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:	Go To Webinar and conference call: (914) 614-3221, access code: 369-320-500		
Date:	January 21, 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**
Diane Morrill	**IME**
Carrie McFarland	**IME**
Wendy Lathrop	**IME**
Charissa Blinkmann	**IME**
Dr. Paul Mulhausen	**Iowa Total Care**
Dr. Nivedita Krishnan	**Amerigroup**

Meeting Participants	
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	
Joseph Dang, Pharm D	**Novartis**
Susie Moroney	**Novartis**
David Cram, PharmD	**Takeda**

Agenda Topics	Responsible Party
New Business Introduction of new Amerigroup staff – Dr. Nivedita Krishnan	Dr. Jagiello
Public Comment Period	Guests
Approval of the October 15, 2021 Meeting Minutes	Dr. Jagiello

Agenda Topics	Responsible Party
Consent Agenda 1. DEN-Periodontic Procedures 2. DME-Mobility Related Device Purchase 3. DME-Power Seat Elevation for Power Wheelchairs 4. DME-Power Wheelchair Attendant Controls 5. LAB-Chromosomal Microarray Analysis 6. LAB-Genetic Testing for Hereditary Breast and Ovarian Cancer Syndrome (BRCA1/BRCA2) 7. LAB-Non-Invasive Prenatal Testing for Aneuploidy Using Cell Free DNA 8. LAB-Whole Exome Sequencing 9. LOC-ICF/ID LOC 10. LOC-Pediatric SNF Level of Care 11. PAM-Brineura (cerliponase alpha) ARCHIVE 12. PAM-Kymriah (tisagenlecleucel) 13. PAM-Lutathera (Lutetium Lu-177 dotatate) 14. PAM-Vyepti (eptinezumab-jjmr) 15. RAD-CT Colonography 16. SRG-Bariatric Surgery 17. SRG-Bone Marrow/Peripheral Blood Stem Cell Transplant 18. SRG-Fecal Microbiota Transplantation 19. SRG-Heart Transplant 20. SRG-Nipple Tattooing 21. SRG-Pancreas Transplant 22. WPA-Environmental Modification and Adaptive Devices 23. WPA-Home and Vehicle Modification 24. WPA-Pre-vocational Services	Dr. Jagiello
Criteria Review 1. DME-RELiZORB 2. DME-Myoelectric Prosthesis Upper Extremity 3. PAM-Elaprase (idursulfase) 4. PAM-Imfinzi (durvalumab) 5. PAM-Orphan Drugs (Rare Diseases) 6. PAM-Tecartus (brexucabtagene autoleucel) 7. SRG-Liver Transplant 8. SRG-Lung Transplant 9. SRG-Ablative Laser Treatment of Burn and Traumatic Scars	Dr. Jagiello
Upcoming Meetings April 15, 2022 July 15, 2022 October 21, 2022	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/clincial-advisory-group

New Business

Dr. Nivedita Krishnan has joined Amerigroup as Medical Director. She practices Pediatrics and lives in Des Moines, Iowa.

Public Comment Period

Joseph Dang from Novartis spoke about Leqvio (inclisiran) and was available for questions. There is not yet a policy for Leqvio. Joseph shared a few brief comments in this meeting so the committee is aware of the new approval and can discuss again at a later meeting when the policy is up for review.

Susie Moroney from Novartis spoke about Lutathera and Kymriah. She had the following question on Kymriah related to the adult indication. She stated there is criteria related to ECOG status, specifically the criteria limits to patients who have ECOG performance status of 0 or 1. There is a fair amount of real-world data in patients that have ECOG performance status of 2. From a guideline perspective, NCCN guidelines do not limit utilization based on ECOG and a from benchmarking perspective, many payors do not limit based on ECOG. Susie asked if this would this be something the committee would consider altering. Else stated the criteria is based on the initial Juliet study. Else stated that in other trials there was a delay between the assessment and start of treatment. Two patients had ECOG of 2, and they were assessed and then did not begin treatment until three months later and then progressed to ECOG of 3. Else asked what the time lapse is between when they were assessed and when they started therapy. Susie stated that, in general, the current manufacturing timeline is 21-22 days but that has improved over the last four years so she cannot speak to how long manufacturing time was. Else also asked whether it was found that for patients with ECOG of 2, if there was any increase in severe reactions versus those with lower ECOG score. Susie stated that in two of the databases they did not see any association with greater risk of cytokine release syndrome or neurological toxicity in ECOG of 2. There is another group made up of eight academic CAR T centers who presented data and summarized the efficacy and outcomes for both Kymriah and Yescarta and noted that patients with ECOG of 2 had higher risk of cytokine release syndrome but the data is blended from both agents. One agent has higher incidence to begin with so it could be with all patients. It has not been split out. In general, patients with an ECOG of 2 would have limited alternate treatment options. The other option would be salvage chemotherapy, which may have greater toxicity than CAR-T. They likely would not receive salvage chemotherapy either.

Else will research this further for better understanding before presenting to the committee. If there is enough new information, this will be brought back to the meeting in April.

David Cram, PharmD from Takeda was available for questions on Elaprase.

Approval of the October 15, 2021 meeting minutes
Motion to approve by Dr. Zachary, Dr. Hubbell seconded. All approved and the motion carried.

Consent Agenda
Request to approve consent agenda. Motion to approve by Diana Smith, Dr. Blanchard seconded. All approved and the motion carried.

Criteria Review

1) RELiZORB
Dr. Reddy asked whether this would be in addition to enzyme replacement, or if they are not able to tolerate enzymes. Dr. Jagiello stated this would be in addition to enzyme replacement. It is to augment or be given in addition to PERT therapy.

Dr. Randleman asked about the cost of RELiZORB versus the cost of straight PERT therapy. Else indicated that RELiZORB comes in a box of 30 cartridges At the Medicaid rate, one cartridge per day would be about $3300 per month, with two cartridges per day being $6600 per month.

Dr. Jagiello presented this policy. Dr. Hubbell motioned to approve; Dr. Blanchard seconded the motion. All approved and the motion carried.

2) Myoelectric Prosthesis Upper Extremity
Dr. Jagiello presented this policy. Dr. Ferguson motioned to approve; Dr. Blanchard seconded the motion. All approved and the motion carried.

3) Elaprase (idursulfase)
Else presented this policy. Dr. Zachary motioned to approve, Dr. Danley seconded the motion. All approved and the motion carried.

Dr. Mandler recommended updating the language to say “progressive intellectual disability” rather than “progressive mental retardation.” This change was made.

4) Imfinzi (durvalumab)
Else presented this policy. Dr. Ferguson motioned to approve; Dr. Hubbell seconded the motion. All approved and the motion carried.

5) Orphan Drugs (Rare Diseases)
Brineura was moved from a stand-alone policy and added to the Orphan Drug policy. Else presented this policy. Diana Smith motioned to approve; Dr. Zachary seconded the motion. All approved and the motion carried.

6) Tecartus (brexucabtagene autoleucel)
Else presented this policy. Dr. Zachary motioned to approve; Dr. Hubbell seconded the motion. All approved and the motion carried.

7) Liver Transplant
Dr. Jagiello presented this policy. Dr. Danley motioned to approve, Dr. Blanchard seconded the motion. All approved and the motion carried.

8) Lung Transplant
Dr. Jagiello presented this policy. Dr. Zachary motioned to approve; Diana Smith seconded the motion. All approved and the motion carried.

9) Ablative Laser Treatment of Burn and Traumatic Scars
Dr. Jagiello presented this policy. Dr. Ferguson motioned to approve; Dr. Zachary seconded the motion. All approved and the motion carried.

Upcoming Meetings: April 15, 2022
Meeting was adjourned.