

MEETING AGENDA				
DIVISION	Iowa Medicaid Quality Improvement Organization (QIO)			
MEETING TITLE	Clinical Advisory Committee (CAC)			
CAC CHAIR	Bill Jagiello, DO			
FACILITATOR	Heidi Weaver			
DATE	April 19, 2024	TIME	1:00pm-4:00pm	
LOCATION	Zoom Meeting https://telligen.zoom.us/meeting/reg	lister/tZwoc-qqrjwjGo	dS3ZepwzglU0HHYJFzVd1KP	

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				
Iowa Medicaid	Elizabeth Matney, Medicaid Director			
	□ Rebecca Curtiss, HHS Deputy Director of Operations			
	□ Paula Motsinger, HHS Bureau Chief of LTSS			
	□ Jenny Erdman, HHS Quality, Innovation & Medical Policy Bureau Chief			
	⊠ Bill Jagiello, DO			
	□ Mark Randleman, DO			
	⊠ Else Umbreit, PharmD			
	⊠ Diane Morrill			
	🛛 Charissa Blinkmann			
Committee Members	□ 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. Chitra Reddy-Endocrinology			
	☑ Dr. Kathleen Lange-Family Practice			
	☑ Dr. Geetanjali Sahu-Child and Adolescent Psychiatrist			



Managed Care Organizations	 Dr. Paul Mulhausen, Iowa Total Care (ITC) Dr. Timothy Gutshall, Molina Healthcare of Iowa (MHC) Dr. Nivedita Krishnan, Wellpoint (previously Amerigroup)
	AGENDA TOPIC
 CAC Speaker Disclosure To be respectful of the 	meeting time if you find your topic will exceed the maximum 5-minute you to submit your detailed information to <u>CAC@dhs.state.ia.us</u> prior .
Old Business 1. Molecular Analysis for 2. Zynyz (retifanlimab-dlv	Targeted Therapy of Non-Small Cell Lung Cancer vr)
New Business	
Consent Agenda <u>Durable Medical Equipmen</u> 1. Augmentative Commu 2. Gait Trainer/ Stander 3. Safety Beds 4. Shower/Commode Chan <u>Home Health (2):</u> 5. Personal Care Service 6. Private Duty Nursing for <u>Lab (1):</u> 7. Genetic Testing (exclu- <u>Level of Care (4):</u>	nication Systems air s for Children or Children udes BRCA)
8. Nursing Facility Level 9. Pediatric SNF Level of	
Surgical Procedures (5): 12. Blepharoplasty 13. Bone Marrow/Peripher 14. Cochlear Implant 15. Cochlear Implant Repa 16. Septoplasty/Rhinoplas	
Waiver Prior Authorization 17. Consumer-Directed At 18. Pre-Vocational Service	tendant Care



Physician Administered Medications	(16):
19. Botulinum Toxins	. ,

- 20. Crysvita (burosumab-twza)
- 21. Elaprase (idursulfase)
- 22. Enjaymo (sutimlimab-jome)
- 23. Jelmyto (mitomycin gel)
- 24. Korsuva (difelikefalin)
- 25. Krystexxa (pegloticase)
- 26. Kymriah (tisagenlecleucel)
- 27. Luxturna (voretigene neparvovec-rzyl)
- 28. Nexviazyme (avalglucosidase alfa-ngpt)
- 29. Ocrevus (ocrelizumab)
- 30. Pluvicto (lutetium Lu 177 vipivotide tetraxetan)
- 31. Radicava (edaravone)
- 32. Spinraza (nusinersen)
- 33. Spravato (esketamine nasal spray)
- 34. Tysabri (natalizumab) Archive effective 3/31/2024

Criteria Review

Lab (1):

1. Serum Iron Studies

Surgical Procedures (2):

- 2. Bariatric Surgery
- 3. Vagus Nerve Stimulator

Physician Administered Medications - New (6):

- 4. Elfabrio (pegunigalsidase alfa-iwxj)
- 5. Lamzede (velmanase alfa-tycv)
- 6. Lunsumio (mosunetuzumab-axgb)
- 7. Natalizumab Agents (Tysabri, Tyruko)
- 8. Qalsody (tofersen)
- 9. Rystiggo (rozanolixizumab-noli)

Upcoming Meetings

- Friday, July 19, 2024
- Friday, October 18, 2024

Adjournment

Additional Information

- Iowa Medicaid CAC contact: CAC@dhs.state.ia.us
- Iowa Medicaid CAC webpage: https://live-hhs-iowa-gov.pantheonsite.io/about/advisorygroups/clinical-advisory-committee-cac
- Guests wanting to speak during the public comment period must complete a • CAC Disclosure Form and email it to CAC@dhs.state.ia.us.



Meeting Minutes (Q2 2024)

Silent roll call proceeded & Committee Member quorum was confirmed.

Introduction: Heidi Weaver, Iowa Medicaid QIO, welcomed everyone to the second quarterly 2024 Iowa Medicaid Clinical Advisory Committee (CAC) Meeting with an overview of the house rules.

Announcements: Introduced Committee Chairman, Dr. Jagiello, who is the Medical Director for Iowa Medicaid QIO.

She provided instructions for the Public Comment presentations, with the use of a new visible timer for each Public Guest Speaker and allotment of 5 minutes to present. She also provided the new CAC email available for any correspondence at <u>CAC@dhs.state.ia.us</u>.

She introduced roll call voting, as it will be used for the method of capturing all committee members' individual votes.

Approval of the January 19, 2024 Minutes: Approved.

Dr. Jagiello opened for a vote to approve the minutes and there were no requests for any changes or corrections.

First motion to approve by Dr. Danley Second motion to approve by Dr. Sahu

Committee Member by vote:

Decision-Motion approved by 7 of 9 members present.

- Dr. Alexandra Hubbell-Family Practice (absent)
- 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. Chitra Reddy-Endocrinology
- Dr. Kathleen Lange-Family Practice
- Dr. Geetanjali Sahu-Child and Adolescent Psychiatrist

Old Business:

1.Molecular Analysis for Targeted Therapy of Non-Small Cell Lung Cancer (LAB011):

Dr. Jagiello communicated the request at the last meeting to revisit this policy. He invited comments from the Public Speakers who registered to speak on this criterion.

1. Deb Brugman, Foundation Medicine, presented comments regarding the two tests they are primarily focusing on is the comprehensive molecular profiling testing (testing a patient's tissue and/or through a blood draw) for genomic changes by in the cancer) for targeted therapies or rule out therapies for patients. She spoke to the lowa policy that has a limit of up to 50 genes, where they know that testing in a more comprehensive way allows more opportunity to identify the targets or rule out therapies if the targets are present.



2. Queentela Abajuo, Foundation Medicine, presented comments, and advised on the growing number of Medicaid programs covering this testing, and 18 states currently cover at lease one of the Foundation Medicines comprehensive genomic profiling tests, they are seeking to expand coverage in Iowa. They would like to offer this under Iowa Medicaid, in thinking of the inequity in access to biomarker testing that Medicaid patients face. They are looking forward to thoughts of leadership and an opportunity of partnering together.

Dr. Jagiello shared gratitude for the presentations and offered comment on the current position is that many (MCO's, Commercial benchmarks and evidence based resources, consider Foundation as emerging technology, that shows great promise, yet at this time the bulk of the coverage will remain at smaller panels that include the key biomarkers and include between 5 through 50 genes, and that with the key biomarkers being included there is good efficacy for treatment/therapeutic options. The current determination at this time, won't include the CDx testing for this type of cancer, with considering the current NCCN guidelines.

This policy is updated, and he opened it to the Committee for any discussion and a vote.

First motion to approve by Dr. Lange Second motion to approve by Dr. Danley

Committee Member by vote:

Decision-This Criteria has been approved.

- Dr. Alexandra Hubbell-Family Practice (absent)
- 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. Chitra Reddy-Endocrinology
- Dr. Kathleen Lange-Family Practice
- Dr. Geetanjali Sahu-Child and Adolescent Psychiatrist

2.Zynyz (retifanlimab-dlwr) (PAM-069):

Dr. Umbreit presented the criteria as follow up from discussion at January's meeting. It's approved under accelerated approval and was tabled at the January 2024 for further review (review NCCN and decide if step therapy is warranted). She advised NCCN is referenced when developing the criteria. Her approach is to set up guardrails with strong literature to support and with clinical markers. The policy remains as originally presented in January. Dr. Umbreit provided a review of the requirements, dosing regimen and duration with quantity limits.

Dr. Jagiello requested comment from Dr. Sahu, regarding the additional review addressing her questions from the January meeting.

Dr. Sahu commented with the guardrails in place, she is comfortable with the policy.

Dr. Ferguson inquired on the prior question for clarification, and Dr. Sahu responded that this medication was under accelerated approval and there was not enough data to understand the efficacy, so the NCCN guidelines recommended 2a, recommendation, with better therapies



approved for treatment of MCC, so should there be step therapy, according to the failure of the first treatment to then go to this one.

Dr. Ferguson inquired on the ECOG Scale and had a question on the criteria indicating that a patient with Grade 2 wouldn't qualify for using the therapy and asked about the reasoning for that determination.

Dr. Umbreit stated that the clinical criteria was written based off of the requirements in the clinical trials.

Dr. Jagiello commented on the ECOG and a reviewer's discretion or flexibility (regarding PBM/pharmacy reference), and opened it up to the MCOs for comment:

Dr. Krishnan, Wellpoint, commented it does go through their PBM, and what the provider categorizes is considered, it is flexible with the patient's challenges factored in, and other criteria is considered and not a denial merely based on the reviewer's interpretation of the ECOG.

Dr. Mulhausen, ITC, commented that performance status is used in a variety of authorizations and medical necessity guidelines, including ECOG's and is an opportunity to engage with the Providers around their understanding of the patient's performance and prognosis.

Dr. Gutshall, MHC, commented gratitude to what has been expressed, and agrees with the questions and processes in place for making the determinations.

Dr. Ferguson confirmed a satisfied response.

Dr. Umbreit confirmed there were no changes made.

Dr. Jagiello opened it up to the Committee for a vote of approval.

First motion to approve by Dr. Ferguson Second motion to approve by Dr. Sahu

Committee Member by vote:

Decision-This Criteria has been approved.

- Dr. Alexandra Hubbell-Family Practice (absent)
- 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. Chitra Reddy-Endocrinology

Dr. Kathleen Lange-Family Practice

Dr. Geetanjali Sahu-Child and Adolescent Psychiatrist

Heidi Weaver announced the next order of business.

Consent Agenda:

Dr. Jagiello provided the purpose of the Consent Agenda, then opened for public comments.

1. Camalyn Woodard, Elevance Health, in attendance, provided inquiry on DME Safety Beds, regarding Iowa Code and the DME Provider's manual about alignment.



Dr. Jagiello motioned for the Committee to remove DME Safety Beds from the Consent Agenda and take it back to the SMEs to determine alignment and create constancy.

He opened for a vote to remove it from the Consent Agenda today for further internal consideration and to bring back under Old Business at the next quarterly meeting.

First motion by Clarice Blanchard Second motion by Dr. Zachary

Committee Member by vote:

Decision-All approved to remove it today and bring it to the next meeting.

- Dr. Alexandra Hubbell-Family Practice (absent)
- 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. Chitra Reddy-Endocrinology
- ⊠ Dr. Kathleen Lange-Family Practice
- Dr. Geetanjali Sahu-Child and Adolescent Psychiatrist

Dr. Jagiello requested the questions from Dr. Woodard along with the motion to review it internally to HHS Policy folks. After reviewing it will be brought back at the next meeting.

He asked if there were any other Public Speakers in attendance to speak on Consent Agenda items or if there were any questions by the Committee.

Dr. Sahu raised a question on LAB criteria for Chromosomal Microarray Analysis (LAB-001), within Genetic Testing item, as it's indicated as approved for Autism Spectrum Disorder, when accompanied by (specific) anomalies, however sometimes Autism is not associated with any anomalies, and the American College of Medical Genetics and Genomics, Chromosomal Microarray should be offered to every child with Autism, therefore to consider updating the criteria.

Dr. Danley commented it is under 81228, page 2, is listed under LAB-Genetic Testing criteria.

Dr. Jagiello commented that CMA has a more current policy that is available. He requested Diane Morrill to present it for review. The updated policy can be pulled up by code or on the website and indicates in the criteria, a third necessity can be the diagnosis of ASD, without requiring congenital anomalies to be present. The older criteria will be archived. There have been no issues presented with this, as the newest policy is available.

Dr. Sahu agreed the criteria looks updated and good.

Dr. Jagiello invited comments from the registered Public Speakers:

- 1. Jeremy Whalen, Genentech, in attendance to represent both PAM Ocrevus (item 29) and Lunsumio (item 6 under Criteria Review) and didn't have formal comments to share but wanted to be available for questions.
- 2. Robert Gerdes, not in attendance. Jeremy Whalen spoke that he was unable to be on the call today, and is a colleague, and yielded back their times.



3. Lynda Finch, Biogen, in attendance to speak on Tysabri under Criteria Review (item 7) to present comment at that time.

Dr. Jagiello opened for a vote by the Committee to approve the Consent Agenda.

First motion by Dr. Lange Second motion by Dr. Danley

Committee Member by vote:

Decision-All Approved and the motion carried.

- Dr. Alexandra Hubbell-Family Practice (absent)
- 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. Chitra Reddy-Endocrinology
- Dr. Kathleen Lange-Family Practice
- Dr. Geetanjali Sahu-Child and Adolescent Psychiatrist

Heidi announced the next order of business.

Criteria Review:

1.Serum Iron Studies (LAB-013)

Dr. Jagiello presented the criteria. Post service review and Pre-pay review with no Prior Authorization required. They will be handled through the claims system with automation, when the claim is received and with an identified ICD-10 codes/conditions associated, will process through the system. And only those that don't pass through automation would require manual review.

Dr. Ferguson provided comment to request hyper Cytokine storm illnesses (primary hemophagocytic lymphocytic cytosis (hyperphagic anemic state), macrophage activation syndrome, which are life threatening disorders, that can be treated by ferritin, and intensivists use it intensively and post covid it's been important to identify people who have MIS-C (multisystem inflammatory syndrome in children) and have those additions included.

Dr. Jagiello advised he is open to making the change to accept those conditions, and asked her to email a list of them to the CAC email at: <u>CAC@dhs.state.ia.us</u> and for review to update the list and bring it back at the next meeting.

Dr. Ferguson inquired if providers would have information and education, so the cost doesn't fall onto the individual.

Dr. Jagiello advised there would be a network education plan. He asked Becki Wedemeier to comment regarding this aspect.

Becki Wedemeier, HHS, indicated the next steps would be to take it to the external Claims and Benefits Policy Committee, informational level, then an information letter goes out to providers, to clarify usage of it would be monitored and if overuse begins, then review will be conducted to ensure its valid.



Dr. Jagiello commented the intent of this initially is to educate the network to ensure medical appropriateness to improve the patient's outcome and health.

He opened it up for questions and comments from the Committee.

Dr. Sahu inquired what the re-check time frame would be? Dr. Ferguson replied with a re-check would be needed and usually about 3 months or so.

Dr. Jagiello requested a motion from the Committee to remove from consideration under new policies today and bring it back under Old Business with a more robust list of conditions.

First motion by Dr. Zachary Second motion by Dr. Danley

Committee Member by vote:

Decision: All approved to table it today and bring it back at the next meeting.

Dr. Alexandra Hubbell-Family Practice (absent)

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. Chitra Reddy-Endocrinology

Dr. Kathleen Lange-Family Practice

Dr. Geetanjali Sahu-Child and Adolescent Psychiatrist

2.Bariatric Surgery (SRG-002)

Dr. Jagiello presented the criteria. This is a revision of a legacy policy with updates included. He discussed the included details.

Dr. Krishnan, Wellpoint, agreed with the criteria for the younger population who are under 18 years of age.

Dr. Mulhausen, ITC, commented that they use InterQual for this age group for discussion to assess meeting the criteria.

Dr. Jagiello presented the new references that were added. He opened it to the Committee for questions. Dr. Ferguson inquired if there will be an algorithm for medication requirements before this procedure.

Dr. Krishnan, Wellpoint, commented on the 6-month period with a provider to lose weight through lifestyle.

Dr. Jagiello responded that lifestyle weight loss is a measure used as a trial for adherence, and commitment to make the changes before surgery.

Dr. Mulhausen, ITC, commented on trends they are seeing for this procedure and thinks it's a good measure and is a constructive aspect of medical necessity.

Dr. Krishnan, Wellpoint, commented weight loss drugs should be viewed separately beginning in coverage, and these are two separate discussions.

Dr. Reddy commented she agrees with the prior comment, that they are two different topics, but believes they will overlap in the future, with the rate of obesity occurring and statistics, a



combination of therapy with lifestyle, medication and procedures are needed. She is board certified in Obesity Medicine and is a practicing physician in this space.

Dr. Krishnan, Wellpoint, commented clarification on her prior comment that not two different approaches needed, but a phased approach to clarify medication usage and baseline.

Dr. Jagiello opened to the Committee for a motion to approve the revised policy.

First motion by Dr. Zachary Second motion by Dr. Ferguson

Committee Member by vote:

Decision-All approved and the motion carried.

- Dr. Alexandra Hubbell-Family Practice (absent)
- 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. Chitra Reddy-Endocrinology
- Dr. Kathleen Lange-Family Practice
- Dr. Geetanjali Sahu-Child and Adolescent Psychiatrist

3.Vagus Nerve Stimulator (SRG-018)

Dr. Jagiello presented this revised policy. Anticonvulsant medications are considered frontline treatment for patients with seizures. His efforts in part were focused on alignment with the MCOs. One change from the Legacy policy, is removal of treatment for Depression, as he found it was only investigational.

Dr. Sahu commented she was comfortable with it.

Dr. Ferguson commented she hasn't seen this therapy used for rheumatoid arthritis patients.

Dr. Jagiello responded that they often come from the commercial policies so at times they are listed out. Dr. Krishnan, Wellpoint, and Dr. Mulhausen, ITC, agreed with comfortability with it.

Dr. Jagiello motioned for an approval of the revised criterion.

First motion by Dr. Ferguson Second motion by Dr. Zachary

Committee Member by vote:

Decision-All approved and the motion carried.

- Dr. Alexandra Hubbell-Family Practice (absent)
- 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. Chitra Reddy-Endocrinology
- Dr. Kathleen Lange-Family Practice
- Dr. Geetanjali Sahu-Child and Adolescent Psychiatrist



4.Elfabrio (PAM-071)

Dr. Umbreit presented the criteria. It is a Hydrolytic lysosomal neutral glycosphingolipid-specific enzyme. FDA-Approved Indication: Treatment of adults with confirmed Fabry disease. Intravenous infusion. Boxed warning for hypersensitivity reactions including anaphylaxis, and monitoring needed. Medical Benefit. There were no questions by the Committee.

Dr. Jagiello opened to the Committee for a vote.

First motion by Dr. Zachary Second motion by Dr. Lange

Committee Member by vote:

Decision-All approved and the motion carried.

- Dr. Alexandra Hubbell-Family Practice (absent)
- 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. Chitra Reddy-Endocrinology
- Dr. Kathleen Lange-Family Practice
- Dr. Geetanjali Sahu-Child and Adolescent Psychiatrist

5.Lamzede (PAM-072)

Dr. Umbreit presented the criteria. It is a recombinant human lysosomal alpha-mannosidase. FDA-Approved Indication: Treatment of non-central nervous system manifestations of alphamannosidosis in adult and pediatric patients. Intravenous infusion. Boxed warning for hypersensitivity reactions, including anaphylaxis and monitoring needed. Medical Benefit. There were no questions by the Committee.

Dr. Jagiello opened to the Committee for a vote.

First motion by Dr. Zachary Second motion by Dr. Lange

Committee Member by vote:

Decision-All approved and the motion carried.

- Dr. Alexandra Hubbell-Family Practice (absent)
- 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. Chitra Reddy-Endocrinology
- Dr. Kathleen Lange-Family Practice
- Dr. Geetanjali Sahu-Child and Adolescent Psychiatrist



6.Lunsumio (PAM-073)

Dr. Umbreit presented the criteria. It is a bispecific CD20-directed CD3 T-cell engager. FDA-Approved Indication: Treatment of adult patients with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy. This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial (s). Intravenous infusion. Boxed warning for Cytokine Release Syndrome, so there is a step-up dosing to reduce risk of CRS. Medical Benefit. There were no questions by the Committee.

Dr. Jagiello opened to the Committee for a vote.

First motion by Dr. Danley Second motion by Dr. Ferguson

Committee Member by vote:

Decision-All approved and the motion carried.

- Dr. Alexandra Hubbell-Family Practice (absent)
- 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. Chitra Reddy-Endocrinology
- Dr. Kathleen Lange-Family Practice
- Dr. Geetanjali Sahu-Child and Adolescent Psychiatrist

7. Natalizumab Agents (Tysabri, Tyruko) (PAM-077)

Dr. Umbreit presented the criteria. It is an Integrin receptor antagonist. FDA-Approved Indication: Treatment of Multiple Sclerosis and Crohn's Disease. Boxed warning for Progressive Multifocal Leukoencephalopathy (PML) and both have REMS programs. Medical Benefit.

 Lynda Finch, public presenter, offered comment Iowa Medicaid has an excellent policy ensuring safe & effective use of Natalizumab for MS patients and wanted to share some important considerations of PML risk management in light of the biosimilar and provided details and risk mitigation efforts.

The previous Tysabri policy (archived consent agenda) and a new policy was created which covers both Tysabri and Tyruko (new biosimilar for Tysabri).

There were no questions by the Committee.

Dr. Jagiello opened to the Committee for a vote.

First motion by Dr. Ferguson Second motion by Dr. Lange

Committee Member by vote: Decision-All approved and the motion carried.



- Dr. Alexandra Hubbell-Family Practice (absent)
- 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. Chitra Reddy-Endocrinology
- Dr. Kathleen Lange-Family Practice
- Dr. Geetanjali Sahu-Child and Adolescent Psychiatrist

8.Qalsody (PAM-075)

Dr. Umbreit presented the criteria. It is an antisense oligonucleotide (ASO). FDA-Approved Indication: Indicated for the treatment of amyotrophic lateral sclerosis (ALS) in adults who have a mutation in the superoxide dismutase 1 (SOD1) gene. This indication is approved under accelerated approval based on reduction in plasma neurofilament light chain observed in patients. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trials. Administered intrathecally using a lumbar puncture. Medical Benefit.

1. Lynda Finch, public presenter, offered comment that policy look excellent and in align with how physicians are treating patients. However, the 6 months authorization is too short to see a benefit and showing on primary end point by 10 months. She provided supporting details. She will send the data to <u>CAC@dhs.state.ia.us</u> for further review.

There were no questions by the Committee.

Dr. Jagiello opened to the Committee for a vote.

First motion by Dr. Danley Second motion by Dr. Zachary

Committee Member by vote:

Decision-All approved and the motion carried.

- Dr. Alexandra Hubbell-Family Practice (absent)
- 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. Chitra Reddy-Endocrinology
- Dr. Kathleen Lange-Family Practice
- Dr. Geetanjali Sahu-Child and Adolescent Psychiatrist

9.Rystiggo (PAM-076)

Dr. Umbreit presented the criteria. Antimyasthenic Agents; neonatal Fc receptor blocker. FDA Approved: treatment of generalized myasthenia gravis (gMG) in adult patients who are antiacetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive. Administered as a subcutaneous infusion. Medical Benefit.



1. Colleen Stoyas, UCB, public presenter, in attendance, stated this is a reasonable policy and provided comment treatment for generalized myasthenia gravis (gMG), significant cost driver to the healthcare system and provided supporting details.

There were no questions by the Committee.

Dr. Jagiello opened to the Committee for a vote.

First motion by Dr. Ferguson Second motion by Dr. Sahu

Committee Member by vote:

Decision- All approved and the motion carried.

- Dr. Alexandra Hubbell-Family Practice (absent)
- 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. Chitra Reddy-Endocrinology
- Dr. Kathleen Lange-Family Practice
- Dr. Geetanjali Sahu-Child and Adolescent Psychiatrist

Heidi Weaver announced the upcoming meetings and thanked all Committee Members.

Upcoming Meetings:

Friday, July 19, 2024 Friday, October 18, 2024

Meeting Process Improvement initiative feedback: The Committee provided comments of satisfaction with the great changes implemented that have contributed to increased efficiency and flow of the meeting.

Motion for Adjournment:

First motion by Dr. Danley, Second motion by Dr. Zachary. All approved. Dr. Jagiello adjourned the meeting.