STATE OF IOWA DEPARTMENT OF
Health AND Human
SERVICES

MEETING AGENDA

DIVISION	Iowa Medicaid Quality Improvement Organization (QIO)		
MEETING TITLE	Clinical Advisory Committee (CAC)		
FACILITATOR	Bill Jagiello, DO		
DATE	April 21, 2023	TIME	1:00pm-4:00pm
LOCATION	Zoom Meeting https://telligen.zoom.us/meeting/register/tZApc-ivrjoiG9z50AeGJM5pm5hrF0cabjPu		

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.

MEETING PARTICIPANTS

Name	**Organization**
☐ Elizabeth Matney, Medicaid Director	Iowa Medicaid
☐ Rebecca Curtiss, DHHS Bureau Chief, LTSS and Medical Policy	Iowa Medicaid
☐ Paula Motsinger, DHHS Bureau Chief, LTSS and Medical Policy	Iowa Medicaid
☒ Bill Jagiello, DO	Iowa Medicaid
☐ Mark Randleman, DO	Iowa Medicaid
☐ Misti Johnson	Iowa Medicaid
☒ Carrie Ortega	Iowa Medicaid
☒ Else Umbreit, PharmD	Iowa Medicaid
☒ Becky Carter	Iowa Medicaid
☒ Cassie Reece	Iowa Medicaid
☒ Barb Cox	Iowa Medicaid
☒ Jennifer Ober	Iowa Medicaid
☒ Pam Lester	Iowa Medicaid
☒ Diane Morrill	Iowa Medicaid

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☐ Carrie McFarland	Iowa Medicaid
☐ Wendy Lathrop	Iowa Medicaid
☒ Charissa Blinkmann	Iowa Medicaid
☒ Dr. Paul Mulhausen	Iowa Total Care
☒ Dr. Nivedita Krishnan	Amerigroup
☒ Dr. Timothy Gutshall	Molina Healthcare of Iowa
☒ Dr. Alexandra Hubbell-Family Practice	Committee Member
☒ Clarice Blanchard, PA-C, Family Practice/ Emergency Medicine	Committee Member
☒ Dr. Dana Danley-Family Practice	Committee Member
☒ Dr. Dennis Zachary-Family Practice	Committee Member
☒ Diana Smith, ARNP-Family Practice	Committee Member
☒ Dr. Polly Ferguson-Pediatric Rheumatology	Committee Member
☒ Dr. Stephen Mandler-Psychiatry	Committee Member
☒ Dr. Chitra Reddy-Endocrinology	Committee Member
☒ Dr. Kathleen Lange-Family Practice	Committee Member

AGENDA TOPIC	RESPONSIBLE PARTY
New Business 1. Continuous Glucose Monitoring Systems, Public Comment.	Dr. Jagiello
Public Comment Period	Guests
Approval of January 20, 2023 Meeting Minutes	Dr. Jagiello
Old Business 1. PAM.Pluvicto (lutetium Lu 177 vipivotide tetraxetan)	Dr. Jagiello
Consent Agenda 1. PAM.Botulinum Toxins 2. PAM.Jelmyto (mitomycin gel) 3. PAM.Luxturna (voretigene neparvovec-rzyl) 4. PAM.Ocrevus (ocrelizumab) 5. PAM.Radicava (edaravone) 6. PAM.Spinraza (nusinersen) 7. PAM.Spravato (esketamine nasal spray) 8. PAM.Tysabri (natalizumab) 9. DME.Augmentative Communication Systems 10. DME.Gait Trainer/ Stander 11. DME.Safety Beds 12. DME.Shower/Commode Chair 13. HHH.Personal Care Services for Children 14. HHH.Private Duty Nursing for Children 15. LAB.Genetic Testing (excludes BRCA) 16. LOC.Nursing Facility Level of Care 17. LOC.Pediatric SNF Level of Care 18. LOC.Psychiatric Medical Institution for Children Level of Care 19. LOC.Skilled Level of Care	Dr. Jagiello

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20. SRG.Autologous Chondrocyte Implantation 21. SRG.Blepharoplasty 22. SRG.Cochlear Implant Repair and Replacement 23. SRG.Septoplasty/ Rhinoplasty 24. SRG.Vagus Nerve Stimulator 25. WPA.Consumer-Directed Attendant Care 26. WPA.Prevocational Services	

Criteria Review ***new order** 1. PAM. Amondys 45 (casimersen) 2. PAM. Exondys 51 (eteplirsen) 3. PAM. Viltepso (viltolarsen) 4. PAM. Vyondys 53 (golodirsen) 5. PAM. Enjaymo (sutimlimab-jome)*NEW* 6. PAM. Korsuva (difelikefalin) *NEW* 7. PAM. Tepezza (teprotumumab-trbw) 8. SRG. Cochlear Implant	Dr. Jagiello
Upcoming Meetings Friday, July 21, 2023 Friday, October 20, 2023 Friday, January 19, 2024	Dr. Jagiello
Adjournment	Dr. Jagiello

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Guests wanting to speak during the public comment period should contact Charissa Blinkmann and complete a Disclosure Form, which is available on our website:
https://dhs.iowa.gov/ime/about/advisory_groups/clinical-advisory-group

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

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Introduction

Dr. Jagiello, Medical Director for IME QIO & Committee Chair, offers the introduction for the quarterly (Q2) Iowa Medicaid Clinical Advisory Committee meeting. Silent roll call proceeded with quorum confirmation.

Announcements

Public Comments

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

1. ***Amy Aikins, Director, Government and Social programs, Little Hercules Foundation, comment on the antisense oligonucleotide policies for DMD (Amondys 45, Exondys51, Viltepso, Vyondys53)***
2. ***Breanne Pink, MSN, ARNP, FNP-C, UnityPoint Clinic-Perinatology, Handout -Written Statement, submitted on CGMs***
3. ***Brian Denger, Community Engagement, Parent Project, Washington D.C., Muscular Dystrophy***
4. ***Chayla Morris, PharmD, BCACP, Ambulatory Care Clinical Pharmacy Coordinator, Broadlawns Medical Center, CGMs***
5. ***Christina Trout, RN, MSN, Neuromuscular Program Nurse Pediatrics, University of Iowa Healthcare Care, Exon Skipping Drugs***
6. ***Emily Beckett, PharmD, BCPS, Family Medicine Residency Clinical Pharmacist, Family Health Center - Broadlawns Medical Center, CGM***
7. ***Kaj Thompson, PharmD, MBA, Principal Scientific Account Lead, Janssen***
8. ***Kate Lanza, Ph.D., Medical Science Liaison, NS Pharma***
9. ***Leslie Zanetti, PharmD, Sr. Director, Medical Managed Care, Team Lead, Sarepta Therapeutics***
10. ***Linda Boehmer, BSN, RN, CPN, Pediatric Neuromuscular Specialty Nurse Pediatric Specialty Clinic, University of Iowa Healthcare. Muscular Dystrophy***
11. ***Marie Frazzitta, DNP, FNP-c, MBA, CDCES, Senior Medical Outcomes Manager, Abbott Diabetes Care***
12. ***Phillip Masters, PharmD, Clinical Pharmacist, Lucas County Health Center, CGM***
13. ***Susie Moroney, PharmD, MS, BCOP, Director, Oncology Value Evidence, Navartis, "Old Business"-Pluvicto,(she's here for questions or comments)***
14. ***Wendy Mobly-Bukstein, PharmD, BCACP, CDCES, CHWC, FAPhA, Associate Professor of Pharmacy Practice, Diabetes Care and Education Specialist. CGM***
15. ***Wendy Sanders, DNP, ARNP, FNP-BC, MercyCare, Diabetes Care***

Approval of the January 20, 2023 Meeting Minutes: Opportunity for additions, corrections, or comments: none requested. The motion to approve by Dr. Ferguson, Diana Smith seconded. All approved and the motion carried.

Old Business:

1. **PAM.Pluvicto (lutetium Lu 177 vipivotide tetraxetan)-**Else Umbreit, PharmD, presented that no changes were made on the policy from when it was opposed in January, and reviewed the criteria. Dr. Jagiello presented the discussion around Criteria C, and advised additional research was completed, and the policy will remain the same.

Public Comment-Susie Moroney, PharmD, MS, BCOP, Director, Oncology Value Evidence, spoke she was in attendance to answer any questions but didn't have any public testimony to present. First motion to approve Dr. Lange, and second motion by Clarice Blanchard, PA-C. All approved and the motion carried.

New Business:

1. **Continuous Glucose Monitoring Systems**-Dr. Jagiello opened this policy up for discussion.

Public Comment-Roy Thomas, PharmD, Director, Dexcom, is in attendance to present their CMS Letter on CGMs (from Gary Parenteau). Dr. Jagiello commented the medical necessity of the device information will be taken into consideration, but it is not within this committee to be able to consider this for pharmacy distribution. And the information will be passed onto the Iowa Medicaid Pharmacy Department. Dr. Jagiello presented Breanne Pink's Written Statement Letter for CGMs. Dr. Reddy, Committee Member, presented comments to the aspect of removing the amount of finger sticks after eligibility approval, as well as the benefit to women who qualify who are pregnant. Dr. Jagiello commented on the changes made to the CGM policy within recent months, and clarified on the technology evolution has increased verifiable validity for treatment. Dr. Reddy advised that was the case and correct. Wendy Sanders, DNP, ARNP, MercyCare, Diabetes Care, spoke to the obstacles her patients have and the testing requirements for Medicaid, and hopeful Medicaid will follow suit with the CMS guidelines, to stop requiring members to jump through hoops for approval of a CGM. She spoke to the member and patient improvements, and benefits of less complications, less hospitalizations, less long term affects, and lessens the financial strain on a strained healthcare system. Marie Frazzitta, DNP, FNP-c, MBA, CDCES, Abbott Diabetes Care, presented testimony and spoke to blinded vs unblinded CGMs, all personal CGMs are unblinded, only professional CGMs have the option for blinded or unblinded. She provided the clinical data showed those who weren't monitoring had the most reduction in A1C, because of the ease of use. She commented on new CMS changes because of the clinical data evidence they have expanded coverage to anyone using insulin, and critical conditions that can happen with the use of sulfonylurea, with the and spoke to the current standard of HbA1c level remaining above 7.0 verse the new standard of care being used by the national care organizations, is time and range, and the added value of CGMs is it picks up hypoglycemia and glucose variability, where without the A1C doesn't show those, as it misses the patient centered data. She provided testimony on the benefits evidenced in a new Medicaid study published in 2023 and the vast member benefits and along with having ease of access with the pharmacy benefit. She provided update details on the latest advances of the devices. Dr. Jagiello requested she send over the study she referenced for review. She confirmed she will send the information. Wendy Mobly-Bukstein, PharmD, BCACP, CDCES, CHWC, FAPhA, Associate Professor of Pharmacy Practice, Diabetes Care and Education Specialist, CGMs, she presented public comment for CGM benefits and the new Medicare guidelines for July 2022, as during the Public Health Emergency, they decreased their requirement to one injection per day, and now making it the standard as of April 16, 2023. She asks that the committee consider aligning the policy for Medicaid. She would also like Medicaid to align with Medicare, as they don't require any finger sticks. She advises the benefits of alignment will also

help decrease confusion on the requirements. Phillip Masters, PharmD, Clinical Pharmacist, Lucas County Health Center, CGMs, communicated support for the testimony given today, and gratitude for policy review, and the committee reviewing this policy, with the prior conversation as when more payors start to cover CGMs for one injection a day, that more consideration in depth going forward in this upcoming July. Emily Beckett, PharmD, BCPS, Family Medicine Residency Clinical Pharmacist, Family Health Center, Broadlawns Medical Center, CGMs, provided testimony on being in support of what has been presented on this policy today and her support in streamlining accessibility for Medicaid is necessary. She recommends removal of finger stick requirements and aligning with the new CMS requirements for Medicare patients and the better clinical outcomes for patients with CGMs; also, to help with improving health equity and accessibility, she supports pharmacy benefit being included. Chayla Morris, PharmD, BCACP, Ambulatory Care Clinical Pharmacy Coordinator, Broadlawns Medical Center, in attendance to speak to CGMs policy and support of alignment, to offer the same standards of CMS for CGM eligibility, including updating the requirements to one injection a day and removing finger sticks, to ensure they are meeting their Mission of providing high quality, affordable and equitable healthcare to the community of the most vulnerable. She spoke to the improvement in patient/member health rate outcomes. Dr. Jagiello thanked all in attendance who presented.

Consent Agenda

Review for Approval of the 26 policies. Opportunity for additions, corrections, or comments: none requested. The motion to approve by Clarice Blanchard and second motion by Dr. Zachary. Public Comment-Kaj Thompson, PharmD, MBA, Principal Scientific Account Lead, Janssen, in attendance and presented information on the Spravato policy, he is requesting removing of criteria 2 from the continuation of therapy criteria, with data support on the second induction phase information. Dr. Jagiello requested he send the links to those studies, for further review. All approved and the motion carried.

Criteria Review Agenda

Amondys 45 (casimersen)
Exondys 51 (eteplirsen)
Viltepso (viltolarsen)
Vyondys 53 (golodirsen)

Public comment by Christina Trout, RN, MSN, Neuromuscular Program Nurse Pediatrics, University of Iowa Healthcare Care, Exon Skipping Drugs. Dr. Jagiello confirmed receipt of their department clinic letter, from their SME experts Dr. Mathews and Dr. Saade for Duchenne Muscular Dystrophy and treatments and outlined their recommendations based off newly published and presented data and the requested changes to the policy. Dr. Jagiello commented on the process for ETP for MCOs and FFS. Dr. Krishnan, AGP, commented on the ETP process and rationale approach for Amerigroup. Dr. Mulhausen, ITC, commented on the process for EPT for Iowa Total Care driven by coverage and benefit structure, or by circumstances around medically necessary where it's not a covered benefit, but essential for the health of the member.

Christina Trout further showed the changes or adjustments requested to the policy and explained the change rationales. Linda Boehmer, BSN, RN, CPN, Pediatric Neuromuscular Specialty Nurse, Pediatric Specialty Clinic, University of Iowa Healthcare. Muscular Dystrophy, in attendance to support the changes requested and thank the committee for the review for the EPT process. Amy Aikins, Director, Government and Social programs, Little Hercules Foundation, DMD, for (Amondys45, Exondys51, Viltepso, Vyondys53) offered public comment with professional experience and personal testimony on the antisense oligonucleotide policies for DMD regarding the benefits of treatments for patients. She supports the requested changes to the policy regarding age range and requests consideration of having assessments for Prior Authorization and presented the available tests that other states use to approve them. Brian Denger, Community Engagement, Washington D.C., Parent Project, DMD, sent shared letter and in attendance. He provided personal testimony and professional experience for criteria changes requested. He outlined the changes he'd like to see for these policies and the reconsideration of restrictions, and expand coverages, based on the FDA label which has no age for ambulatory status restrictions and to the benefits for the members with DMD. Christina Trout, commented on the new additionally published data presented at the MDA conference in March 2023, with new real-world data being presented showing the longer that members are on the Exon Skipping therapies the more benefit they have prolonging ambulatory status, independent breathing, and independent function, and they are willing to further discuss the references detailed or data and send the newest publications over for further review. Kate Lanza, Ph.D., Medical Science Liaison, NS Pharma, is present and offered public comment, spoke to the Viltepso drug therapy criteria, and data with improvements/benefit for patients. She offered the resource website, viltepso.com, for full prescribing information, and they request the policy to be updated with the guidelines of the prescribing information (no ambulatory or age restrictions). Dr. Jagiello requested they send any of the studies forward that they would like reviewed. Leslie Zanetti, PharmD, Sr. Director, Medical Managed Care, Team Lead, Sarepta Therapeutics, in attendance for public comment regarding the exon skipping therapy drugs. She requests the age and ambulatory restrictions be removed by the committee for eteplirsen, golodirsen and casimersen. She outlined clinical studies and benefits to members. Dr. Jagiello requested those studies to be sent over for further review. Else Umbreit, PharmD, presented information on the 4 expedited approval pathways which are: Priority Review, Breakthrough Therapy, Fast Track and Accelerated and thanked everyone for the great information and guidelines they had sent over. Dr. Jagiello expanded on the information for these processes and thanked all presenters. He addressed the existing two criteria for age and ambulatory status within the policies, with the committee members, and opened it for discussion: Christina Trout commented on the difficulty of getting the policy criteria for the MCOs, when submitting a Prior Authorization they aren't unaware of the differences in criteria of the different organizations and it creates confusion when there are differences among the policies, so she requests be aligned and all consistent with the requests they've submitted and they'd appreciate a copy from each of them. Dr. Jagiello advised where to locate the policies. Dr. Mulhausen, ITC, advised their most frequently used 100 policies are posted on their website, and many pharmacy policies used for medical necessity and the best way to obtain a copy would be to email him directly and he is happy to share any policy. Dr. Krishnan, AGP, states most of their policies are up on the external website provided the contact link they can save as a resource.

Dr. Jagiello offered change of time frame for review to 1 year review instead of 6 months. Dr. Zachary agrees to moving it to 1 year. Dr. Lange supports that decision to move it to 1 year for therapy continuation. Dr. Mulhausen, ITC, commented on the process and supports 6 months, instead of 1 year. Dr. Gutshall, MHC, offered comment on support to use data in the review of these therapies, he is open to re-evaluating them to for efficiency. Dr. Krishnan, AGP, offered comment that their criteria is at 6 months, and she doesn't see any obstacles to keeping it at 6 months. Else Umbreit, PharmD, commented the benefits to both options and open to either determination. Dr. Jagiello presents as not a strong consensus on either side, so the policy will remain at 6 months continuation of therapy. The Molina Health Care policy was just received and will also be reviewed before they are live in July. Dr. Jagiello calls to review the continuation criteria. Dr. Krishnan, AGP, commented currently similar, and Dr. Mulhausen, ITC, commented it aligns for the most part with the current policy. Christina Trout advised they are available for any additional information needed to make the determination. Else Umbreit, PharmD, advised the Policy Criteria hasn't changed, only the updated reference or coding had changed. Dr. Jagiello advises a need for further review and to taking vote for motion to consider as a group and asks for any objection, no objections given. First motion to approve by Dr. Zachary and seconded by Clarice Blanchard. All approved these four policies as written and the motion carried.

Enjaymo (sutimlimab-jome)-Else Umbreit, PharmD, presented this new policy. Opened for questions or comments, and no public comment requested. First motion to approve by Dr. Hubbell and seconded by Dr. Danley. All approved and the motion carried.

Korsuva (difelikefalin)-Else Umbreit, PharmD, presented this new policy. Opened for questions or comments, and no public comment requested. First motion to approve by Dr. Zachary and seconded by Dr. Lange. All approved and the motion carried.

Tepezza (teprotumumab-trbw)-Else Umbreit, PharmD, presented this as an annual review for this policy. Public comment offered by Anuj Patel, Regional Medical Director for Horizon Therapeutics, and he provided drug information overview. He needs to send over the signed Disclosure form. Else Umbreit, PharmD, commented a further review for the FDA label change and bring it back to the committee at a later date. She requested he send it over any information newer than 2022 for that review. He confirmed he will send that information over. Dr. Jagiello requested to table this policy for review additional literature and bring it back in July. First motion to table and reconsider by Dr. Lange and seconded by Clarice Blanchard. All approved to table the policy to reconsider in July, and the motion carried.

Cochlear Implant-Dr. Jagiello presented the policy. Reviewed the change to Criteria 2, to expand the indications for unilateral hearing loss for both adults and children, with consistency across the policies of all 3 MCOs and FFS, except one organization that doesn't currently allow for unilateral hearing loss, but would consider it in the near future, and would consider it if a prior authorization request is received. Opened for questions or comments, with no comments from the committee. Public comment by Anne Anthony, she needs to send over the signed Disclosure form, she asks consideration under criteria for the Intended Ear 2 A 1, for reference

there are two different manufacturers that have FDA indications, The Cochlear has a level of greater than 80 decibels, as of January 2022. Dr. Jagiello offered comment on satisfaction of unification and expansion of this current policy and requested she send the new information to him for review and consideration of the expansion in the future. First motion to approve the amended policy by Diana Smith and seconded by Dr. Danley. All approved and the motion carried.

Closing Comments- No further comments or questions.

Next Meeting- July 21, 2023

Meeting was adjourned.