Utah Department of Health & Human Services

Drug Utilization Review Board

Meeting Minutes

Thursday, March 14, 2024
7:15 a.m. to 8:30 a.m.
Google Meet

Board Members Present:

James Keddington, DDS
Jennifer Brinton, MD
Judith Turner, DVM, PharmD
Katherine Smith, PharmD
Michelle Hofmann, MD
Sharon Weinstein, MD
Susan Siegfreid, MD

Board Members Excused:

Colby Hancock, PharmD
Eric Cannon, PharmD, FAMCP, Board Chair

Dept. of Health/Div. of Health Care Financing Staff Present:

Andrea Rico, CPhT, CPC, Tech Mgr
Bryan Larson, PharmD, P&T Mgr
Craig Hummel, MD
Luis Moreno, PharmD, CDCES
Ngan Huynh, PharmD, DUR Mgr
Sepideh Daeery, PharmD, Pharmacy Director
Stephanie Byrne, PharmD, Policy Mgr
Yoon Kim-Butterfield, MD, Medical Director

University of Utah Drug Regimen Review Center Staff Presenter:

Monet Luloh, PharmD

Other Individuals Present:

Chad Duncan, PharmD, Vertex
Lisa Pulver, Johnson & Johnson
Miles Rooney, Optum
Monet Luloh, Medicaid DRRC
Pam Storey, Azurity Pharmaceuticals
Robert Pearce, Karuna Therapeutics
Roberto Pedraza, Vertex
Valarie Gonzales, Medicaid DRRC
4 joined by phone

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Meeting Minutes

Meeting conducted by: Ngan Huynh, PharmD, DUR Manager

1. **Welcome:**
   Ngan Huynh opened the meeting and reminded everyone in attendance to identify themselves via meeting chat or by sending an email to medicaidpharmacy@utah.gov. Ngan Huynh announced a quorum.

2. **Review and Approval of Choose an item Minutes:**
   Ngan Huynh motioned to approve the minutes from February 2024. Judith Turner proposed the motion and Michelle Hoffman seconded the motion. Edits were suggested. Ngan Huynh motioned to approve the minutes pending the suggested edits. Sharon Weinstein proposed the motion and Judith Turner seconded the motion. Unanimous approval.

3. **Housekeeping:**
   Ngan Huynh
   1) Addressed the board and announced the new Medicaid Pharmacy Director, Sepideh Daeery. Sepideh Daeery introduced herself to the board.

   Sepideh Daeery
   2) Updated the board on the Change Healthcare outage and that pharmacies are now able to submit claims through the Point of Service (POS), although edits are currently being bypassed until all systems are functioning. She also mentioned the dispensing fee payment for pharmacies on all prescriptions.

   Yoon Kim-Butterfield
   3) Thanked Miles Rooney for his support from the Change Healthcare/Optum side and expressed gratitude to the Utah Medicaid Pharmacy Team for working extra hours to help support members and pharmacy providers during the outage.

4. **P&T Committee Update:** None

5. **Topic:**
   - **a.** Lovotibeglogene autotemcel (Lyfgenia) and Exagamglogene autotemcel (Casgevy) for Sickle Cell Disease, presented by Monet Luloh, PharmD, with the Medicaid Drug Regimen Review Center

   - **b.** Public Comment: Chad Duncan, PharmD, with Vertex shared information about Casgevy , specifically for the Sickle Cell Disease indication.

   - **c.** Board Discussion: Ngan Huynh, asked if there were any questions. No questions from the board.

     Ngan Huynh shared the proposed Casgevy prior authorization draft.

     Michelle Hofmann asked a question regarding the 4-month time frame required after failure of hydroxyurea or one other disease-modifying agent, specifically if this referred to the hydroxyurea trial.

     Ngan Huynh responded that was correct.

     Sharon Weinstein asked about the bullet point stating “Erythropoietin, hydroxyurea and other disease-modifying agents will be discontinued for at least 2 months prior to mobilization and 2 days prior to conditioning.” She mentioned this criterion could be more precise. She asked Monet Luloh to share slide information that might help with updating the verbiage. Monet shared the slide.

     Ngan Huynh responded that she would review the feedback.

     Chad Duncan contributed information from the Casgevy label and clinical trials, based on patients who have Human Immunodeficiency Virus (HIV) and Hepatitis B or C with active infections. He asked that the Board revisit that information while creating the criteria. Active

infections can be treated to become inactive, which should not exclude them from treatment.

Katherine Smith asked to add verbiage surrounding pregnancy testing and prevention.

Ngan Huynh asked the board for feedback on that recommendation.

Sharon Weinstein recalled a general statement about counseling patients regarding risks which included pregnancy and other associated risks. She said she believes this would be part of the discussion.

Katherine Smith asked that we consider a bullet point with the provider attestations ensuring patient counseling of risks occurs.

Ngan Huynh asked if the board agreed with an attestation stating, “Discussion about the risk/benefit of the therapy including fertility preservation and reproductive consultation with the patient.”

d. Board Action:
Ngan Huynh asked for a motion to approve the Casgevy prior authorization as stated.

Michelle Hofmann suggested edits to the final sub-bullet to read, “Discussion with patient about the risk/benefit of the therapy including fertility preservation and teratogenicity.”

Katherine Smith agreed with the proposed verbiage.

Ngan Huynh asked if we have a motion with the proposed updates.
Katherine Smith motioned to approve.
Ngan Huynh asked if there was a second.
Sharon Weinstein seconded with the updates recommended.
Unanimous approval.

6. **Topic:**
   - **a.** Lyfgenia Prior Authorization Draft presented by Ngan Huynh
   - **b.** Public Comment: None
   - **c.** Board Discussion:
     Ngan Huynh shared the proposed Lyfgenia prior authorization draft.

     Monet Luloh mentioned that the Lyfgenia package insert did not specifically state Hepatitis B and C and the prior authorization should be updated.

     Katherine Smith asked that the same provider attestation that was added to Casgevy regarding fertility preservation and teratogenicity be included as a provider attestation on the Lyfgenia prior authorization form.

     Ngan Huynh agreed to the addition.

     Sharon Weinstein asked about the active infection status requirement prior to therapy. She is asking if this is referring to seropositivity or the active infection status, and how that would be distinguished at the time of therapy.

     Ngan Huynh reported the Lyfgenia package insert states that a patient with a seropositive test for Human Immunodeficiency Virus (HIV) will not be accepted for Lyfgenia treatment.

     Sharon Weinstein asked if we were also adding the Hepatitis B and C virus criteria, as with the Casgevy prior authorization criteria.

     Ngan Huynh responded that is correct.

     Chad Duncan added context regarding the criterion stating, “The

patient does not have an available/willing Human Leukocyte Antigen (HLA) match sibling allogeneic donor." Chad Duncan shared that only ~20% of patients have a match. This seems to suggest that if you have that option, this therapy is not an option, which should be a decision for the health care team to evaluate.

Monet Luloh shared that the discontinuation of duration of therapies may vary.

Ngan Huynh asked for any additional questions.

Michelle Hofmann mentioned that she was considering the HLA match criteria and any modifications that should be made to make it more of a discussion rather than an absolute.

Sharon Weinstein asked if we are making this a step requirement.

Katherine Smith asked if it could be altered to make it a discussion about risk/benefit of allogeneic transplant versus Lyfgenia.

Michelle Hofmann suggested editing that bullet point to state, "The patient is not a suitable candidate for Human Leukocyte Antigen (HLA)." She also suggested we also make this update on the Casgevy prior authorization form.

Katherine Smith asked for an addition of stem cell transplant to the end of that bullet point.

Ngan Huynh agreed to make the addition.

d. Board Action:
Michelle Hofmann moved to approve the Lyfgenia prior authorization form with the suggested updates. Sharon Weinstein seconded the motion with the added clarification on the discontinuation timing. Unanimous approval.
Based upon the updates to the Lygenia prior authorization which also

applies to Casgevy, Ngan Huynh asked if there was a motion to adjust the Casgevy prior authorization similarly to Lyfgenia?

Michelle Hofmann moved to approve the adjustment to the Casgevy prior authorization form. Susan Siegfreid seconded the motion. Unanimous approval.

7. **Topic:**
    a. Adakveo (criznlizumab) Prior Authorization, presented by Stephanie Byrne, PharmD, Policy Manager

    b. Public Comment: None

    c. Board Discussion: Stephanie Byrne asked if there were any questions.

    Michelle Hofmann asked if all the criteria must be met for approval.

    Stephanie Byrne responded affirmatively and updated the prior authorization form to reflect that information.

    Sharon Weinstein posed a question about the definition of pain episodes on the fifth bullet requirement. She further explained, we might want to put something additionally in the reauthorization criteria.

    Stephanie Byrne asked if there were any recommendations on verbiage updates.

    d. Board Action:
    Ngan Huynh asked for a motion to approve the Adakveo prior authorization.

    Michelle Hofmann moved to approve as amended. Katherine Smith seconded the motion. Unanimous approval.

8. **Meeting Chat Transcript:**

9. **The next meeting scheduled for:** April 11, 2024
   Topic: Short-Acting Beta 2 Agonist Utilization

10. **Public Meeting Adjourned:**
    Katherine Smith motioned to adjourn the meeting. Judith Turner seconded the motion. Unanimous approval.

Audio recordings of DUR meetings are available online at:
https://www.youtube.com/watch?v=k_TLsmGZ1wg