	Meeting Age	nda	
Division	Iowa Medicaid Quality Improveme	nt Organizat	ion (QIO)
Meeting Title	Clinical Advisory Committee (CAC	3)	
CAC Chair	Bill Jagiello, DO		
Facilitator	Heidi Weaver		
Date	October 18, 2024	TIME	1:00pm - 4:00pm
Location	Virtual: Via Zoom https://telligen.zoom.us/meeting/register/tz In-Person: Hoover Building Capitol Complex, 1305 E		

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 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.

Medicald Insurance that would constitute a violation of Federal FIFAA standards.		
	Meeting Participants	
Iowa Medicaid	 □ Elizabeth Matney, Medicaid Director □ Rebecca Curtiss, HHS Deputy Director of Operations □ Jenny Erdman, HHS Quality, Innovation & Medical Policy Bureau Chief ⋈ Bill Jagiello, DO □ Mark Randleman, DO ⋈ Else Umbreit, PharmD ⋈ Charissa Blinkmann 	
Committee Members	 ☑ Dr. Alexandra Hubbell-Family Practice ☑ Clarice Blanchard, PA-C, Family Practice/Emergency Medicine ☑ 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 	



Managed Care	☑ Dr. Paul Mulhausen, Iowa Total Care
Organizations	☐ 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 signed <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.

Announcements

- Welcome:
 - o Dr. James Elliot, Dental Director, Managed Care of North America
 - o Dr. Jeff Chaffin, Dental Director, Delta Dental of Iowa
 - o Dr. Jason Kessler, Medical Director, Wellpoint
 - o Wendy Sanders, ARNP, New Committee Member
- Recognition of Service:
 - o Dr. Alexandra Hubbell

Approval of July 19, 2024 Meeting Minutes

New Business

Consent Agenda

Level of Care (1):

1. Children's Mental Health Waiver Level of Care

Surgical Procedures (2):

- 2. Autologous Chondrocyte Implantation
- 3. Panniculectomy

Waiver Prior Authorization (1):

4. Medical Day Care for Children

Physician Administered Medications (14):

- 5. Amondys 45 (casimersen)
- 6. Bavencio (avelumab)
- 7. Briumvi (ublituximab-xiiy)
- 8. Danyelza (naxitamab-gggk)
- 9. Elahere (mirvetuximab soravtansine-gynx)
- 10. Exondys 51 (eteplirsen)
- 11. Kadcyla (ado-trastuzumab emtansine)
- 12. Legembi (lecanemab-irmb)
- 13. Margenza (margetuximab-cmkb)
- 14. Phesgo (pertuzumab, trastuzumab, and hyaluronidase-zzxf)
- 15. Trodelvy (sacituzumab govitecan-hziy)
- 16. Viltepso (viltolarsen)
- 17. Vyondys 53 (golodirsen)
- 18. Yescarta (axicabtagene ciloleucel)



Criteria Review

Durable Medical Equipment (4):

- 1. Insulin Pumps (New)
- 2. Negative Pressure Wound Therapy
- 3. Pneumatic Compression Devices
- 4. Wearable Automatic External Defibrillator

Level of Care (1):

5. Habilitation Eligibility (Non-Financial)

Therapy-Counseling (3):

- 6. Family Functional Therapy
- 7. Multi-Systemic Therapy
- 8. Repetitive Transcranial Magnetic Stimulation

Physician Administered Medications - New (6):

- 9. Kisunla (donanemab-azbt)
- 10. Loqtorzi (toripalimab-tpzi)
- 11. Spevigo (spesolimab-sbzo)
- 12. Veopoz (pozelimab-bbfg)
- 13. Vyjuvek (beremagene geperpavec-svdt)
- 14. Ycanth (cantharidin)

Physician Administered Medications – Review (6):

- 15. Abecma (idecabtagene vicleucel)
- 16. Aduhelm (aducanumab-avwa)
- 17. Breyanzi (lisocabtagene maraleucel)
- 18. Carvykti (ciltacabtagene autoleucel)
- 19. Enhertu (fam-trastuzumab deruxtecan-nxki)
- 20. Padcev (enfortumab vedotin-efjv)

Upcoming Meeting

• Friday, January 17, 2025

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
- 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 (Q4 2024)

Introduction: Heidi Weaver, Iowa Medicaid QIO, welcomed everyone to the fourth quarterly Iowa Medicaid Clinical Advisory Committee (CAC) Meeting for 2024, and provided an overview of the house rules.



Verbal roll call of the Committee Members: Quorum was confirmed with 7 of 8 members.

Introduction: Heidi introduced Committee Chairman, Dr. Jagiello, who is the Medical Director for Iowa Medicaid QIO. She 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. She also provided the new CAC email available for any correspondence at CAC@hhs.iowa.gov.

Announcements:

Welcome

- o Dr. James Elliot, Dental Director, Managed Care of North America
- o Dr. Jeff Chaffin, Dental Director, Delta Dental of Iowa
- o Dr. Jason Kessler, Medical Director, Wellpoint
- Wendy Sanders, ARNP, Family Medicine

Recognition of Service

o Dr. Alexandra Hubbell

Approval of the July 19, 2024 Minutes: Approved by votes below. Dr. Jagiello opened for a vote to approve the minutes, with no requests for any changes or corrections.

First motion-Diana Smith; Second motion-Dr. Hubbell

Committee Member b	y vote:
	dra Hubbell-Family Practice
	nchard, PA-C, Family Practice/Emergency Medicine
☐ Dr. Dana D	Danley-Family Practice (abstained from vote-absent last meeting)
	th, ARNP-Family Practice
Dr. Polly Fe	erguson-Pediatric Rheumatology (abstained vote-absent last meeting)
	Reddy-Endocrinology (absent)
	jali Sahu-Child and Adolescent Psychiatrist
•	·
Old Business:	

Old Business:

No items

Consent Agenda:

Dr. Jagiello provided the purpose of the Consent Agenda, then opened it up to the Committee Members for review. There was an opportunity given for public comment, with no comments presented.

First motion-Dr. Ferguson; Second motion-Diana Smith
Committee Member by roll call vote for approval:
☑ Dr. Alexandra Hubbell-Family Practice
☐ Clarice Blanchard, PA-C, Family Practice/Emergency Medicine
□ Dr. Dana Danley-Family Practice
□ Diana Smith, ARNP-Family Practice
□ Dr. Polly Ferguson-Pediatric Rheumatology
☐ Dr. Chitra Reddy-Endocrinology (absent)



⊠ Wendy Sanders, ARNP, Family Medicine

Criteria Review:

1.Insulin Pumps

Dr. Jagiello deferred presentation for later in the meeting to allow SME participation.

2. Negative Pressure Wound Therapy

Dr. Jagiello presented the medical criteria as amended. He opened for comments, with no comments, then motioned for an approval from the Committee.

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3.Pneumatic Compression Devices

Dr. Jagiello presented the medical criteria as amended. He opened for comments, with no comments, then motioned for an approval from the Committee.

First motion- Dr. Hubbell; Second motion- Clarice Blanchard Committee Member by roll call vote for approval:

\boxtimes	Dr. Alexandra Hubbell-Family Practice
\boxtimes	Clarice Blanchard, PA-C, Family Practice/Emergency Medicine
\boxtimes	Dr. Dana Danley-Family Practice
\boxtimes	Diana Smith, ARNP-Family Practice
\boxtimes	Dr. Polly Ferguson-Pediatric Rheumatology
	Dr. Chitra Reddy-Endocrinology (absent)
\boxtimes	Dr. Geetanjali Sahu-Child and Adolescent Psychiatrist
\boxtimes	Wendy Sanders, ARNP, Family Medicine

4.Wearable Automatic External Defibrillator

Dr. Jagiello presented the medical criteria as amended. He opened for comments, with no comments, then motioned for an approval from the Committee.

☑ Dr. Dana Danley-Family Practice☑ Diana Smith, ARNP-Family Practice

☑ Dr. Polly Ferguson-Pediatric Rheumatology☑ Dr. Chitra Reddy-Endocrinology (absent)



☐ Dr. Geetanjali Sahu-Child and Adolescent Psychiatrist

⊠ Wendy Sanders, ARNP, Family Medicine

8. Repetitive Transcranial Magnetic Stimulation

Dr. Jagiello presented the medical criteria as amended. He opened for comments, with comments from Dr. Sahu, Dr. Ferguson, and Dr. Mulhausen. Dr. Jagiello revised the contraindications to strike #4, 5 & 6. Next comment from Dr. Sahu on medical criteria #1 regarding member age, Dr. Mulhausen & Dr. Ferguson commented, Dr. Jagiello advised on a motion from the Committee to withdraw the policy & table it at this time for further review and revision at this time. He requested that all the medical directors send a copy of their respective policies to him, as well as Dr. Sahu on how it can be improved with references. Committee Member by roll call vote for to withdrawal it for revision and bring it back January 2025 (Q1):

∇	Dr. Alexandra Hubbell-Family Practice
	Clarice Blanchard, PA-C, Family Practice/Emergency Medicine
\boxtimes	Dr. Dana Danley-Family Practice
\boxtimes	Diana Smith, ARNP-Family Practice
X	Dr. Polly Ferguson-Pediatric Rheumatology
	Dr. Chitra Reddy-Endocrinology (absent)
X	Dr. Geetanjali Sahu-Child and Adolescent Psychiatrist
$ar{\boxtimes}$	Wendy Sanders, ARNP, Family Medicine

9.Kisunla (donanemab-azbt)

Dr. Umbreit presented this new policy with complete review of the medical criteria. Pharmacologic category: Antidementia agent; amyloid beta-directed antibody. *Aduhelm will no longer be available after November 1, 2024. The two fully FDA approved therapies available are Leqembi and this new therapy, Kisunla. Dr. Jagiello opened for comments, with no comments provided, he then motioned for an approval from the Committee.

First motion-Clarice Blanchard; Second motion-Diana Smith Committee Member by roll call vote:

\boxtimes	Dr. Alexandra Hubbell-Family Practice
\boxtimes	Clarice Blanchard, PA-C, Family Practice/Emergency Medicine
\boxtimes	Dr. Dana Danley-Family Practice
\boxtimes	Diana Smith, ARNP-Family Practice
\boxtimes	Dr. Polly Ferguson-Pediatric Rheumatology
	Dr. Chitra Reddy-Endocrinology (absent)
\boxtimes	Dr. Geetanjali Sahu-Child and Adolescent Psychiatrist
\boxtimes	Wendy Sanders, ARNP, Family Medicine

10.Loqtorzi (toripalimab-tpzi)

Dr. Umbreit presented this new policy with complete review of the medical criteria. Pharmacologic category: Antineoplastics; immune checkpoint inhibitor; PD-1 blocking antibody. Dr. Jagiello opened for comments, with no comments provided, he then motioned for an approval from the Committee.

First motion-Dr. Ferguson; Second motion-Dr. Hubbell Committee Member by roll call vote:

Health and Human Services
 ☑ Dr. Alexandra Hubbell-Family Practice ☑ Clarice Blanchard, PA-C, Family Practice/Emergency Medicine ☑ Dr. Dana Danley-Family Practice ☑ Diana Smith, ARNP-Family Practice ☑ Dr. Polly Ferguson-Pediatric Rheumatology ☑ Dr. Chitra Reddy-Endocrinology (absent) ☑ Dr. Geetanjali Sahu-Child and Adolescent Psychiatrist ☑ Wendy Sanders, ARNP, Family Medicine
11.Spevigo (spesolimab-sbzo)
Dr. Umbreit presented this new policy with complete review of the medical

criteria. Pharmacologic category: Immunological agent; interleukin blocker; interleukin-36 receptor antagonist. Dr. Jagiello opened for comments, Diana Smith inquired question on if they started on one type, but then needed to switch to the other type, what is the approval process? Dr. Umbreit explained the process. There were no further questions. Dr. Jagiello then motioned for an approval from the Committee.

First motion-Dr. Ferguson; Second motion-Clarice Blanchard Committee Member by roll call vote: ☐ Dr. Alexandra Hubbell-Family Practice ☐ Clarice Blanchard, PA-C, Family Practice/Emergency Medicine □ Dr. Dana Danley-Family Practice ☐ Diana Smith, ARNP-Family Practice ☑ Dr. Polly Ferguson-Pediatric Rheumatology Dr. Chitra Reddy-Endocrinology (absent) □ Dr. Geetanjali Sahu-Child and Adolescent Psychiatrist

12. Veopoz (pozelimab-bbfg)

Dr. Umbreit presented this new policy with complete review of the medical criteria. Pharmacologic category: Immunological agent; complement inhibitor. Dr. Jagiello opened for comments, there were no comments, he then motioned for an approval from the Committee.

First motion-Dr. Hubbell; Second motion-Dr. Ferguson Committee Member by roll call vote:

☑ Dr. Alexandra Hubbell-Family Practice
⊠ Clarice Blanchard, PA-C, Family Practice/Emergency Medicine
☑ Dr. Dana Danley-Family Practice
☑ Diana Smith, ARNP-Family Practice
☑ Dr. Polly Ferguson-Pediatric Rheumatology
☐ Dr. Chitra Reddy-Endocrinology (<mark>absent)</mark>
☑ Dr. Geetanjali Sahu-Child and Adolescent Psychiatrist
⊠ Wendy Sanders, ARNP, Family Medicine

13. Vyjuvek (beremagene geperpavec-svdt)

Dr. Umbreit presented this new policy with complete review of the medical criteria. Pharmacologic category: Dermatological agents; herpes-simplex virus type 1 (HSV-1) vector-



based gene therapy. Dr. Jagiello opened for comments, there were no comments, he then motioned for an approval from the Committee.

Public Comments: Karen Ward, Regional Medical Director, Krystal Biotech

 Public Comments: Karen Ward, Regional Medical Director, Krystal Biotech
First motion-Dr. Hubbell; Second motion-Dr. Danley Committee Member by roll call vote: Dr. Alexandra Hubbell-Family Practice Clarice Blanchard, PA-C, Family Practice/Emergency Medicine Dr. Dana Danley-Family Practice Diana Smith, ARNP-Family Practice Dr. Polly Ferguson-Pediatric Rheumatology Dr. Chitra Reddy-Endocrinology (absent) Dr. Geetanjali Sahu-Child and Adolescent Psychiatrist Wendy Sanders, ARNP, Family Medicine
14.Ycanth (cantharidin)
Dr. Umbreit presented this new policy with complete review of the medical criteria. Pharmacologic category: Dermatological agents; miscellaneous. Dr. Jagiello opened for comments, Diana Smith commented, Dr. Ferguson commented, Dr. Hubbell commented, Dr. Jagiello motioned to strike #6 under medical criteria then to strike #5 under the continuation, (removing the requirement for a specialist), Dr. Jagiello then motioned for an approval from the Committee.
First motion-Dr. Hubbell; Second motion-Dr. Ferguson Committee Member by roll call vote: Dr. Alexandra Hubbell-Family Practice Clarice Blanchard, PA-C, Family Practice/Emergency Medicine Dr. Dana Danley-Family Practice Diana Smith, ARNP-Family Practice Dr. Polly Ferguson-Pediatric Rheumatology Dr. Chitra Reddy-Endocrinology (absent) Dr. Geetanjali Sahu-Child and Adolescent Psychiatrist Wendy Sanders, ARNP, Family Medicine
15. Abecma (idecabtagene vicleucel)
Dr. Umbreit presented a criteria review of this policy and outlined changes: Medical criteria, #3 (\underline{two} or more prior therapies), then Dosing criteria #11 (300 to $\underline{5x10^6}$ CAR-positive T cells), also a change in the language for the HCPCS codes, Dr. Jagiello opened for comments, there were no comments, he then motioned for an approval from the Committee.
First motion-Dr. Ferguson; Second motion-Dr. Danley Committee Member by roll call vote: Dr. Alexandra Hubbell-Family Practice Clarice Blanchard, PA-C, Family Practice/Emergency Medicine Dr. Dana Danley-Family Practice Diana Smith, ARNP-Family Practice Dr. Polly Ferguson-Pediatric Rheumatology

Health and Human Services
 □ Dr. Chitra Reddy-Endocrinology (absent) □ Dr. Geetanjali Sahu-Child and Adolescent Psychiatrist □ Wendy Sanders, ARNP, Family Medicine
16. Aduhelm (aducanumab-avwa)
Dr. Umbreit presented the review of the policy: this therapy is being discontinued November 1, 2024. She added information on Kisunla. In January this will be seen on the Consent Agenda to archive. Dr. Jagiello opened for comments, there were no comments, he then motioned for an approval from the Committee.
First motion-Dr. Hubbell; Second motion-Dr. Ferguson Committee Member by roll call vote: Dr. Alexandra Hubbell-Family Practice Clarice Blanchard, PA-C, Family Practice/Emergency Medicine Dr. Dana Danley-Family Practice Diana Smith, ARNP-Family Practice Dr. Polly Ferguson-Pediatric Rheumatology Dr. Chitra Reddy-Endocrinology (absent)

17. Breyanzi (lisocabtagene maraleucel)

Dr. Umbreit presented a review of this policy and outlined changes. She included the new indications with review of the correlating medical criteria and advised on an update to the Box Warning for T cell malignancies. Dr. Jagiello opened for comments, there were no comments, he then motioned for an approval from the Committee.

First motion-Clarice Blanchard; Second motion-Dr. Hubbell
Committee Member by roll call vote:
☑ Dr. Alexandra Hubbell-Family Practice
☐ Dr. Dana Danley-Family Practice
Diana Smith, ARNP-Family Practice
Dr. Delly Forgueen Dedictric Phaymetelessy

Dr. Geetanjali Sahu-Child and Adolescent Psychiatrist

⊠ Wendy Sanders, ARNP, Family Medicine

Dr. Chitra Reddy-Endocrinology (absent)

□ Dr. Geetanjali Sahu-Child and Adolescent Psychiatrist

Wendy Sanders, ARNP, Family Medicine

18. Carvykti (ciltacabtagene autoleucel)

Dr. Umbreit presented a review of this policy and outlined changes. She presented a revision of the FDA-Approved indication: now required only one prior line of therapy, 4/5/2024, also the line added to the Box Warning regarding T cell malignancies. Dr. Jagiello opened for comments, there were no comments, he then motioned for an approval from the Committee.

First motion-Dr. Ferguson; Second motion-Dr. Danley Committee Member by roll call vote:

☐ Dr. Alexandra Hubbell-Family Practice

☐ Clarice Blanchard, PA-C, Family Practice/Emergency Medicine

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ommittee Member by roll call vote:
□ Dr. Alexandra Hubbell-Family Practice
□ Dr. Dana Danley-Family Practice
□ Diana Smith, ARNP-Family Practice
□ Dr. Polly Ferguson-Pediatric Rheumatology
☐ Dr. Chitra Reddy-Endocrinology (absent)
☑ Dr. Geetanjali Sahu-Child and Adolescent Psychiatrist
Wendy Sanders, ARNP, Family Medicine ■

20. Padcev (enfortumab vedotin-efjv)

Dr. Umbreit presented a review of this policy and outlined changes. She provided the expanded indication and in addition it was granted regular approval, as prior it was under accelerated approval, no changes in dosing. Dr. Jagiello opened for comments, there were no comments, he then motioned for an approval from the Committee.

Dr. Reddy was able to join the meeting, and the Committee followed back around on Criteria Review for Insulin Pumps.

1.Insulin Pumps



Dr. Jagiello presented the medical criteria for this new policy. He opened for comments, Dr. Reddy provided comments, Wendy Sanders provided comments, requested for a change to the language regarding the replacement of insulin pumps. Dr. Mulhausen provided comments, suggestions and clinical examples. Dr. Kessler provided comments. Dr. Jagiello suggested to table the policy to rework the replacement section to add clarity. Dr. Mulhausen provided further response on granularity to the language to be added, Dr. Reddy provided further response on further clarity with the peer-to-peer opportunity added is a benefit. There were no further questions or changes requested. Dr. Jagiello motioned to table the policy and bring it back at the January 2025 (Q1) meeting for a revision, from the Committee.

First motion- Dr. Ferguson; Second motion- Dr. Danley
Committee Member by roll call vote for approval:
☐ Dr. Alexandra Hubbell-Family Practice (absent)
☐ Clarice Blanchard, PA-C, Family Practice/Emergency Medicine
☑ 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 Medicine

Heidi Weaver presented closing announcements on the added links in the chat that will direct individuals who may be interested in serving as a CAC Committee Member. The CAC webpage has a link to the Member Interest Form, and she included a direct link to the form. Reminder: please send any questions or comments to the CAC email: CAC@hhs.iowa.gov

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

Upcoming Meetings:

Friday, January 17, 2025

Motion for Adjournment:

First motion by Dr. Danley, Second motion by Dr. Ferguson.

Dr. Jagiello adjourned the meeting.