Department of HUMAN SERVICES

Meeting Agenda			
Division:	Iowa Medicaid Enterprise Quality Improvement Organization (QIO)		
Meeting Title:	Clinical Advisory Committee (CAC)		
Facilitator:	Bill Jagiello, D.O.		
Location:	**Zoom Meeting** Register in advance for this meeting: https://telligen.zoom.us/meeting/register/tZcsfuqhrjIrE92AAFQ-Kn9paOwDvllGeeM8 After registering, you will receive a confirmation email containing information about joining the meeting.		
Date:	July 15, 2022	**Time:**	1:00 p.m. – 4:00 p.m.

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 Human Services (DHS) for the Iowa Medicaid program.

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, D.O.	**Iowa Medicaid**
Mark Randleman, D.O.	**Iowa Medicaid**
Tami Lichtenberg	**Iowa Medicaid**
Else Umbreit, PharmD	Iowa Medicaid
Becky Carter	**Iowa Medicaid**
Cassie Reece	Iowa Medicaid
Barb Cox	Iowa Medicaid
Jennifer Ober	**Iowa Medicaid**
Diane Morrill	**Iowa Medicaid**

Meeting Participants	
Carrie McFarland	**Iowa Medicaid**
Wendy Lathrop	**Iowa Medicaid**
Charissa Blinkmann	**Iowa Medicaid**
Dr. Paul Mulhausen	**Iowa Total Care**
Dr. Nivedita Krishnan	**Amerigroup**
Dr. Alexandra Hubbell – Family Practice	
Clarice Blanchard, PA-C, Family Practice/Emergency Medicine	
Dr. Dana Danley – Family Practice	
Dr. Dennis Zachary – Family Practice	
Diana Smith, ARNP – Family Practice	
Dr. Polly Ferguson – Pediatric Rheumatology	
Dr. Stephen Mandler – Psychiatry	
Dr. Chitra Reddy – Endocrinology	
Dr. Kathleen Lange – Family Practice	

Agenda Topics	Responsible Party
New Business	Dr. Jagiello
Public Comment Period	Guests
Approval of the April 15, 2022, Meeting Minutes	Dr. Jagiello
Old Business	Exondys 51 discussion from April meeting

Agenda Topics	Responsible Party
Consent Agenda 1. DME.Back-up Ventilator-ARCHIVE 2. DME.Enteral Products and Supplies 3. DME.Pneumatic Compression Devices 4. DME.Strollers and Wheelchairs for Safety 5. DME.Wearable Automatic External Defibrillator 6. LAB.Gene Expression Profiling for the Management of Breast Cancer 7. LAB.Genetic Testing for Lynch Syndrome 8. LOC.Habilitation Eligibility (Non-Financial) 9. MED.Namenda (memantine) for Autistic Spectrum Disorder 10. SRG.Artificial Disc Replacement 11. SRG.Laser Linear Accelerator Based Stereotactic Radiosurgery 12. SRG.Left Ventricular Assist Device 13. SRG.Reduction Mammoplasty-Mastopexy 14. SRG.Risk Reduction Mastectomy 15. PAM.Fasenra (benralizumab) 16. PAM.Sarclisa (isatuximab-irfc) 17. PAM.Spinraza (nusinersen) 18. PAM.Trodelvy (sacituzumab govitecan-hziy) 19. PAM.Uplizna (inebilizumab-cdon)	Dr. Jagiello
Criteria Review 1. DME.Continuous Glucose Monitoring 2. DME.Custom Knee Orthotics 3. DME.Medical Foods 4. LAB.Molecular Analysis for Targeted Therapy of Non-Small Cell Lung Cancer 5. LOC.Children's Mental Health Waiver Level of Care 6. PAM.Jemperli (dostarlimab-gxly) **NEW** 7. PAM.Nexviazyme (avalglucosidase alfa-ngpt)**NEW** 8. PAM.Rylaze (asparaginase, recombinant) **NEW** 9. PAM.Zynlonta (loncastuximab tesirine-lpyl) **NEW** 10. PAM.Adakveo (crizanlizumab-tmca) 11. PAM.Crysvita (burosumab-twza) 12. PAM.Yescarta (axicabtagene ciloleucel) 13. PAM.Zolgensma (onasemnogene abeparvovec-xioi)	Dr. Jagiello
Upcoming Meetings October 21, 2022 January 20, 2023 April 21, 2023	Dr. Jagiello
Adjournment	Dr. Jagiello

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

Next Meeting: October 21, 2022

Dr. Jagiello offered the introduction for the quarterly Iowa Medicaid meeting. Roll call proceeded with quorum confirmation.

Announcements

Dr. Jagiello advised on the determination to not present the Aduhelm (physician administered medication) policy at this meeting; it has pulled back for further consideration. Instead, the Medical Foods Policy has been added for consideration. The public comment period will be deferred until the policy is presented.

Public Comment Period

- Liz Dragolovich, BSN, MJ, Fountain Medicine, Inc. speaking on molecular profiling
- Roy Thomas, PharmD, Dexcom, speaking on Continuous Glucose Monitors
- Emily Beckett, PharmD, BCPS-Broadlawns, speaking on Continuous Glucose Monitors
- Leslie Zanetti, PharmD, Sarepta Therapeutics, speaking on Exondys 51
- Wendy Mobley, PharmD, Drake Univ, speaking on Continuous Glucose Monitors
- Christina Trout, RN, MSN, Univ of Iowa Stead Family Children's Hospital- indicated she may comment if there are criteria changes for Exondys 51, Spinraza, Nexviazyme, or Zolgensma
- Emmeline Painstil, PharmD, Iowa Pharmacy Association, speaking on Continuous Glucose Monitors

Approval of April 15, 2022 Committee Meeting Minutes

Opportunity provided for additions, corrections, or comments: none. Motion to Approve by Dr. Ferguson, Diana Smith seconded. All approved and the motion carried.

New Business

No new business presented at this time.

Old Business

Dr. Jagiello reviewed prior criteria for Exondys 51, in which restrictions were inadvertently tightened on the ambulatory/non-ambulatory factor, regarding criteria #5, and it was emailed out to the committee members for review, resulting in the agreement to have the original policy language restored and amended:

1. **(#5. Member must have useful function of upper extremities; AND).**

Comments: Dr. Leslie Zanetti in attendance to present updated data and give feedback on corrective action the committee made.
Dr. Jagiello inquired on policy language from AGP and ITC on age range restrictions, and clarified with Leslie Zanetti, on FDA label for approval, she stated there is no age or ambulatory status restriction.
Dr. Krishnan, Amerigroup (AGP), policy confirmed it matches the presented criteria listed. Dr. Jagiello shared they are willing to consider waiving the age restriction when it's submitted as an ETP with appropriate data.
Christina Trout, RN, MSN, University of Iowa, Neuromuscular Clinic commented on known problems concerning the age range restriction, as they diagnose Duchenne Muscular Dystrophy (DMD) at a younger age with outcomes being better with starting treatment as early as diagnosis, and they would submit as ETP for member younger than 7 years. She gives examples of the foreseeable problems with age range restrictions and why they *clinically prefer* not to have an age range restriction.
Dr. Mulhausen, Iowa Total Care (ITC) commented ITC's current criteria has an age restriction of less than 13 years and would take into consideration mitigating factors on any that would be submitted for appeal. Dr. Krishnan agreed AGP would take into consideration mitigating factors as well.
Dr. Jagiello states he is interested in reviewing the information sent over with having it added back to the agenda in the future, for the MCO Medical Directors to consider loosening the age restriction for age 3 on this policy and on the other Exon Skipping Policies.
Christina Trout, comments reviewing with Dr. Mathews and Dr. Sadeh and will follow up from the prior letter in April and provide an update to him.
Leslie Zanetti commented, she will send over the newer recently published literature & data to include for review.
Dr. Ferguson question, on how often an age restriction is placed within criteria, if it's not included in the FDA label?
Dr. Jagiello provided information these drugs received expedited approval from the FDA on midpoint measurements and not actual improvement in clinical outcomes, and our chosen criteria for eligibility are from the clinical trial guidelines.
Christina Trout comments with insight on the reason behind the chosen age range of 7-13 for clinical trials, rather than younger than 7, was so they could cooperate with the standardized measures (often physical therapy) being used to monitor responses to therapy, and not due to safety issues outside of that age range nor that younger children wouldn't benefit outside that age range, but rather so they could have a co-hort (around the same age) of clinical trial members that were able to be appropriately looked at, and shares her concern over mixing clinical trial measurements with clinical care, because the information shows the benefits of starting therapy as early as possible for better health outcomes and for later life benefits.
Dr. Jagiello thanked each participant in this discussion and appreciates the information for review.

Consent Agenda

Consent Agenda items review by committee members: no concerns. Motion to approve by Dr. Zachary, Clarice Blanchard, PA-C seconded. All approved and the motion carried.

Criteria Review

1.Continuous Glucose Monitoring

Dr. Jagiello presented the policy. Introduced from past meeting the availability of (CGM) continuous glucose monitors for now members diagnosed with either Type 1 or Type 11 diabetes that are using insulin 3 or more times per day. Update to old criteria #2 modified from requirement of testing glucose 4x's a day to now state "multiple glucose tests are required daily", meaning 2 or more a daily.

Public speaker comments:

1. Wendy Mobley-Bukstein, Certified Diabetes Care & Education Specialist, with Primary Healthcare, provided comment she is in favor of this and making sure they can obtain access to these devices.
2. Emily Beckett, PharmD, Board Certified Pharmacotherapy Specialist, Diabetes Educator with Broadlawns Family Health Center, commented in strong favor of reducing members having to test 4x/daily, noting also from a cost and an accessibility standpoint. Comments on Medicare has reduced their eligibility criteria to 1x/day, and she would be in favor of for this policy, to reducing to 1x/day. She provided benefits to broadening the criteria and not putting a max A1C criteria amount.

Dr. Jagiello requested the CMS website link resource for review, that includes the exception for leniency on number of injections to 1x/day. He also acknowledged the concerns, regarding distribution channels with requests for moving it from a DME Benefit to the Pharmacy Benefit under Medicaid and clarifies making that change isn't under his advising accountability controls but appreciates her comments.

3. Emmeline Paintsil, Director of the Professional Affairs for the Iowa Pharmacy Association, they are in support of Iowa Medicaid taking the same steps as CMS to eliminate the requirement of 4 blood glucose test a day, as a means of addressing Health Disparities and Improving Equity of diabetes patients. And commented that coverage and fee reimbursement is equally important in increasing access for Iowans that need CGM's. She provides that the American Diabetes Association recommends that states make as many open channels as possible for the availability of CGM's. They are noticing the trend of decrease in Pharmacy participation with it shifting from medical benefit to pharmacy benefit. They recommend expanding CGM's, and test strips, syringes, needles back to a pharmacy benefit in addition to maintaining CGM coverage as a medical benefit.

Dr. Jagiello shared appreciation for her presentation, and notes her concerns are heard today, and noted by Medicaid Administration and Committee members.

4. Roy Thomas, MSL with Dexcom and Pharmacist- requesting that the finger stick requirement be removed for CGM coverage. CGM be added to the preferred drug list and covered a pharmacy benefit. He presented testimony and data to support the

utilization and access of the CGM at the pharmacy without a fingerstick requirement, comparable to commercial coverage, ensuring equitable access to those with poorer social determinates of health, with many border states currently at or going to pharmacy with CGMs and he provided supportive examples of the importance of this.

Dr. Jagiello advised the information presented today will be reviewed by the medical directors and he will examine the additional evidence that is submitted, and complete due diligence in also to going back to the ADA Standards to review those for consistency and review the policy with those standards. As well as for commercial benchmarking.

5. Daniel Iloh- Senior Strategic Accounts Manager for Abbott, presented support for coverage of the CGM for a pharmacy benefit, and he advised MN Medicaid, IL Medicaid and many other states (around 17) have updated their coverage criteria regarding CGM's, the ADA has highlighted standards of care associated with CGM use that allows for liberality in coverage, they ask for consideration for this category, with review of the available information as they advocate choice and for the pharmacy benefit that will save in the state significant cost and negative events associated with hypoglycemia. They are able to provide supportive data and additional information regarding this request.

Dr. Jagiello commented appreciation for his presentation. Next acknowledged letters that have been received regarding this policy. The letters were presented for committee review and are listed below.

Letter Acknowledgments:

Letter 1, Emmeline Paintsil. PharmD, MSLD, BCPS, Director of Professional Affairs for Iowa Pharmacy Association, was in attendance today and presented information in person on support to eliminate 4 tests, fee reimbursement and support maintaining CGM's under medical benefits.
Letter 2, John L'Estrange, PharmD, RPh, BCACP, email sent after Director Matney's listening session, showing advocacy to align our policy criteria with CMS.
Letter 3, Sarah Haveman- RD, LD, CDCES letter acknowledged-showing advocacy for CGM utilization, easier access to CGM's and using the pharmacy distribution channel stating faster and more efficient than going through medical benefits.
Letter 4, Dr. Mobley-Bukstein, PharmD, BCACP, CDCES, CHWC, FAPhA, letter acknowledged and who presented in person for needs of patients in Iowa.

Opening discussion on policy change, to the committee members, for comments:
Dr. Ferguson-comments it is a positive change. Roy Thomas comments it's open to interpretation by DME provider as to how many finger stick tests are required when trying to get coverage for the CGM, so not having the finger stick requirement, and to align with CMS, would be ideal. Dr. Jagiello reviewed with AGP and ITC to offer clarity on aligning and requested Dr. Krishnan to confirm AGP policy regarding using the language as "multiple" finger stick tests, and she confirmed that is how it's stated. He inquired with Dr. Mulhausen, ITC, states they use the language of is 3 tests. Dr. Jagiello encourages ITC to consider changing policy language to "multiple" as well and will offer further review and bring the policy back for consideration at the October meeting. Dr.

Ferguson comments that “multiple means 2 or more”, so updating the language to state “2 or more” instead of “multiple” as a benefit for alignment and hoping to achieve more similar outcomes. Dr. Jagiello enacts the suggestion, and the policy is updated:

1. **“2 or more” instead of multiple**

Dr. Paul Mulhausen, ITC, comments a correction for ITC uses the term “frequent” glucose testing. Dr. Krishnan, AGP, adding comment, that based on the experiences with performing these reviews that they would interpret “multiple or frequent tests” as “2 or more” blood glucose tests. Dr. Jagiello comments the language change is an improvement to offer alignment with the MCO’s and to provide more ease to the DME providers in the network, to obtain similar determinations & outcomes for this population.
Dr. Zachary motioned to approve. Clarice Blanchard, PA-C seconded.
Dr. Mark Randleman commented and offered support for this policy update/change and the long-term benefits for individuals.
All motioned to Approve the policy as amended, and the motion carried.
Dr. Jagiello states this policy will yet return in 3 months at the October meeting, after the new material is reviewed. He concludes with appreciation of all the comments and insight from those in our network and others that helps to build a stronger policy which has input from a lot of stakeholders, and thanked everyone for their participation.

2.Custom Knee Orthotics
New policy. No public presenters. Dr. Jagiello presented the policy. No further committee member comments. Motion to approve by Dr. Zachary. Diana Smith, ARNP seconded. All approved and the motion carried.

3.Medical Foods-New policy
No public presenters. Dr. Jagiello presented the policy. The policy was provided for review & vetting to Sheryl, Nutritionist, with the University of Iowa Hospital, Genetic Clinic as SME, on the criteria presented. Dr. Polly Ferguson comments, clarifying the list is not all inclusive, what happens for patients with IEM needing this type of special diet, but aren’t on this list. Dr. Jagiello presents review of resource titled Recommended Uniform Screening Panel that includes a more comprehensive list for referral, so it’s not exclusionary, but if the disorder isn’t on the list above, then the steps would be to submit a PA and if that fails, then would need to submit an ETP for approval. Motion to approve policy as it written. Clarice Blanchard motioned to Approve. Dr. Zachary seconded. Before confirming Dr. Jagiello requested Dr. Ferguson’s professional opinion & experience and she requested to amend list and update made:

1. **Added Lysinuric Protein Intolerance**

Dr. Ferguson motioned to approve the amended policy. Dr. Mandler seconded. All approved the modified policy, and the motion carried.

4.Children’s Mental Health Waiver Level of Care
Jen Ober, for IME introduces Courtney Ackerson, LMHC, for the state of Iowa and introduces her experience with completing the state of Iowa CMH Level of Care reviews up until March 2022 but is now in a new position as the IME, HCBS Training Specialist. Courtney Ackerson presented this policy. She reviewed the changes to policy language:

1. **An added paragraph to the Introduction Criteria. Then under "Admission" section some additions and changes, removing section, Criteria A, under #1, removed "initial and ongoing certification" added a separate section at the bottom, so it's been pulled out only to be moved to another location with the policy.**
2. **Next, change to breakdown of the wording for Criteria #1 because it had the full definition for serious emotional disorder in the SED, in the criteria section, but really, it's in the definition of IAC so it has now been added to the bottom of the criteria with the other 2 definitions (it hasn't changed, it is just being moved in location).**
3. **Under "Admission" Criteria A needs to be deleted, it's just one criterion, no A or B.**
4. **The Application Date should be changed to Assessment Date. Then under Criteria #1 it should say Assessment date. The reason being is the Application Date is a different criterion not within the level of care and instead as a part of the application process which the IMW will review and not a part of LOC reviews.**
5. **Review of #2-Level of Stability #2, proposed change to adjust to align with PMIC and IAC chapter 79 general provision. They need to be accessing outpatient services, to take out Criteria B- Treatments at lower level of care (outpatient services such as mental health therapy, behavioral health intervention services, group therapy, family therapy, and/or medication) are in place, but additional supports are needed and recommended.**
6. **Continued Stay Criteria-Added new paragraph: The member must meet All criteria in section 1, and meet sections 2, 3, and 4 or 5 to meet the level of care required for continued state in the HCBS CMH waiver. All 5 criteria detail now listed. MHP-all 3 are from IAC and inserted for reference.**

Opened to committee for comments: Dr. Mandler offered comments from experience with Orchard Place PMIC, patients go through PMIC who are getting considerably better be ready for discharge date but required to need high level of care after discharge, and under current policy they can't apply for the CMH waiver until discharged from facility and causes frequent lapses in service such as respite care for families and is there a way to address this? Courtney Ackerson responded for clients coming into admissions, the admissions team ensures they have applied for the CMH waiver prior to coming, so the application can be done prior to going into PMIC, and it's on hold for 120 days, if they currently have the CMH waiver, they go into PMIC they have 120 days before they lose the waiver, but after that, there are release reserve slot for those cases, or for new members coming out of PMIC, for the Reserve Capacity Slots, which had been increased during Covid-19, and available and can be tracked on the DHS website. Courtney Ackerson will send the Reserved Capacity Slots link to Dr. Mandler. No further comments. Dr. Ferguson motioned to approve the policy as amended. Dr. Mandler seconded. All approved and the motion carried.

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

Public comment: Liz Dragolovich with colleague Queentela Benjamin-on behalf of Foundation Medicine present to speak today. She requested the policy overview. Dr. Jagiello presented this policy overview.

Liz Dragolovich presented on information from the Foundation One, regarding the size of their panel has considerable evidence that suggests comprehensive genomic profiling technique regardless of the number of genes that profiled does identify more predictionable alterations particularly within the context of NSCLC, and specific data of Medicaid patients who are younger and who about 1/3 who are diagnosed under the age of 65 and their disease does tend to be enriched for targetable alterations, so there is importance not just in the name, or number of genes but in the technique used and evidence emerging involving those. She asks for consideration in liquid biopsy and data for its importance in lung cancer, in which Foundation Medicine does have a liquid biopsy foundation One liquid CDx, and the NCCN does support it when tissue is unavailable. Many patients don't have enough tissue for even smaller tests, she would like to see the foundation One liquid CDx or a liquid biopsy in the molecular analysis of lung cancer opinion. Dr. Jagiello commented on the new information emerging on liquid biopsy testing and welcomes pertinent information from Foundation One testing and /or liquid biopsy testing and he will include in his queue for early 2023 consideration. Liz Dragolovich indicates she will send the information over to him.
Dr. Mulhausen, ITC, comments on the point of evolving evidence that's emerging, indicating Iowa Medicaid's distinct policies on medical necessity for gene panels, welcomes the recent information.
Dr. Krishnan, AGP, comments agreeing on its helpfulness to support members in receiving currently robust evidence-based care and this interaction and ongoing communication with this group and Foundation One, leads the path open for a patient as rapidly as it happens.
Committee members comments: Dr. Ferguson commented importance of reviewing this frequently due to the emerging information is changing. Dr. Ferguson motioned to approve. Diana Smith seconded. All approved and the motion carried.

6.Jemperli
Else Umbreit, PharmD, prepared policy. Dr. Jagiello presented this policy. He confirmed the testing for genetic mismatch repair was covered and verified with Cassie Reece, IME. No further comments. Dr. Ferguson motioned to approve. Clarice Blanchard, PA-C seconded. All approved and the motion carried.

7.Nexviazyme
Else Umbreit, PharmD, prepared policy. Dr. Jagiello presented this policy. Christina Trout, RN, MSN commented this was her first time seeing the criteria, upon quick review she has concerns about the age restriction on this policy. Provided insight on current needs that would serve existing members. Dr. Jagiello responds he will work to send a policy for review to her and Dr. Mathews, for SME review, especially in the realm of serving younger members, especially under the age of 1. She next offered comments on concerns regarding #4 (Member is able to walk 40 meters on a 6-min walk test without assistive devices), is not feasible test in a standard clinic setting, they could instead do a 10-meter walk run, a north star ambulatory assessment, rise to stand and suggests adding these as alternative relevant motor assessments. Dr. Jagiello advises she can email him a list of suggested options, and he will consider amending the policy

at a later time to include the suggested language and then he will then send to her and Dr. Matthews for closer review and give them the opportunity to fully comment. She included it's treated in general genetics and can manifest later in life, as Limb-girdle Muscular Dystrophy and that is how it overlaps with the neuromuscular clinic. She requested communication also be sent over to Dr. Dima Sadeh other neuromuscular doctor who is current provider and prescriber for the younger Pompe patients. Dr. Jagiello advised at this time withholding making changes and get the additional information and rework the policy with Else, considering their SME insights. No other comments on policy. Dr. Zachary motioned to approve. Diana Smith, ARNP seconded. All approved and the motion carried.

8.Rylaze

Else Umbreit, PharmD, prepared policy. Dr. Jagiello presented the policy. Comments: No public or committee comment. Clarice Blanchard, PA-C motioned to approve. Dr. Zachary seconded. All approved and the motion carried.

9.Zynlonta

Else Umbreit, PharmD, prepared policy. Dr. Jagiello presented the policy. Comments: No public or committee comment. Dr. Ferguson motioned to approve. Dr. Zachary seconded. All approved and the motioned carried.

10.Adakveo

Else Umbreit, PharmD, prepared policy. Dr. Jagiello presented the policy. Reviewed past changes which were mostly technical in nature to align more consistently with professional society guidelines. Comments: Dr. Ferguson comment on prior suggestion to change the prior approval duration from the Initial Authorization of 6 months and questioning if it is enough. Dr. Jagiello responded on the prior review of the 6 months aligning with most initial prior authorization guidelines for the expense of this treatment. She would like to see the data that 6 months is enough, and her concern with the data that is driving that guideline. Dr. Jagiello requested insight from both MCO directors:
Dr. Krishnan, AGP, comments their policy was updated 3 weeks ago, and allows for a year for the initial approval and 12 months subsequent authorization.
Dr. Mulhausen, ITC, comments their policy shows the 6 months initial authorization and 12 months subsequent.
Dr. Jagiello followed up with no objection based on number of episodes per assessment time frame, and to enact the update:

1. **to 12 months for initial authorization**

Diane Morrill, IME will email Else the updated change to the policy. Dr. Ferguson motioned to approve the amended policy. Dr. Zachary seconded. All approved and the motion carried.

11.Crysvita

Else Umbreit, PharmD, prepared policy. Dr. Jagiello presented the policy. Revision. Overview provided. Comments: No public or committee comment. Dr. Ferguson motioned to approve. Dr. Zachary seconded. Motion to approve and the motion carried.

12.Yescarta
Else Umbreit, PharmD, prepared policy. Dr. Jagiello presented the policy. Revision. Overview provided. Comments: Jennifer Davis, public comment, states it looks great. Dr. Zachary motioned to approve. Diana Smith, ARNP, seconded. All approved and the motion carried.

13.Zolgensma
Else Umbreit, PharmD, prepared policy. Dr. Jagiello presented the policy. Notes this drug therapy is one that received expedited review. Comments: Christina Trout, RN, MSN, reviewing as SME, and states this policy looks great but has concerns on the age criteria, regardless of SMN2 copies up to 4 copies, for AGP and ITC policies. She states they need to avoid late delivery of the gene therapy to prevent permanent loss of motor neurons for best outcomes. Dr. Krishnan commented on the AGP policy language. Dr. Mulhausen commented on ITC policy language. Both Medical Directors for AGP and ITC will send a copy of their current policies to Dr. Jagiello for further review. Dr. Jagiello is withdrawing policy from the committee at this time and will review the policies the AGP and ITC policies with Elsa and get better alignment on eligibility. He agrees aligning with member centered intent, on getting early access to prevent development of symptoms or disease as clinically appropriate. Dr. Ferguson comments support to turn around as quickly as possible. No further comments and no vote needed at this time.

Meeting concluded, no further closing comments or questions