STATE OF IOWA DEPARTMENT OF
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MEETING AGENDA

DIVISION	Iowa Medicaid Quality Improvement Organization (QIO)		
MEETING TITLE	Clinical Advisory Committee (CAC)		
FACILITATOR	Bill Jagiello, DO		
DATE	October 20, 2023	TIME	1:00pm-4:00pm
LOCATION	Zoom Meeting https://telligen.zoom.us/meeting/register/tZMrdO6spj0oHdE1F0J4Pkns53XnPPCQbW6t		

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
☒ Else Umbreit, PharmD	Iowa Medicaid
☒ Misti Johnson	Iowa Medicaid
☒ Carrie Ortega	Iowa Medicaid
☒ Heidi Weaver	Iowa Medicaid
☒ Diane Morrill	Iowa Medicaid
☒ Charissa Blinkmann	Iowa Medicaid
☐ Becky Carter	Iowa Medicaid
☒ Cassie Reece	Iowa Medicaid

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☐ Barb Cox	Iowa Medicaid
☒ Pam Lester	Iowa Medicaid
☐ Carrie McFarland	Iowa Medicaid
☐ Wendy Lathrop	Iowa Medicaid
☒ Cindy Palmer	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. Chitra Reddy-Endocrinology	Committee Member
☐ Dr. Kathleen Lange-Family Practice	Committee Member

AGENDA TOPIC	RESPONSIBLE PARTY
New Business	Dr. Jagiello
Public Comment Period	Guests
Approval of July 21, 2023 Meeting Minutes	Dr. Jagiello
Old Business 1. Continuous Glucose Monitoring Systems (CGMs)	Dr. Jagiello
Consent Agenda 1. DME.Negative Pressure Wound Therapy 2. DME.Percussors 3. SRG.Panniculectomy 4. THR.RepetitiveTranscranial Magnetic Stimulation 5. PAM.Abecma (idecabtagene vicleucel) 6. PAM.Bavencio (avelumab) 7. PAM.Breyanzi (lisocabtagene maraleucel) 8. PAM.Carvykti (ciltacabtagene autoleucel) 9. PAM.Danyelza (naxitamab-gqgk) 10. PAM.Kadcyla (ado-trastuzumab emtansine) 11. PAM.Zulresso (brexanolone)	Dr. Jagiello
Criteria Review 1. DME.Wearable Automated External Defibrillator 2. SRG.Autologous Chondrocyte Implantation 3. THR.Family Functional Therapy (FFT) *new* 4. THR.Multi-Systemic Therapy (MST) *new* 5. WPA.Medical Day Care for Children *new* 6. PAM.Briumvi (ublituximab-xiiy) *new*	Dr. Jagiello

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7. PAM.Darzalex and Darzalex Faspro (daratumumab; daratumumab and hyaluronidase) *new* 8. PAM.Elahere (mirvetuximab soravtansine-gynx) *new* 9. PAM.Leqembi (Lecanemab-irmb) *new* 10. PAM.Phesgo (pertuzumab, trastuzumab, and hyaluronidase-zzxf) *new* 11. PAM.Tecvayli (teclistamab-cqyv) *new* 12. PAM.Aduhelm (aducanumab-avwa) 13. PAM.Padcev (enfortumab vedotin-efjv) 14. PAM.Amondys 45 (casimersen) 15. PAM.Exondys 51 (eteplirsen) 16. PAM.Viltepso (viltolarsen) 17. PAM.Vyondys 53 (golodirsen)	
Upcoming Meetings Friday, January 19, 2024 Friday, April 19, 2024 Friday, July 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 webpage at: https://dhs.iowa.gov/ime/about/advisory_groups/clinical-advisory-group

Meeting Minutes

Introduction

Dr. Jagiello, Medical Director for IME QIO & Committee Chair, offers the introduction for the quarterly (Q4) Iowa Medicaid Clinical Advisory Committee meeting. Silent roll call proceeded with quorum confirmation.

Announcements

Dr. Jagiello acknowledged our registered public speakers and will give an opportunity for each presentation when the policy is reviewed, and provided a reminder there is a maximum time allotment of five minutes for each guest.

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Approval of the July 21, 2023 Meeting Minutes: First motion to approve by Dr. Ferguson. Second motion by Dr. Hubbell. All approved and the motion carried.

Public Comments

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

1. *Roy Thomas, PharmD, Director, Medical Science, Managed Markets, CGMs*
2. *Gary Parenteau, National Accounts Executive, Medicaid, Dexcom, CGMs,*
3. *Petra Gorombei, ZOLL, she will speak on behalf of her colleagues for Wearable Cardioverter Defibrillator (WCD)*
4. *Kate Walton, ZOLL, Sent information for review only.*
5. *Dena Benson-Scearce, ZOLL, JD Government Relations, sent Information for review only.*
6. *Michael Wolnerman, RPh, CCIM, OneroRx, CGMs*
7. *Hannah Martin, MPH, RDN, Director of Advocacy, Association of Diabetes Care & Education Specialists, CGMs, Submitting written comments only.*
8. *Kaj Thompson, PharmD, MBA, Janssen*
9. *Christina Trout, RN, MSN, UIHC, Neuromuscular Program Nurse, Letter from the UIHC (April 2023) & (October 2023) on Exon Skipping therapies. Duchenne Muscular Dystrophy (DMDs)Rachel Kinn, UIHC, (Sarepta) and Dr. Mathews, UIHC*
10. *Gary Doughtry, Director, State Government Affairs, American Diabetes Association, CGMs,Sent Letter for review.*
11. *Daniel Cornett, PharmD, BCPS Director, ImmunoGen, Mirvetuximab/ PAM.Elahere (mirvetuximab soravtansine-gynx)*
12. *Emily Beckett, PharmD, BCPS, Broadlawns Medical Center, CGMs*
13. *Peter Bak, Senior Advisor, Vericel Corporation, with Dan Doyle who sent packet of information, reviewed; SRG.Autologous Chondrocyte Implantation*
14. *Rhonda Showman, personal testimony of her child on Vyondys 53 since 2021. Exon Skipping therapy (DMD)*
15. *Lisa Sershon, DMSc, PA-C, MSCS, Midwest, TG Therapeutics, Ublituximab*
16. *Dr. Katherine Mathews, UIHC, Stead Family Department of Pediatrics, Pediatric Neurology, Sarepta Therapeutics, DMD therapies*
17. *Marie Frazzitta, DNP, FNP-c, PNP, MBA, CDCES, Abbott, CGMs*

18. *Linda Boehmer, BSN, RN, CPN UIHC, Stead Family Department of Pediatrics, Pediatric Neuromuscular Specialty Nurse, DMD therapies*

19. *Julie Babbage, Diabetespac.org, DPAC, patient advocacy, CGMs*

20. *Melissa M. Batt, ARNP, DNP, MercyOne Iowa, CGMs, Letter sent for review*

Old Business:

1. **Continuous Glucose Monitoring Systems, CGMs:**
   Dr. Jagiello provided a brief update and context for this discussion and policy movement through 2023. Medicare has revised their policy criteria twice and a lot of interest from DME providers and network advocacy groups to adopt our policy to the changing environment, so this is the third time this year the criteria has come before the committee. There were some technical issues with the last set of criteria approved by the committee, HHS has redesigned the website so there was length of time the CAC webpage was down and not available, and the requested changes to be implemented have been slower going, so the older policy still remains, and he assured that after this policy is approved all of the changes will be posted together to the website.
   Iowa Medicaid staff, Rebecca Wedemeier will present updates today on CGMs and the internal request to change administration of CGMs from a Medical Benefit to a Pharmacy Benefit.
   Becki Wedemeier, HHS, presented on the exciting opportunity, they have to participate in the CGM Access Accelerator Program, through the center for Health Care Strategies, with submission of their application for the program back in May, and accepted. There was discussion on changing the Iowa Medicaid administration of CGMs from the DME policy to the Pharmacy Program and she submitted it through this program to work through, with Dr. Jagiello's recommendation to change to pharmacy benefit, and it was recognized that the work behind changing it at this time, was more extensive and more that what Iowa Medicaid could complete, and Rebecca Curtiss had the program on hold, as they continue to explore if it is in Iowa's best interests for our members to move from the medical policy to the pharmacy policy with a decision to be made in the future. They had their first meeting with the 6 other states who are participating in this program, with 5 of them having the goal to change from medical to pharmacy and one state that has already implemented it. They are looking to learn from those states' decisions while exploring social determinants of health on if there is any effect on the CGMs. She states that Dr. Jagiello and members from each MCO are participating as they explore change opportunity. Dr. Jagiello presented the criteria changes on the revised policy.

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Criteria

Prior authorization is required.

A CGM device is medically necessary when **ALL** the following are met:

1. Member has a diagnosis of Type 1 or Type 2 diabetes mellitus requiring the use of insulin multiple times daily or are on an insulin pump; **AND**
2. The member (or their caretaker) has demonstrated the ability to use such a device and analyze the data to make adjustments; **AND**
3. Treatment guidelines have been provided to the member (or their caretaker) that allows them to safely and effectively take advantage of the information provided by the device; **AND**
4. The member has **ONE** of the following:
   a. Experiencing reoccurring episodes of hypoglycemia; **OR**
   b. Inadequate glycemic control, as demonstrated by HbA1c measurements 7.0% or greater, despite multiple alterations in self-monitoring and insulin administration regimens to optimize care; **OR**
   c. Type 1 diabetes and 18 years of age or younger.

These criteria refer to outpatient chronic interstitial real-time CGM. They do not include acute CGM in a hospital setting. Only long-term use is approved for coverage. CGM is not covered for convenience of the member, provider, or caretaker.

Dr. Jagiello opened the meeting to public comments on CGMs:

Roy Thomas, NSL Dexcom, PharmD- requesting CGM access be allowed for anyone using insulin regardless of diabetes type and for pregnant women with gestational diabetes regardless of their treatment, their label is broad, G6 and G7 are FDA approved as replacement for finger sticks in patients 2 years and older to make diabetes treatment decisions. He presented recognition that CGMs are safety tools, Medicare covers CGMs for any insulin using patients and any patients experiencing problematic hypoglycemia, evidence, guidelines from ADA, policy organizations such as Center for Healthcare Strategies, they ask Iowa Medicaid patients in the groups above have allowance to access CGMs without the fingerstick requirement, at the pharmacy or through DME benefit.

Gary Parenteau, Dexcom, CGMs, he is in attendance, but not testifying today.

Michael Wolnerman, RPh, OneroRX, CGMs, offered personal testimony on the health improvements with the use of CGMs and how it's motivating patients and making a huge difference in their lives, which he sees firsthand. He asks that Iowa Medicaid expand its CGM benefit from the current intensive insulin therapy (IIT), to one that includes "any insulin" and for gestational diabetes regardless of if they are on insulin, and in patients with significant hypoglycemia, which would align with the ADA Standard of Care 2023. Many states (MO, OK, WY) Medicaid programs have implemented this type of benefit and have gone to pharmacy insulin lookback, that improves outcomes and quality of life for these patients. It will save taxpayer dollars in the long run and improve the lives of Iowans who need it the most, in underserved Populations.

Gary Doughtry, Director, State Government Affairs, American Diabetes Association, Sent Letter for review, CGMs. His letter was displayed, and he is in favor of reducing the number of daily

insulin administration from multiple down to basal insulin dosing and asked about the channel improvement of access to pharmacy versus medical benefit, and for use in treatment of gestational diabetes.

Emily Beckett, PharmD, BCPS, Broadlawns Medical Center, CGMs, she appreciates the simplicity and advocates to continue to make things more open to "any insulin" use and she requested Medicaid remove the multiple insulin shots daily criterion and make a vote on it today to minimize the confusion with suppliers, and also agrees with previous speakers regarding use for gestational diabetes. She speaks to the minimal cost with a great benefit of maternal-fetal outcomes, she urged a motion from the committee today.

Marie Frazzitta, DNP, FNP-c, PNP, MBA, CDCES, Abbott, CGMs, presented and thanked the committee for the removal of multiple finger-sticks a day criterion, as that move is a step in the right direction, and shared recently NCQA added glucose management index (GMI) as a quality metric for HEDIS 2024. She shared a study after the last CAC meeting done by the NIH, that highlighted the benefits of the use of CGMs with insulin using patients, within a retrospective study of over 3,000 Medicaid patients with Type 2 Diabetes, that showed that CGM use showed a statistical significance of 1.2% reduction of hemoglobin A1c, and that the outcome was comparable across all major racial/ethnic groups, and to share that data again in support of expanding to all patients with IUP. Lastly, she shared on utilizing CGMs for gestational diabetes, as she was a high-risk pregnancy nurse practitioner running a diabetes and pregnancy program and thanked Dr. Thomas, who spoke to the maternal-fetal complications that are associated with hyperglycemia, and she wanted to highlight that babies that exposed to hyperglycemia in utero are metabolically programmed differently and that those children are at a much higher risk for childhood obesity and diabetes. So investing in good maternal care by minimizing exposure of hyperglycemia, provides long term benefits as well as improvement in immediate outcomes.

Julie Babbage, Diabetespac.org, DPAC, CGMs, presented on behalf of the diabetes patient population on how critical this tool is, and the significant return on the investment, for ensuring the people with diabetes have the tools to manage diabetes, and the CGM has emerged as a critical aspect of this care, as diabetes is an incredibly complex chronic condition. DPAC urges the criteria to be adopted to close the gaps in access, as CGMs are the standard of care.

Marie Frazzitta, provided an additional comment on the criteria that requires people with diabetes to experience an adverse event (hypoglycemia) in order to qualify for a CGM, as hypoglycemia or DKA are both life threatening, and hypoglycemia can cause cognitive decline, so the CGM is a patients safety tool that studies have shown significance in outcomes with reduction of hypoglycemia and DKA. Being proactive regarding prevention, of these life altering events, improves quality of life and positive impact by reducing cost of care by preventing avoidable utilizations, and thanked the committee for their consideration to remove that requirement. Dr. Jagiello responded on the research regarding hypoglycemic events, and he simplified the language on it and aligns with not wanting a patient to risk harm prior to accessing the device.

Melissa Batt, ARNP, DNP, MercyOne Iowa, CGMs, and was not in attendance but she sent a letter that was presented during the meeting and reviewed.

Roy Thomas, responded with comments on hypoglycemia, and that Medicare advocates for the use of a CGM as soon as a patient is prescribed insulin, because it's a safety tool which helps the patient prevent hypoglycemia and gives patients the confidence to use their insulin, the Medicare specifications on problematic hypoglycemia criteria exists when a patient is not using insulin.

Wendy Mobley-Bukstein, Chair of the Iowa ADCES, presented comments from this group and the national group as well. She wants to echo what the other presenters have commented on today with any amount of insulin should be a criterion, instead of requiring multiple daily injections, as well as including gestational diabetes and presented information on how it helps maternal-fetal health and wellness. She asks these two criteria are considered.

Dr. Dana Danley, committee member, provided a statement on evidence regarding time in range (TIR) versus A1c, and that the lower time in range corresponds with lower complication rates with diabetes, and can help prevent problems. With a CGM, patients can monitor it more closely and the American Academy of Clinical Endocrinology (AACE) talks about the economic analysis of CGMs and how it maybe an initial slight increased cost, but over time it does improve quality of life, years of life, decrease of strip use, decrease non severe hypoglycemic events and has significant benefits, so she is in favor of removing the need for twice daily insulin, as there is increasing evidence in time in range (TIR), not just A1c preventing complications both short term and long term, and there are other options now with medications, and give patients a variety of medications to try but it's difficult to get patients in range, with insulin being the last therapy physicians go to as it has metabolic complications, so she advocates to see this change within the policy.

Dr. Jagiello provided responses to the feedback provided regarding gestational diabetes and comments it is not excluded even though it's not specifically called out in this iteration of the CGM policy and that there is allowance for more research and to consider the standard of care, to add further criteria. He will explore development of criteria or conditions. He commented on the evidence-based resources for improved outcomes and requested Dr. Danley to send over her resource she presented on today for review.

Dr. Jagiello opened the policy to the committee for comments: Dr. Ferguson comments she agrees that gestational diabetes needs to be addressed and outlined options for including it. He responded on options to have it included in the future. Dr. Ferguson added another comment on the approval/review process for this policy and when it comes back for review, Dr. Jagiello advised it will be brought back in January 2024. He will explore the areas for adding criteria to the policy. He asks for approval today for policy as it stands, and then for it to be brought back in January. First motion to approve by Dr. Zachary. Second motion to approve by Dr. Ferguson. All approved and the motion carried. Dr. Jagiello thanked everyone who has been involved in the conversation on this policy today.

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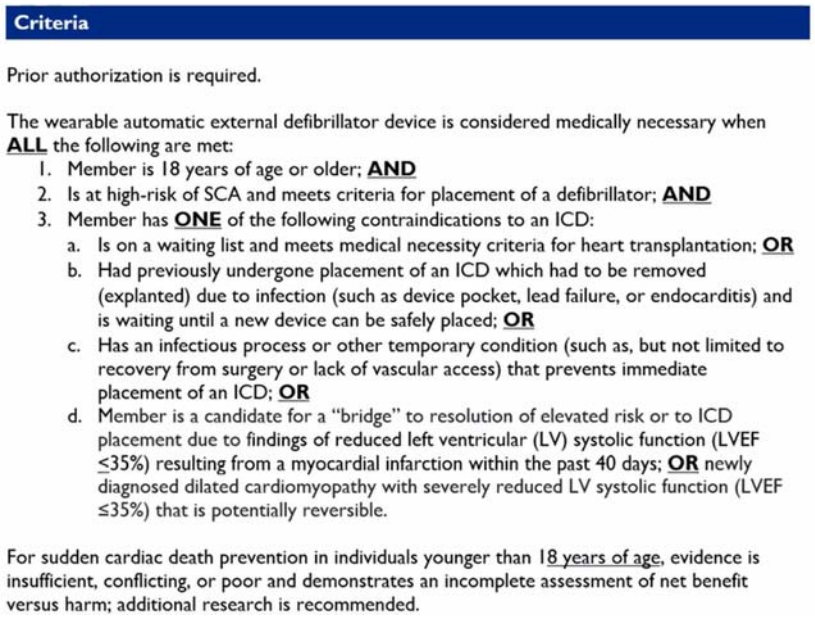
Consent Agenda Items: opened for discussion or comments and no additional comments provided. First motion to approve by Dr. Zachary. Second motion to approve by Dr. Hubbell. All approved and the motion carried.

Criteria Review Items review:

1. **Medical Day Care for Children:** LeAnn Moskowitz. HHS presented a high-level view presentation for this new policy. During the PHE, Iowa Medicaid requested Appendix K flexibility for Respite Care provision while the primary care giver was working, CMS approved it for while working from home, but didn't approve for while they are working outside the home. They worked with CMS to develop alternative services to fill that need during the PHE, so this policy replaces Respite while the primary care giver was working inside or outside the home. They have submitted the waiver amendments to permanently adopt this service under the waivers that serve children-BI, CMH, HD & ID. It is intended for children with complex medical needs or complex behavioral health needs who don't have access to any other daycare or childcare services. The limitations, exclusions, and continued services were presented. The policy was opened to the committee for comment, with no comments.
    - First motion to approve by Dr. Zachary.
    - Second motion to approve Dr. Hubbell.
    - All approved and the motion carried.
2. **Family Functional Therapy:** Jenny Erdman, HHS, presented this new policy. The main goal is to improve family communication and supports to decrease intense negativity and dysfunctional patterns of behavior, and the therapy also includes training for the parents on how to assist their child based on their diagnosis. She presented the service expectations, admission criteria, continued stay criteria, discharge criteria, exclusion criteria, coding, and compliance. There were no comments or questions from the committee.
    - First motion to approve Dr. Ferguson.
    - Second motion to approve Clarice Blanchard.
    - All approved and the motion carried.
3. **Multi-Systemic Therapy:** Jenny Erdman, HHS, presented this new policy. It is an evidenced-based intensive treatment process that focuses on diagnosed behavioral health disorders and on the environmental systems that contribute to potential involvement in the juvenile justice system. She presented the service expectations, admission criteria, continued stay criteria, discharge criteria, exclusion criteria, coding, and compliance. There were no comments or questions from the committee.
    - First motion to approve Dr. Zachary.
    - Second motion to approve Diana Smith.
    - All approved and the motion carried.
4. **Wearable Automated External Defibrillator:** Revision of the policy. Zoll is the manufacture of the device and presented gaps that have been reviewed. Dr. Jagiello presented this policy. He reviewed the criteria. Additional criteria needed under "d" was added.



Criteria

Prior authorization is required.

The wearable automatic external defibrillator device is considered medically necessary when **ALL** the following are met:

1. Member is 18 years of age or older; **AND**
2. Is at high-risk of SCA and meets criteria for placement of a defibrillator; **AND**
3. Member has **ONE** of the following contraindications to an ICD:
   a. Is on a waiting list and meets medical necessity criteria for heart transplantation; **OR**
   b. Had previously undergone placement of an ICD which had to be removed (explanted) due to infection (such as device pocket, lead failure, or endocarditis) and is waiting until a new device can be safely placed; **OR**
   c. Has an infectious process or other temporary condition (such as, but not limited to recovery from surgery or lack of vascular access) that prevents immediate placement of an ICD; **OR**
   d. Member is a candidate for a "bridge" to resolution of elevated risk or to ICD placement due to findings of reduced left ventricular (LV) systolic function (LVEF ≤35%) resulting from a myocardial infarction within the past 40 days; **OR** newly diagnosed dilated cardiomyopathy with severely reduced LV systolic function (LVEF ≤35%) that is potentially reversible.

For sudden cardiac death prevention in individuals younger than 18 years of age, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit versus harm; additional research is recommended.

Multiple letters were received by cardiologists, and these were presented and identified the cardiologists that signed in support of updating the criteria.
Petra Gorombei, ZOLL, presented on the policy and submitted information before the meeting. She confirmed that the addition of "d" addresses their concerns about the current criteria.

- First motion to approve by Dr. Hubbell.
- Second motion to approve by Dr. Danley.
- All approved and the motion carried.

5. **Autologous Chondrocyte Implantation:** Dr. Jagiello presented this policy. This is an existing policy. The manufacturer Vericel pointed out that "minced" ACI is not medically necessary, so the criterion was updated, and the J-Code was opened.
   Peter Bak, Senior Advisor, Vericel, presented on the MACI product within the 351 category for the approval. And he presented how their product is different from the policy product. He confirmed the code J7330 is correct. He confirmed the criteria describes the essential components and presented how MACI is not investigational. Dr. Jagiello confirmed the policy modification. Peter confirmed the policy addresses their concerns. There were no further comments from the committee.
   - First motion to approve Dr. Zachary.
   - Second motion to approve by Dr. Hubbell.
   - All approved and the motion carried.
6. **Briumvi:** Dr. Else Umbreit presented the new policy. A new medication for Multiple Sclerosis (MS). She presented the overview, descriptive narrative and criteria, coding and product information, compliance. Lisa Sershon, PA-C, TG Therapeutics, and she is present to provide commentary to encourage adding it to the Preferred Agents, which can limit access to high quality care. Early initiation results at less disability at 5 and 10 years. She advocates for high efficacy therapy to prevent CNS damage. Dr. Umbreit commented on the availability of the high efficacy therapies which are available on the medical benefit side, so they won't be seen on

preferred drug list, and they can be found on the Fee Schedule. There were no additional comments for questions on the policy.

- First motion to approve by Dr. Zachary.
- Second motion to approve by Dr. Ferguson.
- All approved and the motion carried.

7. **Darzalex and Darzalex Faspro:** Dr. Umbreit presented the new policy and will be found under the medical benefit for treatment of multiple myeloma (MM) and systemic light chain amyloidosis. She presented the policy overview, descriptive narrative, guidelines, criteria, continued therapy, approval duration and quantity limits, coding and product information. There were no additional comments.
    - First motion to approve by Dr. Ferguson
    - Second motion to approve by Dr. Zachary.
    - All approved and the motion carried.
8. **Elahere:** Dr. Umbreit presented the new policy and is a folate receptor alpha (Fra)-directed antibody and microtubule inhibitor conjugate. She provided the overview, descriptive narrative, criteria, Dr. Daniel Cornett, PharmD, ImmunoGen, is present to give comments on the completed randomized study and the confirmatory study and showed a significant difference with prior drug therapies to be published in a prominent medical journal soon. Dr. Else Umbreit commented on the requested resources, and he will email over for review. Dr. Jagiello recommended Dr. Cornett's information be reviewed by Dr. Umbreit, and is in favor of having the current policy approval and can bring it back for review after the further evidence is reviewed. There were no further questions or comments.
    - First motion to approve by Dr. Danley.
    - Second motion to approve by Clarice Blanchard.
    - All approved and the motion carried.
9. **Leqembi:** Dr. Umbreit presented the new policy for treatment of Alzheimer's disease. She presented overview, guidelines, criteria, approval duration and quantity limits, coding and product information. Dr. Jagiello opened it up for comments. Dr. Ferguson commented on lesions and number of new lesions. Dr. Umbreit clarified on the follow up and caution used with new lesions. Dr. Danley commented on the FDA recent approval and clarification on the respective comparative study. Dr. Umbreit clarified the change in the end point and clinical trial, due to the accelerated approval, then in July it became fully approved, so there are still respective comparative studies done by the physician to submit to the registry, for Medicare patients. There were no further questions.
    - First motion to approve by Dr. Danley.
    - Second motion to approve by Dr. Ferguson.
    - All approved and the motion carried.
10. **Amondys 45:** Dr. Umbreit presented this policy and the changes or new information. She commented for all four of the DMD therapies that are listed, the criteria 3, she added criteria. That was the extent of the changes, along with updated references. She presented the change table. Dr. Jagiello commented to clarify no changes to the eligibility criteria or testing for functional status and Dr. Umbreit confirmed. Rhonda Showman, present to provide personal testimony for her son, who is diagnosed with DMD. She provided how the disease progresses and affects individuals, and now due to advancement of the DMD therapies these individuals are

surviving into their 30s. She spoke to Vyondys 53 and their experience with being to hold off the progression of the disease, and the benefit as it has helped him to look forward to his future. Dr. Jagiello thanked her for being here today to speak to the committee and share the benefit they have experienced. Christina Trout, RN, MSN, UIHC, present for comments and spoke to their letter that was presented during the meeting, that outlines their recommendations and updated references the exon skipping therapies and targets their specific requests detailed in the letter on file with removing age and ambulatory restrictions. Dr. Jagiello clarified the age range currently and consideration for extending that time and clarified on home infusion therapy and the internal work to remove barriers for home infusions. Dr. Jagiello requested comment on the approval durations. Paul Mulhausen, ITC confirmed 6 months. Dr. Nivedita Kirshnan, AGP, is 6 months. Dr. Gutshall, Molina, also is 6 months and he appreciates the logic provided and input. Dr. Jagiello requested the new referenced guidance they have for longer duration request approval and will send it over. Dr. Ferguson commented on the process for Prior Authorizations and the health care provider burden. Dr. Jagiello requested Dr. Umbreit to clarify on the age restrictions. Christina Trout, commented further on the FDA approval for consideration. Dr. Umbreit outlined the FDA advisory committee findings. Dr. Mulhausen, ITC, provided comment on the age restrictions and acknowledges this is a controversial topic and continues to remain controversial, and observation of the comprehensive care strategies to help these patients, and the challenges of needing solid clinical data and the added value of the treatments, with expansion of the use beyond the original clinical trials, and so he is comfortable with a rigorous evidenced based process. Christina Trout followed up to clarify on the historical control wasn't used, since the age and mutation matched controls in cohorts in the newer studies. Dr. Krishnan, AGP, commented by phone but she states that their policy aligns right now with this policy and that their policy is currently under review by the policy committee comprehensively. Dr. Gutshall, MHC, commented on acknowledgement of the different perspectives and thanked Christina Trout for all the information provided. Linda Boehmer, BSN, RN, CPN, UIHC, present to speak to exon skipping therapies/DMD treatments and supports the removal of the restrictions and spoke to the therapies are most commonly started by in home infusions and tolerated very well, with the great value and health benefits the therapies contribute to these individuals' quality of life. Mariam Alboustani, medical representative for Sarepta, present to add her advocacy to remove the age and ambulation restrictions and presented the benefits demonstrated in patients. Dr. Rachel Kinn, PharmD, UIHC, spoke in agreement of the prior speakers today, and agrees with removing the restrictions, to the benefits their patients with DMD therapies, however if the restrictions aren't able to be removed, she agrees that the DMD policies are acceptable, so long as they don't become more restrictive. Dr. Jagiello acknowledged and thanked everyone for their information and presentations today, and that review on individual basis will be available. He opened the discussion up to the committee for comments. Dr. Ferguson, committee member spoke in support of the presenters' requests on policy changes to remove the restrictions based on the data and that she'll abstain from voting yes today. Dr. Jagiello opened it up for a vote and made comment on his compassion and thanked all for their advocacy.

- First motion to approve by Dr. Zachary.
- Second motion to approve by Clarice Blanchard.
- The policy was approved by number of votes.

11. **Exondys 51:** Dr. Umbreit encompassed this policy change in the prior policy discussion for Amondys 45.
12. **Viltepso:** Dr. Umbreit encompassed this policy change in the prior policy discussion for Amondys 45.
13. **Vyondys 53:** Dr. Umbreit encompassed this policy change in the prior policy discussion for Amondys 45.
14. **Aduhelm:** Dr. Umbreit presented the policy and the changes in the overview. Dr. Jagiello opened it up for discussion. There were no comments.
    - First motion to approve by Dr. Ferguson.
    - Second motion to approve by Dr. Hubbell.
    - All approved and the motion carried.
15. **Padcev:** Dr. Umbreit presented the policy and the changes overview. Dr. Jagiello opened it up for discussion. There were no questions or comments.
    - First motion to approve by Dr. Ferguson.
    - Second motion to approve by Dr. Danley.
    - All approved and the motion carried.
16. **Phesgo:** Dr. Umbreit presented the policy and the changes overview with claims review and utilization acknowledged. Dr. Jagiello opened it up for discussion. There were no questions or comments.
    - First motion to approve by Dr. Zachary.
    - Second motion to approve by Dr. Danley.
    - All approved and the motion carried.
17. **Tecvayli:** Dr. Umbreit presented the policy and the changes overview. Dr. Jagiello opened it up for discussion. There were no questions or comments.
    - First motion to approve by Dr. Ferguson.
    - Second motion to approve by Dr. Hubbell.
    - All approved and the motion carried.

There were no further comments or questions offered from the Committee Members or by the public guests.

Closing comments: He thanked everyone for their contributions and engagement.

Next meeting: January 19, 2024

Meeting Adjournment: Dr. Jagiello