

Meeting Agenda	
Division:	Iowa Medicaid Enterprise Quality Improvement Organization (QIO)
Meeting Title:	Clinical Advisory Committee (CAC)
Facilitator:	Bill Jagiello, D.O.
Location:	Go To Webinar and conference call: (415) 655-0052, code: 253-419-674
Date:	April 16, 2021
Time:	1:00 p.m. – 4:00 p.m.

Meeting Objectives
<p>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.</p> <p>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.</p>

Meeting Participants	
Name	Organization
Bill Jagiello, D.O.	IME personnel
Mark Randleman, D.O.	IME personnel
Tami Lichtenberg	IME personnel
Diane Morrill	IME personnel
Teri Stolte	IME personnel
Jen Ober	IME personnel
Barb Cox	IME personnel
Becky Carter	IME personnel
Cassie Reece	IME personnel
Else Umbreit	IME personnel
Pam Lester	IME personnel
Lisa Roush	IME personnel
Dr. Polly Ferguson- Pediatric Rheumatology	
Dr. Stephen Mandler- Psychiatry	
Dr. Andrea Silver- Family Practice	
Dr. Dennis Zachary- Family Practice	

Dr. Dana Danley- Family Practice	
Dr. Kathy Lange- Family Practice	
Clarice Blanchard, PA-C- Family Practice/Emergency Medicine	
Sherry Buske ARNP- Family Practice	
Dr. Alexandra Hubbell- Family Practice	
Jennifer Stoffel	Jansen Scientific
Jo Ann Antenor	Horizon Therapeutics
Linda Morgan	Horizon Therapeutics
Mahima Chojar	Spark Therapeutics
Leslie Zanetti	Sarepta Therapeutics
Dr. Erin Shriver	UIHC
Dr. Robert Jackson	

Agenda Topics	Responsible Party
<p>New Business:</p> <ol style="list-style-type: none"> 1. Retiring from the committee: Sherry Buske and Dr. Silvers 2. Introduction of Else Umbreit, PharmD. 3. Discussion on how meetings will be held going forward 4. Integrated Health Home (IHH) update 	<p>Dr. Jagiello Dr. Jagiello Dr. Jagiello Pam Lester, IME</p>
<p>Public Comment Period</p>	<p>Guests</p>
<p>Consent agenda-</p> <p>Approval of the minutes from the January meeting</p> <ol style="list-style-type: none"> 1. Augmentative Communication Systems 2. Gait Trainer/ Stander 3. Negative Pressure Wound Therapy 4. Safety Beds 5. Shower/Commode Chair 6. Personal Care Services for Children 7. Private Duty Nursing for Children 8. Genetic Testing (excludes BRCA testing and 21-gene RT-PCR assays, which are covered using NCCN guidelines, under separate criteria) 9. Nursing Facility Level of Care 10. Skilled Level of Care 11. Exondys 51 (Eteplirsen) 12. Vitamin, Mineral, Amino Acid Supplements 13. Blepharoplasty 14. Septoplasty/ Rhinoplasty 15. Vagus Nerve Stimulator 	<p>Dr. Jagiello</p>

Criteria Review 1. CDAC WPA 2. Enhertu **NEW 3. Jelmyto **NEW 4. Krystexxa® (Pegloticase) 5. Luxturna **NEW 6. Spravato **NEW 7. Tepezza **NEW 8. Vyondys 53 **NEW	Dr. Jagiello
Upcoming Meetings July 16, 2021 October 15, 2021	Dr. Jagiello
Adjournment	Dr. Jagiello

New Business:

- Retiring from the committee: Sherry Buske and Dr. Silvers:** Dr. Jagiello recognized the retiring members from the committee. Sherry Buske expressed her gratitude to the committee. Dr. Silvers stated we did a great job transitioning to virtual meetings and congratulated Dr. Jagiello and Tami Lichtenberg for adding efficiency to the meeting by implementing the consent agenda.

We are looking for committee members to replace those that are leaving. Tami Lichtenberg mentioned that if we can recruit someone from the eastern part of the state or far west part of the state and with Diabetes experience background that would be in line with what is needed.
- Introduction of Else Umbreit, PharmD.** Dr. Jagiello introduced Else Umbreit, who has joined our team as pharmacist. Else stated she has 5 years of experience working in managed care and that is where she will be applying most of her knowledge in her new role with IME. She will be assisting in the development of the criteria for Physician Administered Medications (PAM), assist with new codes and as needed on other pharmacy projects.
- Discussion on how meetings will be held going forward:** Dr. Jagiello stated we will continue to meet virtually through the end of the year. If any committee member has any thoughts on how they would prefer to see the meetings be held going forward, please send them to Teri Stolte. Tami Lichtenberg will be researching any guidelines that we would need to follow as stated in the Iowa Administrative Code.
- Integrated Health Home (IHH) update:** Pam Lester presented, (see handout labeled 4.16.21 Health Home Program Update for CAC). Dr. Randleman asked how many people are being served under this program? There are 20,000 in the program- 11,000 adults, 5,000-6,000 kids and about 2,000 that are listed as having a chronic condition. How many Case Managers do you have and is it hard to get them and keep them? Pam has worked closely with the MCOs to get them in alignment with the standards they all need to meet, which has really helped with retention.

Public Comment Period

There were requests to speak at this time

Consent agenda:

Request to approve agenda items and approval of the January meeting minutes. Motion to approve by Dr. Hubbell Dr. Ferguson seconded. All approved and the motion carried.

Criteria Review:

1. **CDAC WPA-** Lisa Roush presented the updates that have been made to the criteria. A motion was requested to approve with changes. Dr. Zachary motioned to approve, and Dr. Hubbell seconded the motion. All approved, the motion carried.
2. **Spravato-** Dr. Jagiello presented the updates. Jennifer Stoffel, from Jansen Scientific Affairs, pointed out various aspects of the drug and was available for questions. REMS programs available in Iowa are located at the University of Iowa Hospitals and Clinics, Mercy One in Webster City and Waterloo, and Prairie Ridge Community Mental Health Center. Dr. Mandler discussed the augmentation process. Dr. Jagiello revised item #5 under the initial approval for induction phase for treatment resistant depression. A motion was requested to approve with changes, Dr. Ferguson motioned to approve the modified version and Dr. Mandler seconded the motion. All approved, the motion carried. The new code is in the process of being approved, the final policy will go to leadership for final approval within the next couple of weeks. In the interim, this therapy will be available by utilizing the exception to policy process.
3. **Tepezza-** Dr. Jagiello presented this new medication. Dr. Erin Shriver discussed situations in which Tepezza would be considered not medically necessary. Item #2 was revised and item #3 removed under this section. A motion was requested to approve with changes, Dr. Ferguson motioned to approve, and Clarice Blanchard seconded the motion. All approved, the motion carried.
4. **Enhertu-** Dr. Jagiello presented the new medication. A motion was requested to approve, Dr. Silvers motioned to approve and Dr. Zachary seconded the motion. All approved, the motion carried.
5. **Jelmyto-** Dr. Jagiello presented the new medication. A motion was requested to approve, Dr. Ferguson motioned to approve and Sherry Buske seconded the motion. All approved, the motion carried.
6. **Krystexxa® (Pegloticase)-** Else Umbreit presented this medication and Jo Ann Antenor from Horizon Therapeutics provided comments,. Dr. Robert Jackson, rheumatologist, discussed aspects of contraindications to the medication and utilization. His call quality was not very good and Dr. Jagiello asked that he submit any concerns offline for review. A motion was requested to approve, Dr. Silvers motioned to approve with a small amendment made to the narrative description. Motion to approve made by Dr. Ferguson and Dr. Danley seconded the motion. All approved, the motion carried. (Note: no subsequent communication was received from Dr. Jackson).
7. **Luxturna-** Dr. Jagiello presented this new medication. Mahima Chojar, Spark Therapeutics, recommended revisions to items #3 and 4. Dr. Jagiello added item d. to criteria #3 and requested it to be approved as modified. Dr. Ferguson motioned to approve as modified and Clarice Blanchard seconded the motion. All approved, the motion carried.
8. **Vyondys 53-** Leslie Zanetti with Sarepta Therapeutics was available for questions. Dr. Jagiello presented the new treatment. Leslie Zanetti felt item #4 was too strict in the criteria and with the age restriction noted in item #2. The MCO medical directors discussed leaving in the 6 minute walk test in item #4 under the criteria, both felt it was needed and is included in their own policies. Dr. Jagiello stated he will keep the criteria as written. The policy criteria were based on the action by the FDA granting accelerated approval of this treatment and noting that the clinical benefit remains unproved at this

time. Dr. Jagiello also read the statement submitted by Ryan Fisher from the Parent Project Muscular Dystrophy in support of approving Vyondys 53. A motion was requested to approve, Dr. Zachary motioned to approve and Dr. Silvers seconded.. All approved, the motion carried.

Upcoming Meetings: July 16th

Meeting was adjourned.