Meeting Agenda			
Division	Iowa Medicaid Quality Improvement Organization (QIO)		
Meeting Title	Clinical Advisory Committee (CAC)		
CAC Chair	Bill Jagiello, DO		
Facilitator	Heidi Weaver		
Date	April 18, 2025	TIME	1:00pm - 4:00pm
Location	Virtual: Via Zoom <a href="https://telligen.zoom.us/meeting/register/Ut3hGQowRJC4VzGv03lDjQ">https://telligen.zoom.us/meeting/register/Ut3hGQowRJC4VzGv03lDjQ</a>		

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



## **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.

#### **Announcements**

- Welcome:
  - Kartik Anand, MD, Hematology/Oncology

## Approval of January 17, 2025, Meeting Minutes

#### **Old Business**

1. Power Seat Elevation for Power Wheelchairs

#### **New Business**

## **Consent Agenda**

#### Dental (1):

1. Periodontic Procedures

#### Durable Medical Equipment (3):

- 2. Augmentative Communication Systems
- 3. Back-up Ventilator
- 4. Shower/Commode Chair

#### Home Health (2):

- 5. Personal Care Services for Children
- 6. Private Duty Nursing for Children

#### Lab (3):

- 7. Genetic Testing Archive
- 8. Genetic Testing for Hereditary Breast and Ovarian Cancer Syndrome(BRCA1/BRCA2) Archive
- 9. Testing for Hereditary Cancer Susceptibility Syndromes Using Multi-Gene Panels Archive

#### Level of Care (4):

- 10. Nursing Facility Level of Care
- 11. Pediatric Skilled Nursing Facility Level of Care
- 12. Psychiatric Medical Institution for Children Level of Care
- 13. Skilled Level of Care

## Surgical Procedures (8):

- 14. Bariatric Surgery
- 15. Blepharoplasty Archive
- 16. Cochlear Implant Archive
- 17. Cochlear Implant Repair and Replacement
- 18. Pancreas Transplant
- 19. Septoplasty-Rhinoplasty Archive
- 20. Vagus Nerve Stimulator Archive



#### 21. Varicose Vein Treatment - Archive

## Physician Administered Medications (25):

- 22. Briumvi (ublituximab-xiiy)
- 23. Crysvita (burosumab-twza)
- 24. Elaprase (idursulfase)
- 25. Elfabrio (pegunigalsidase alfa-iwxj)
- 26. Enjaymo (sutimlimab-jome)
- 27. Imjudo (tremelimumab-actl)
- 28. Jelmyto (mitomycin gel)
- 29. Korsuva (difelikefalin)
- 30. Krystexxa (pegloticase)
- 31. Kymriah (tisagenlecleucel)
- 32. Lamzede (velmanase alfa-tycv)
- 33. Lunsumio (mosunetuzumab-axgb)
- 34. Luxturna (voretigene neparvovec-rzyl)
- 35. Natalizumab Agents (Tysabri, Tyruko)
- 36. Nexviazyme (avalglucosidase alfa-ngpt)
- 37. Ocrevus (ocrelizumab)
- 38. Qalsody (tofersen)
- 39. Radicava (edaravone)
- 40. Rystiggo (rozanolixizumab-noli)
- 41. Spinraza (nusinersen)
- 42. Tepezza (teprotumumab-trbw)
- 43. Tzield (teplizumab-mzwv)
- 44. Veopoz (pozelimab-bbfg)
- 45. Xenpozyme (olipudase alfa-rpcp)
- 46. Zolgensma (onasemnogene abeparvovec-xioi)

#### **Criteria Review**

#### Waiver Prior Authorization (2):

- 1. Consumer Directed Attendant Care
- 2. Prevocational Services

#### Durable Medical Equipment (2):

- 3. Gait Trainer/Stander
- 4. Safety Beds

#### Lab (1):

5. Molecular Analysis for Targeted Therapy of Non-Small Cell Lung Cancer

## Surgical Procedures (1):

6. Lung Transplant

#### Physician Administered Medications - New (1):

7. Elevidys (delandistrogene moxeparvovec-rokl)

#### Physician Administered Medications - Review (4):

8. Botulinum Toxins



- 9. Spravato (esketamine nasal spray)
- 10. Vyepti (eptinezumab-jjmr)
- 11. Vyvgart and Vyvgart Hytrulo (efgartigimod alfa-fcab; efgartigimod alfa and hyaluronidase-qvfc)

## **Upcoming Meetings**

- Friday, July 18, 2025
  - Virtual Meeting Link: <a href="https://telligen.zoom.us/meeting/register/Fj7AfNT5Q7G1Pdx7xKTALA">https://telligen.zoom.us/meeting/register/Fj7AfNT5Q7G1Pdx7xKTALA</a>
- Friday, October 17, 2025
  - o Virtual Meeting Link: <a href="https://telligen.zoom.us/meeting/register/LBFFkAvCRrqMX8mCVzbdrw">https://telligen.zoom.us/meeting/register/LBFFkAvCRrqMX8mCVzbdrw</a>

## Adjournment

## **Additional Information**

- Iowa Medicaid CAC contact: CAC@hhs.iowa.gov
- Iowa Medicaid CAC webpage: <a href="https://hhs.iowa.gov/about/advisory-groups/clinical-advisory-committee-cac">https://hhs.iowa.gov/about/advisory-groups/clinical-advisory-committee-cac</a>
- **lowa Medicaid Fee Schedules webpage**: <a href="https://hhs.iowa.gov/programs/welcome-iowa-medicaid/policies-rules-and-regulations/covered-services-rates-and-payments/fee-schedules">https://hhs.iowa.gov/programs/welcome-iowa-medicaid/policies-rules-and-regulations/covered-services-rates-and-payments/fee-schedules</a>
- 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 (Q2 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.

#### **Announcements:**

- Welcome
  - Kartik Anand, MD, Hematology/Oncology

**Approval of the January 17, 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 motioned to approve from the Committee.



- First motion to approve by Dr. Danley
- 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
 ☑ Wendy Sanders, ARNP-Family Practice
 ☑ Dawn Schwartz, ARNP- Neonatology/Pediatrics
 ☑ Dr. Kelli Roenfanz-Family Medicine, OB/Gyn

#### **Old Business:**

#### 1. Power Seat Elevation for Power Wheelchairs

Dr. Jagiello communicated that Power Seat Elevation for Power Wheelchairs was requested at the last meeting to be moved to the April meeting. The existing criteria will now mirror the CMS criteria.

☐ Dr. Kartik Anand-Hematology/Oncology (abstained from voting – new member)

Dr Jagiello opened for Committee Member comments. No comments were offered. Dr Jagiello asked for a motion for approval as amended from the committee.

- First motion to approve by Dr. Sahu
- 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. Geetaniali 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:**

Dr. Jagiello provided the purpose of the Consent Agenda and explained the procedure for archiving a policy. Dr. Jagiello opened for Committee Member comments. No comments were offered.

Dr Jagiello motioned for an approval to the Consent Agenda.

- 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
- ☑ Dawn Schwartz, ARNP- Neonatology/Pediatrics
- ☑ Dr. Kelli Roenfanz-Family Medicine, OB/Gyn
- ☑ Dr. Kartik Anand-Hematology/Oncology

#### **Criteria Review:**

#### 1. Consumer Directed Attendant Care

Lisa Roush with the Iowa Medicaid Quality Improvement Organization presented Consumer Directed Attendant Care (CDAC) as amended. Under the Services Not Covered section, additional verbiage was added to number 22 to reflect, activities the member is able to perform or due to member's age would be considered parental responsibility. This addition was included due to a change that parents can provide CDAC services to minor children.

Example: Some services have been requested that would still be considered parental responsibility, such as, for a child under 16 years of age, a parent would still need to drive them.

Dr. Jagiello clarified that the only change was in line 22 under the Services Not Covered section and opened for Committee Member comments.

- Dr. Ferguson commented on the vagueness and asked for clarification regarding if the parent cannot work and has to stay home.
- Lisa Roush explained in prior rule it stated that a parent can only be a CDAC provider for a person over the age of 18. Recently that rule changed to where a parent can be a CDAC provider for a minor child. If they chose to become a CDAC provider for a member under 18 years of age, they don't necessarily have to stay at home. The child could be attending school or daycare. It is only while providing a CDAC service, such as, feeding, bathing, transfers, toileting, and housekeeping; the services listed in the CDAC agreement.



After clarification Dr. Jagiello offered further opportunity for questions, no other questions were received. Dr. Jagiello motioned for an approval as amended from the Committee.

- First Motion to approve by Dr. Ferguson
- 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

## 2. Prevocational Services

Lisa Roush with the Iowa Medicaid Quality Improvement Organization presented Prevocational Services as amended. Changes included the addition of the Limitations section.

Dr Jagiello opened for Committee Member comments.

- Dr. Danley and Dr. Ferguson asked for clarification on the referenced material.
- Lisa explained that members can have prevocational services with limitations. Prevocational services are used to get the member training to be able to work in the community with established goals. The limitations provide members with the opportunity to succeed in those goals and other pathways for them to continue to work on goals before sending the member into the community to work.

After clarification Dr. Jagiello offered further opportunity for questions, no other questions were received.

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

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

- ☑ 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. Gait Trainer - Stander

Dr. Jagiello presented Gait Trainer – Stander as amended. He explained that the changes to the criteria were minor and grammatical with clarity around the language.

Dr. Jagiello opened for Committee Member comments.

- Dr. Ferguson communicated that she found the wording under number one within the Stander section of the criteria a little confusing and sent a re-drafted paragraph via chat to provide clarity. Dr. Ferguson proposed amending the wording as follows:
  - ...'1) to improve skin integrity, postural alignment, improved circulation and to 2) minimize muscle spasms, atrophy of the leg muscles, the development of contractures or to minimize bone density loss, and to 3) assist with transfer and transition ability.
- Dr. Anand asked if equipment increases bone density?
- Dr. Ferguson explained that sitting and lying down are the least weight bearing things.
   Standing and doing something that is "pounding" is best for your bones.
- Dr. Anand asked if the patient has decreased bone density, and they start standing, is there a measurable change in their bone density or DEXA?
- Dr. Ferguson responded that she was unsure but clarified in general the more weight bearing you have on your bones the more you will maintain your bone density.

Dr. Jagiello asked if there were more questions or discussion, no further comments or questions were received.

Dr. Jagiello motioned for an approval as amended per Dr. Ferguson's recommendation from the Committee.

- First Motion to amend and approve by Dawn Schwartz
- Second Motion to amend and approve by Diana Smith

- ☑ 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



## 4. Safety Beds

Dr. Jagiello presented Safety Beds as amended. He explained that a safety bed is a type of bed typically used for children with behavioral issues to prevent them from harming themselves or eloping during the night. The criteria were changed to include elopement and/or participation in behaviors that result in a significant safety risk. Dr. Jagiello opened for Committee Member comments. No comments were offered.

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

- First Motion to amend and approve by Diana Smith
- Second Motion to amend and 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
- ☑ Dawn Schwartz, ARNP- Neonatology/Pediatrics
- ☑ Dr. Kelli Roenfanz-Family Medicine, OB/Gyn
- ☑ Dr. Kartik Anand-Hematology/Oncology

## 5. Molecular Analysis for Targeted Therapy of Non-Small Cell Lung Cancer

Dr. Jagiello presented Molecular Analysis for Targeted Therapy of Non-Small Cell Lung Cancer as amended. He shared that under the Guidelines section he added information from the NCCN guidelines to provide some additional clarity.

Changes were made to the medical necessity criteria, the NCCN lists at least eight genes that are key in making therapeutic determinations in treating this type of lung cancer and the individual is a candidate for targeted therapy that may be prescribed based on the results. In other words, these are crucial testing, and the testing is going to make a difference in the outcome or the treatment plan for the member. The section on larger testing was eliminated. Some of these panels have over 300 tests, and it is hard to determine clinical utility on every single test. Intentionally kept the panel size to 50 genes or under for the code 81445. Eliminated the section that spoke of larger panels and make changes to the codes as well.

Dr. Jagiello asked Dr. Anand for his thoughts as a subject matter expert for oncology. Dr. Anand supported the changes to the criteria expressing that it would make a big difference for patients at the clinic level. Dr. Jagiello opened for Committee Member comments. No comments were offered.



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

- First Motion to amend and approve by Dr. Ferguson
- Second Motion to amend and approve by Dr. Anand

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. Lung Transplant

Dr. Jagiello clarified that the Lung Transplant criteria was externally reviewed by a transplantation specialist. The specialist added some clarifying conditions or situation where a transplant would not be appropriate.

- o Dr. Anand questioned for acute coronary syndrome, what time frame is it referencing?
- Dr. Danley said that she wouldn't necessarily use that diagnosis unless the individual is having active chest pain and agree it would be helpful to have the length of time clarification.
- Dr. Ferguson said the typical is six weeks for acute and two weeks for sub-acute and agree with getting that clarification from the specialist.

Dr. Jagiello motioned to table the criteria and bring it back to the July 18, 2025, meeting for additional clarification, from the Committee.

- First Motion to table the motion by Dr. Danley
- Second Motion to amend and approve by Wendy Sanders

- ☑ 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

Dr. Jagiello announced the next order of business. Dr. Umbreit will present Physician Administered Medications. Dr. Jagiello clarified that we have public commenters registered to speak. Registered speakers will have their opportunity to provide their comments after Dr. Umbreit has presented.

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

## 7. Elevidys (delandistrogene moxeparvovec-rokl)

Dr. Umbreit presented a complete review of new criteria Elevidys (delandistrogene moxeparvovec-rokl). Dr. Umbreit clarified baseline anti-AAVrh74 antibody titers must be measured and less than 1:400. The Adeno-Associated Virus (AAV) that is used to deliver the gene therapy, if there are certain antibodies to it, they can interfere with the effectiveness of the gene therapy treatments that utilize that specific vector as a delivery vector. Measurement of the antibody titers first provides confirmation the body is going to have the best chance of accepting the treatment.

Dr. Umbreit also shared information regarding Elevidys recently in the news. A report in the middle of March was released disclosing a patient had died suffering acute liver failure after receiving treatment. Throughout the studies they have been aware of the risk of liver damage and is why they have the steroid treatments. They did temporarily pause trials and review data. On April 4, 2025, a group of independent monitors met to review the data. Upon review, it was concluded that the risk benefit profile remained favorable, and dosing should continue without any changes to the study protocols. Based on a European report, they did find and share with regulators the studies with findings within a week. Then at that time the European Medical Association would evaluate the findings. The three trials have resumed dosing as they are aware of the risk of liver damage and are doing what they can to mitigate it. They are making sure the patients are appropriate for therapy and following forward as planned.

Dr. Jagiello asked if this proposed FDA approval is accelerated.

Dr. Umbreit clarified that there are two subdivisions of the approval.

- Patients who are ambulatory and have the mutation. That is a full approval.
- Patients who are non-ambulatory, that is an accelerated approval. That one will require confirmation studies.

Dr Jagiello recognized Dr. Miriam Alboustani, PharmD, Sarepta, who yielded her time back to the Committee but was available for questions.

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

Dr. Jagiello motioned for an approval from the Committee.

- First Motion to amend and approve by Diana Smith
- Second Motion to amend and 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

## 8. Botulinum Toxins (Botox)

Dr. Umbreit presented a complete review of Botulinum Toxins (Botox) as amended. She explained last year when this was brought up for review, we addressed an approval of an additional fifth botulinum toxin, Daxxify (daxibotulinumtoxinA-lanm). Last year the product was not rebate eligible but since has become rebate eligible and is open on the fee schedule. Daxxify is approved for adults 18 years and older with an indication of cervical dystonia.

Updates were made to the Guidelines section including adding a link to a position statement released by the American Headache Society on use of CGRP therapies for migraine prevention. Dr. Umbreit also discussed the off-label usages for Botulinum Toxins (Botox), including primary palmer hyperhidrosis.

Dr. Jagiello opened for Committee Member comments.

- Dr. Danley asked if there was any evidence for trigeminal neuralgia.
- Dr. Umbreit explained that there were some but wasn't listed as a strong recommendation in AHFS when she last reviewed it. She further explained that she limited these criteria to those that had the strongest clinical evidence to support.

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

- First Motion to amend and approve by Dawn Schwartz
- Second Motion to amend and approve by Dr. Danley

- ☑ Dr. Dana Danley-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

#### 9. Spravato (esketamine nasal spray)

Dr. Jagiello recognized a registered speaker, Dr. Valerie Householder, to speak on Spravato (esketamine nasal spray) and explained that Dr. Umbreit would explain the changes and then comments would be accepted.

Dr. Umbreit presented a complete review of Spravato (esketamine nasal spray) as amended. She reported the biggest change was in January of this year. The FDA changed the approval for treatment-resistant depression. Previously Spravato was only indicated in conjunction with oral antidepressant therapy. Now it is indicated as a monotherapy for treatment of treatment-resistant depression. Removed the requirement that the member will continue to use oral antidepressant therapy for treatment-resistant depression. Also removed this requirement from the continuation of therapy criteria. These two changes align with current FDA approval indication. No changes were made to the major depressive disorder. It has not been approved for use as monotherapy.

Dr. Jagiello recognized Dr. Householder, PharmD, BCACP, J&J Innovative Medicine, who yielded her time back to the Committee but was available for questions.

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

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

- First Motion to amend and approve by Dr. Ferguson
- Second Motion to amend and approve by Dr. Sahu

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

#### 10. Vyepti (eptinezumab-jjmr)

Dr. Umbreit presented Vyepti as amended. She explained the guidelines were updated with the biggest change being the recommendation of the small-molecules and monoclonal antibodies targeting the CGRP receptor, which includes Vyepti. The list of therapies was updated with in the criteria as well. Updates were also made to the continuation of therapy section.



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

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

- First Motion to amend and approve by Dawn Schwartz
- Second Motion to amend and 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

# 11. <u>Vyvgart and Vyvgart Hytrulo (efgartigimod alfa-fcab; efgartigimod alfa and</u> hyaluronidase-qvfc)

Dr. Umbreit presented a complete review for Vyvgart and Vyvgart Hytrulo as amended. She clarified the medication differences. Vyvgart is administered intravenously, whereas Vyvgart Hytrulo has the hyaluronidase and is administered as a subcutaneous injection. The new indication, chronic inflammatory demyelinating polyneuropathy (CIDP) in adult patients, is for Vyvgart Hytrulo only at this time and was approved on June 21, 2024. Medical necessity criteria were added for the CIDP indication for Vyvgart Hytrulo only and was presented in detail by Dr. Umbreit. Dr. Umbreit clarified that the details of the electrodiagnostic testing guidelines were not included in the criteria. There is a standard guideline consistent with EFNS/PNS, European Federation of Neurological Societies and the Peripheral Nerve Society, for electrodiagnostic testing that would confirm the diagnosis.

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

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

- First Motion to amend and approve by Dr. Ferguson
- Second Motion to amend and approve by Diana Smith

- ☑ 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:**

Dr. Jagiello thanked everyone for their participation and welcomed Dr. Anand to the Committee.

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

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

#### **Upcoming Meeting:**

Friday, July 18, 2025

## **Motion for Adjournment:**

Dr. Jagiello motioned for approval to adjourn the meeting from the Committee.

• First motion: Dr. Danley

• Second motion: Dr. Sahu

Dr. Jagiello adjourned the meeting.