 medications are CAR-T therapies. The changes in these therapies aren't new indications or new dosing. The changes occurred in the requirements in place by the FDA for safety.

When CAR-T therapies came out there were many side effects to become familiar with, treatment strategies and additional care that could be needed based on the side effects. These drugs were put into a REMS program or a Risk Evaluation Mitigation Strategy program. This required that the providers were certified with the company. It required them to go through certain training to verify that they had certain facilities and certain treatment options available on hand for the patient, and it enforced additional monitoring requirements.

The FDA has now decided that the REMS requirement is no longer necessary to ensure the safe use of these therapies, as both physicians and hospitals are well-versed in the potential risks of these therapies and how to manage these risks should they occur. In place of the requirement for the REMS program, the FDA has amended the prescribing information to implement additional post-infusion monitoring requirements.

Patients must be monitored daily for at least 7 days following an infusion to monitor for signs and symptoms of the cytokine release syndrome or other neurological toxicities. They must remain within proximity of a healthcare facility for at least 2 weeks following the infusion and are advised to avoid driving for at least 2 weeks following the infusion. These changes apply to all CAR-T therapies, not just the ones reviewed at today's meeting (Abecma, Breyanzi, Carvykti, and Yescarta).

3. Abecma (idecabtagene vicleucel)

No changes to approved indication or dosing. Policy was updated to remove the REMS requirement as previously discussed. Updates to the statistics to include the 2025 SEER registry estimates.

Dr Ferguson commented that the post-infusion monitoring seemed intentionally vague. Dr Umbreit confirmed that the change to remove the REMS program requirement was identical in all of the drugs being reviewed and clarified that patients may be monitored on an outpatient basis.

Dr Jagiello asked the committee if there were any further questions or comments on the revisions of the policy.

Hearing none he asked for a motion and a second to approve the revised criteria.

- First motion to approve by Dr. Reddy
- 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
☒ Wendy Sanders, ARNP-Family Practice
☒ Dawn Schwartz, ARNP- Neonatology/Pediatrics
☐ Dr. Kelli Roenfanz, Family Medicine, OB/Gyn
☐ Dr. Kartik Anand-Hematology/Oncology

4. Breyanzi (lisocabtagene maraleucel)

No changes to approved indications or dosing since the last review. Again, the change to the policy is for the removal of the REMS requirement and the addition of language regarding post-infusion monitoring.

Dr Jagiello asked the committee if there were any further questions or comments on the revisions of the policy.

Hearing none he asked for a motion and a second to approve the revised criteria.

- First motion to approve by Dr. Ferguson
- Second motion to approve by Dr. 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
☒ Wendy Sanders, ARNP-Family Practice
☒ Dawn Schwartz, ARNP- Neonatology/Pediatrics
☐ Dr. Kelli Roenfanz, Family Medicine, OB/Gyn
☐ Dr. Kartik Anand-Hematology/Oncology

5. **Carvykti (ciltacabtagene autoleucel)**
   No changes to approved indication or dosing. Policy updated to remove the REMS program requirement as previously discussed, including the addition of updated post-infusion monitoring recommendations as listed in the prescribing information.

Dr Jagiello asked the committee if there were any further questions or comments on the revisions of the policy.

Hearing none he asked for a motion and a second to approve the revised criteria.

- First motion to approve by Dr. Reddy
- 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
☒ Wendy Sanders, ARNP-Family Practice
☒ Dawn Schwartz, ARNP- Neonatology/Pediatrics
☐ Dr. Kelli Roenfanz, Family Medicine, OB/Gyn
☐ Dr. Kartik Anand-Hematology/Oncology

6. **Yescarta (axicabtagene ciloleucel)**
   The same revisions were made to this policy as were made to the other CAR-T policies. Removal of the REMS requirement from coverage criteria, and the addition of updated post-infusion monitoring recommendations as listed in the prescribing information.

Heidi Weaver noted that the order of the presentation was different than on the agenda because Dr. Umbreit presented all of the CAR-T policies together.

Dr Jagiello asked the committee if there were any further questions or comments on the revisions of the policy.

Hearing none he asked for a motion and a second to approve the revised criteria.

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

7. Vyjuvek (beremagene geperpavec-svdt)

Dr. Umbreit presented Vyjuvek, approved for the treatment of wounds in adults and pediatric patients with dystrophic epidermis and epidermolysis bullosa with mutation(s) in the *collagen type VII alpha-1 chain (COL7A1) gene*.

The FDA changed the approval for use in patients from birth (previously only recommended in 6 months of age and older). Because of the decreased age, there is a variation in the dosing, but the dose by wound size and the frequency of treatment have not changed.

Additionally, the labeling now states that it may be administered by a patient of appropriate age or a caretaker, once they have received training from a provider's office (previous labeling only indicated administration by a healthcare provider).

Registered speaker, Dominic Marchese, PharmD, from Krystal Biotech (the manufacturer of Vyjuvek™) was allowed a maximum of 5 minutes to speak to the committee about the updates to the criteria.

Vyjuvek™ is a herpes-simplex virus type 1 (HSV-1) vector-based gene therapy indicated for the treatment of wounds in adults and pediatric patients with dystrophic epidermolysis bullosa with mutations in the *collagen type VII-alpha-1 chain (COL7A1)* gene.

We appreciate the comprehensive and thorough evidence-based evaluation in the development of the updated criteria, and as you noted, on September 15, 2025, the United States Food and Drug Administration approved a label update for Vyjuvek to include use in patients with dystrophic epidermolysis bullosa from birth.

As was noted in your criteria, in addition to that expanded label, the following updates have also been approved: an increase in the maximum weekly dose to 1 mL, which is 2 billion plaque forming units, or 2 x 10^9 plaque forming units, for patients from birth up to 3 years of age, and an increase in the maximum weekly dose to 2 mL, which is 4 billion plaque forming units, or 4 x 10^9 plaque forming units, for patients 3 years of age and older.

It is important to note that with these increases, there is no change in the NDC nor the package sizes. These remain the same with the dosing increases. Lastly, the FDA has approved Vyjuvek, as was noted, to be applied by a patient, a caregiver, or a healthcare professional, either in the healthcare professional setting or in a home setting.

For patients and caregivers administering Vyjuvek, the FDA has approved a consumer-friendly medication guide that is provided with the prescribing information for distribution to the patient, and an instruction for use document that contains steps for applying Vyjuvek gel.

The link to this document can be found on the top toolbar of the patient section of the vyjuvek.com website.

Some prescribing providers and patients may still elect to have a healthcare provider administer Vyjuvek, and the Krystal Connect services are still available to help patients evaluate appropriate administration site options, either in a healthcare professional setting or in a home setting, for Vyjuvek to be administered by a healthcare professional.

Thank you again for the opportunity to provide these updates. If there are no questions, I will yield the remainder of my time back to the committee.

Dr. Jagiello thanked the speaker and asked the committee if they had any questions or comments about the revised policy or criteria.

Hearing none he asked for a motion and a second to approve the revised criteria.

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

Heidi Weaver thanked the everyone for joining and welcomed everyone to join the upcoming Quarter 1 CAC meeting on January 16, 2026.

Dr Jagiello thanked the committee for their involvement and engagement and asked if there any questions or comments.

Hearing none, he asked for a motion to adjourn.

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