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/tZ0rc-muqTIpE9d9TX4GcNMq-7X9siFHvQdw After registering, you will receive a confirmation email containing information about joining the meeting.		
Date:	April 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	IME
Paula Motsinger, DHS Bureau Chief, LTSS and Medical Policy	IME
Bill Jagiello, D.O.	**IME**
Mark Randleman, D.O.	**IME**
Tami Lichtenberg	IME
Else Umbreit, PharmD	**IME**
Becky Carter	**IME**
Cassie Reece	**IME**
Barb Cox	**IME**
Jennifer Ober	**IME**
Diane Morrill	**IME**
Carrie McFarland	IME

Meeting Participants	
Wendy Lathrop	**IME**
Charissa Blinkmann	**IME**
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	
Leslie Zanetti, PharmD	**Sarepta Therapeutics**
Susie Moroney	**Novartis**
Christina Trout, RN, MSN	**University of Iowa Stead Family Children's Hospital, Neuromuscular Program-Pediatrics**
Tami Sova, Pharm.D	**Biogen**

Agenda Topics	Responsible Party
New Business	Dr. Jagiello
Public Comment Period	Guests
Approval of the April 15, 2022, Meeting Minutes	Dr. Jagiello

Agenda Topics	Responsible Party
Consent Agenda 1. DME.Augmentative Communication System 2. DME.Gait Trainer-Stander 3. DME.High Frequency Chest Wall Oscillation 4. DME.Negative Pressure Wound Therapy 5. DME.Safety Beds 6. DME.Shower-Commode Chair 7. HH.Personal Care Services for Children 8. HH.Private Duty Nursing for Children 9. LAB.Genetic Testing 10. LOC.Nursing Facility Level of Care 11. LOC.Psychiatric Medical Institution for Children Level of Care 12. LOC.Skilled Level of Care 13. MED.Vitamin, Mineral, Amino Acid Supplements 14. PAM. Enhertu (fam-trastuzumab deruxtecan-nxki) 15. PAM.Exondys 51 (eteplirsen) 16. PAM.Jelmyto (mitomycin gel) 17. PAM.Krystexxa (pegloticase) 18. PAM.Luxturna (voretigene neparvovec-rzyl) 19. PAM.Viltepso (viltolarsen) 20. PAM.Vyondys 53 (golodirsen) 21. SRG.Blepharoplasty 22. SRG.Cochlear Implant Repair and Replacement 23. SRG.Cochlear Implant 24. SRG.Septoplasty 25. SRG.Vagus Nerve Stimulator 26. WPA.Consumer Directed Attendant Care	Dr. Jagiello
Criteria Review 1. PAM.Amondys 45 (casimersen) 2. PAM.Botulinum Toxins 3. PAM.Keytruda (pembrolizumab) 4. PAM.Kymriah (tisagenlecleucel) 5. PAM.Ocrevus (ocrelizumab) 6. PAM.Radicava (edaravone) 7. PAM.Spravato (esketamine nasal spray) 8. PAM.Tepezza (teprotumumab-trbw) 9. PAM.Tysabri (natalizumab) 10. SRG.Autologous Chrondrocyte Implantation	Dr. Jagiello
Upcoming Meetings July 15, 2022 October 21, 2022 January 20, 2023	Dr. Jagiello
Adjournment	Dr. Jagiello

Contacts:

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Wendy Lathrop
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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

New Business
No new business presented.

Approval of the January 21, 2022 meeting minutes
Motion to approve by Dr. Ferguson, Dr. Lange seconded. All approved and the motion carried.

Public Comment Period
Dr. Jagiello announces the Public Comment period is available and suggests reserving the public comment to take place during the time of the policy presentation as benefit to those presenting or may have comments.

- Leslie Zanetti, PharmD- Sarepta Therapeutics
- Susie Moroney- Novartis
- Christina Trout, RN, MSN- University of Iowa Stead Family Children's Hospital, Neuromuscular Program-Pediatrics. Input was provided regarding Amondys 45, sent an email from Dr. Matthews to Dr. Jagiello summarizing their comments and she will present it during the policy review. Dr. Jagiello will share the email for comments.
- Tami Sova, PharmD, Biogen

Consent Agenda
Request to approve consent agenda as presented. Motion to approve by Dr. Randleman, Dr. Hubbell seconded. All approved and the motion carried.

Criteria Review
1. Amondys 45 (casimersen)
Else presented this policy. (Guidelines update: She tried to standardized guidelines of this policy between the other 3 exon skipping therapies and create a consistent format of review, so they are reviewed on an equal basis, not yet formally FDA approved.)

Dr. Jagiello opens the public comment on this: and he presents the email from Dr. Katherine Mathews, Director of Neuromuscular clinic with University of Iowa, as she provides care for the majority of children with Duchenne Muscular Dystrophy (DMD) in our state. Comments: Dr. Mathews appreciates the ETP submissions always welcomed, found the criteria used by Iowa Medicaid to be appropriate for Exondys 51 and would like to see the new exon-skipping medications have similar criteria and potential alignment as Exondys 51. Else commented the

alignment in her review of guidelines except for minor differences in the clinical trials regarding walk test and age differences. Dr. Mathews would like to see expansion for inclusion in criteria for:

1. Age and disease-stage requirements updating to-age of 3. Dr. Jagiello states following requirements, aligned with FDA approval, policy has to remain as written, but an ETP with supportive clinical information, on an individual basis, for full consideration review to allow treatment with the medication for a younger patient. (Flexibility request with walk test)
2. Appropriate monitoring of response to therapy
3. Requirement for co-administration of corticosteroid

Christina Trout, RN, nurse on the neuromuscular team with Dr. Mathews, commenting expansion on the email and addressed the ETP review and reasons why some patients would not be on a corticosteroid, even though their standard of care is to use a corticosteroid. Also looking for flexibility with walk test and using the upper extremity evaluation “The Pull” for non-ambulatory status, they would like to see softening of the ambulatory status and wider age range due to boys being diagnosed with Duchenne Muscular Dystrophy (DMD) at much younger age than what some of the ages used in the clinical trials and how the trials were developed. The FDA does not use age restrictions.

Else spoke to the rationale behind following the clinical trial guidelines and crafting policy. Dr. Jagiello summarized all of the exon-skipping drugs have been approved by the FDA based on the accelerated approval process, in which midpoints in the clinical trials have been established but not final outcomes, so they are available for patients and given early access so that the manufacturers can submit the data to the FDA to provide longer term end-points. They will continue to come through as an ETP in hopes he standardizes these requests and rules appropriately.

Leslie Zanetti, PharmD- Sarepta Therapeutics-with the manufacturer in the medical science liaison payor space, presented information and requested revision to not restrict by age and ambulatory status, and is asking for the Exondys 51 policy clarification, from the April 2021 online publication to have clarification on criteria that Exondys 51 does not restrict by age or ambulatory status and asking to revise Amondys-45 to align with the criteria of Exondys 51. Dr. Jagiello and Else commented that they will review the Exondys-51 for updates.

Clarice Blanchard motioned to approve; Diana Smith seconded. All approved and the motion carried.

2. Botulinum Toxins

Else presented this policy. Dr. Jagiello followed up with comments. Diana Smith commented requesting wording change from neurologist to neurology specialist and orthopedist to orthopedic specialist so that Nurse Practitioners who are working in those specialties can be included as well. Dr. Jagiello approves, and Else said she will put “in consultation with" which includes Nurse Practitioner and Physician Assistant. Dr. Jagiello agrees to have this changed to include specialists. To clarify it further, that it is someone currently practicing within that type of a specialty office. Dr. Mandler provided comment on policy change. Dr. Krishnan

commented no concerns for the suggestions of language changes to be incorporated. Dr. Mulhausen provided comment no concerns on suggestions mentioned for language changes as they modify to accommodate advanced practice nursing in Iowa. He agrees with the comments and is comfortable with the language alterations made in this policy. A revision will be made to provide clarity for some of the applications. No new codes involved.

There was a motion to approve the modified version. Diana Smith motioned to approve; Dr. Ferguson seconded the motion. All approved and the motion carried.

3. Keytruda (pembrolizumab)
Else presented this policy. Dr. Mandler motioned to approve; Dr. Lange seconded the motion. All approved as written and the motion carried.

4. Kymriah (tisagenlecleucel)
Else presented this policy. Update for B-Cell Acute Lymphoblastic Leukemia (ALL) criteria #6 from DLBCL added as # 6.

Susie Moroney- Novartis-(manufacturer), commented on criteria for DLBCL, #3 ECOG PS of 0-1 to update to ECOG 2, Dr. Jagiello offered feedback. Dr. Krishnan commented AGP uses ECOG measures and Dr. Mulhausen offered comments ITC does not use ECOG factor. Dr. Ferguson commented. Dr. Krishnan commented. Dr. Mandler commented. Motion to Modify to ECOG of 2.

Dr. Hubbell motioned to approve; Dr. Ferguson seconded the motion. All approved and the motion carried.

5. Ocrevus (ocrelizumab)
Else presented this policy. Clarice Blanchard motioned to approve; Dr. Ferguson seconded the motion. All approved and the motion carried.

6. Radicava (edaravone)
Else presented this policy. Dr. Jagiello reviewed letter response from Dr. Christopher Nance with the University of Iowa. Else provided commented responses.

Dr. Zachary motioned to approve policy as written; Dr. Danley seconded the motion. All approved and the motion carried.

7. Spravato (esketamine nasal spray)
Else presented this policy. This policy had been updated for clarification and acknowledgment for awareness that it is covered as a medical benefit for Iowa Medicaid and clarification on appropriate codes for billing.

Dr. Mandler motioned to approve; Dr. Randleman seconded the motion. All approved and the motion carried.

8. Tepezza (teprotumumab-trbw)
Else presented this policy. Updated commentary to clarify the clinical activity scoring for disease and added criteria did not require surgical intervention and one course of treatment. Dr. Ferguson commented. Dr. Jagiello offered comment on follow up to review on additional research for whether there is data on new treatments at this time with repeat courses and will follow up at the next meeting. It is currently only available as one course.

Motion to approve as written Dr. Ferguson; Dr. Zachary seconded the motion. All approved and the motion carried.

9. Tysabri (natalizumab)
Else presented this policy.
Tami Sova, PharmD- Biogen did not have any comments to present but is in attendance to answer any questions from the committee. There are no further comments.

Dr. Zachary motioned to approve; Dr. Lange seconded the motion. All approved and the motion carried.

10. Autologous Chrondrocyte Implantation
Dr. Jagiello presented this policy. Dr. Zachary motioned to approve; Dr. Hubbell seconded the motion. All approved and the motion carried.

Closing Comments: No further comments or questions.

Next Meeting: July 15, 2022
Meeting was adjourned.