Utah Department of Health & Human Services

Drug Utilization Review Board

Meeting Minutes

Thursday, July 13, 2023

7:15 a.m. to 8:30 a.m.
Google Meet

Board Members Present:

Susan Siegfreid, MD
Judith Turner, DVM, PharmD
Kumar Shah, MSc, PEng
Jennifer Brinton, MD
Sharon Weinstein, MD
Eric Cannon, PharmD, FAMCP, Board Chair
James Keddington, DDS
Michelle Hofmann, MD

Board Members Excused:

Colby Hancock, PharmD
Katherine Smith, PharmD
Neal Catalano, PharmD

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

Lisa Angelos, PharmD, Pharmacy Director
Jennifer Strohecker, PharmD, Medicaid Director
Ngan Huynh, PharmD
Bryan Larson, PharmD
Stephanie Byrne, PharmD
Joe Busby, RPh, MBA
James Stamos, Office Director

University of Utah Drug Regimen Review Center Staff Presenter:

Monet Luloh, PharmD U of U DRRC

Other Individuals Present:

Ashlee Waring, Axsom Therapeutics
Don McCaffrey, Vertex Pharmaceutical
Derek Traister, Acadia Pharmaceutical
Dan O'Donnell, Axsome
Madeline Shurtleff, Otsuka
Matthew Call, UUHP
Beth D'Ambrosio
Dawn Bey
Gary Parenteau
Gina Heinen
Heather Freml
Heidi Goodrich, Molina Healthcare
Julia Zhu
Lisa Pulver
Miles Rooney, Change Healthcare
Rob Booth, Abbive
Todd Dickerson, Jazz Pharmaceuricals
Valerie Gonzales, U of U DRRC
Ming Lim, U of U Hematology
Rick Kegler
Michael Zarob, Alkermes Inc

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Meeting Minutes

Meeting conducted by: Board Chair

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

2. **Housekeeping:**
   Jennifer Strohecker shared information regarding the legislative report on the immunosuppressant carve out and DAW-1 override for psychotropic medications.

3. **Review and Approval of June Minutes:** Kumar Shah motioned to approve the minutes from June. Judith Turner seconded the motion. Unanimous approval.

4. **Topic:**
   a. **Sickle Cell Disease**
      1. Ngan Huynh stated the reason for reviewing Sickle Cell Disease (SCD) today. This review is a result of H.B.487 Sickle Cell Disease.
      2. Monet Luloh, DRRC, presented on Sickle Cell Disease prevalence, pathophysiology, complications, screening/diagnosis, pharmacotherapies, and potential barriers to sickle-cell disease medication utilization.
      3. Questions/comments from the Board:
         1) Kumar asked about most recent data on SCD's prevalence in the United States and in Utah. Monet Luloh answered that the prevalence data presented in the presentation is the most recent data from the Centers for Disease Control and Prevention (CDC) for SCD in the United States. There is no specific SCD data published on the CDC website for Utah.
         2) Jen Strohecker reiterated the importance of getting the SCD prevalence in Utah and suggested potentially

reviewing the Utah Medicaid's data for claims with SCD diagnosis codes to evaluate the SCD's prevalence of in the state of UT.

3) Michelle Hoffman suggested reviewing newborn screening. In 2010, there were 126 infants with a positive trait for SCD, but no disease data.
4) Jennifer Brinton commented that based on the discussion with Primary Children Hospital (PMC) Hematology & Oncology physicians, there is an average of 4 children/year that test positive for SCD.

b. Public Comment

1. Ming Lim stated that she has been working to determine the SDC prevalence in Utah. She stated Primary Children's Medical Center has 3 to 4 kids newly diagnosed with SCD every year through newborn screening, and overall, Primary Children's Medical Center has 25 to 50 pediatric patients currently with SCD. There are approximately 20 adult patients with SDC being treated at the University of Utah Adult Clinic. Dr. Lim wasn't sure why there is a gap in the number of pediatric patients and adult patients because patients transition from pediatric care to adult care. She also commented that using ICD-10 codes to analyze SCD prevalence might not be as accurate due to different genotypes having different ICD-10 codes, which can lead to miscoding. She also estimated around 100 SCD patients currently in Utah.
2. Ngan Huynh read the written comment from "Sick Cells" patient advocacy group that urged the Board to recognize gaps in pharmacotherapies coverage that can affect SCD patient's lives.

c. Board Discussion

1. Sharon Weinstein shared her prior experiences with treating Sickle Cell Disease patients.

d. Board Action

1. No Board Action is needed.

5. **Topic:**
    a. **Hormone Therapy for Gender Dysphoria**
        1) Ngan shared the "Hormone Therapy for Gender Dysphoria" Prior Authorization form. The prior authorization criteria have been shared with the Accountable Care Organizations (ACOs) and published on Medicaid's Prior Authorization website.

Criteria for Approval in Adults:

- ❑ Patient is 18 years of age or older

Gender Dysphoria Diagnosis [1,2]

- ❑ Persistent, well documented gender dysphoria/gender incongruence including a marked incongruence between one's experienced/expressed gender and natal gender of at least 6 months in duration. **Must meet two of the following:**
    - Marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics
    - Strong desire to rid of one's primary and/or secondary sex characteristics
    - Strong desire for the primary and/or secondary sex characteristics of other gender
    - Strong desire to be or be treated as the other gender
    - Strong conviction that one has the typical feelings and reactions of the other gender

Additional Criteria [1,2] **Must meet all of the following:**

- ❑ Capacity to make a fully informed decision and provide consent for treatment ***(minimum of 18 years of age)***
- ❑ If significant medical or mental health concerns are present, they must be managed accordingly.
- ❑ Discussion of risks/benefits and expectations of hormone therapy *(virilization, feminization or development of adverse reactions)*
- ❑ Documented monitoring plan
    - Male to Female
        - Testosterone level for suppression: below upper limit of normal female range (<50 ng/dL)

        - Estradiol levels within premenopausal female range but below supraphysiologic levels (100-200 pg/dL)
    - Female to Male
        - Testosterone level: maintain levels within normal male range and avoid supraphysiological levels
- ❑ Other applicable preventative screenings: cancer, osteoporosis *(baseline bone-mineral density test)*, etc.

Criteria for Approval in Children/Adolescents:

- ❑ Patient less than 18 years of age
- ❑ Hormonal treatment is prescribed by or in consultation with an endocrinologist(s) or physician(s) who is experienced in hormonal therapy treatments in pediatric and adolescent patients.
- ❑ **The patient was diagnosed with gender dysphoria prior to January 28, 2023**. Documentation demonstrates the date of diagnosis: _____
- ❑ Documentation demonstrates that the **provider has been treating the patient for gender dysphoria for at least 6 months.**
- ❑ Documentation demonstrates assessing and treating any physical or mental health if needed.
- ❑ Documentation that the provider has discussed alternative treatments or behavioral interventions for gender dysphoria.
- ❑ The patient has reached Tanner stage 2 of puberty (*if requesting gonadotropin releasing hormone as puberty blocker*).
- ❑ Documentation of health evaluation by a mental health professional that:
  - Different from the provider providing the hormonal transgender treatment.
  - Have a transgender treatment certification (starting 1/1/2024)
  - Have documentation of history of at least 3 therapy sessions with the patient.
  - Have documentation of all mental health diagnoses and any significant life events that may be contributing to the diagnoses of the patient.
  - Have documentation that the patient has persistent, well documented gender dysphoria/gender incongruence including a marked incongruence between one's experienced/expressed gender and natal gender of at least 6 months in duration. **Must meet two of the following:**
    - Marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics
    - Strong desire to rid of one's primary and/or secondary sex characteristics
    - Strong desire for the primary and/or secondary sex characteristics of other gender
    - Strong desire to be or be treated as the other gender
    - Strong conviction that one has the typical feelings and reactions of the other gender
- ❑ Submit laboratory values at baseline before hormonal transgender initiation: *(select applicable option)*
  - Estradiol levels in females; **OR**
  - Testosterone levels in males
- ❑ Documented monitoring plan, *if applicable*
  - Male to Female
    - Testosterone level
    - Estradiol levels
  - Female to Male
    - Testosterone level
    - Hematocrit level
- ❑ Documentation that the provider has discussed with patient and parent/guardian all the following: reproductive health counseling, risks/benefit and expectations of hormone therapy and monitoring plan and other applicable preventive screenings.
- ❑ Documentation of written consent from:
  - The patient, and
  - The patient's parent or guardian, unless the patient is emancipated.

UTAH MEDICAID PHARMACY PRIOR AUTHORIZATION REQUEST FORM

Re-authorization Criteria:

- ❑ Updated chart notes demonstrating positive clinical response to hormones
- ❑ Reassessment of appropriate management of patient's mental health status
- ❑ Submit laboratory hormone levels and any other relevant monitoring values
  - Male to Female: testosterone and estradiol
  - Female to Male: testosterone and hematocrit

Initial Authorization: Up to six (6) months
Re-authorization: Up to one (1) year

b. **Public Comment:** No public comment.
c. **Board Discussion:** No Board Discussion.
d. **Board Action:** No Board Action needed.

6. **Meeting Chat Transcript:**
   00:10:17.863,00:10:20.863
   Susan L. Siegfreid, M.D.: I apologize but I will need to be off camera today.

   00:29:02.332,00:29:05.332
   Sharon M Weinstein MD: wondering if that is because Utah is not reporting to CDC?

   00:29:58.624,00:30:01.624
   Dawn Bey: CMS may have availability data, given its a high Medicaid population

7. **The next meeting is scheduled for Thursday, August 10, 2023** Hemgenix (etranacogene dezaparvovec).

8. **Public Meeting Adjourned:** Sharon Weinstein motioned to adjourn the meeting. Kumar Shah seconded the motion. Unanimous approval.

Audio recordings of DUR meetings are available online at:
https://medicaid.utah.gov/pharmacy/drug-utilization-review-board?p=DUR%20Board%20Audio%20Recordings/