Utah Department of Health & Human Services

Drug Utilization Review Board

Meeting Minutes

Thursday, June 8, 2023
7:15 a.m. to 8:20 a.m.
Google Meet

Board Members Present:

Eric Cannon, PharmD, FAMCP, Board Chair
Colby Hancock, PharmD
James Keddington, DDS
Jennifer Brinton, MD
Judith Turner, DVM, PharmD
Katherine Smith, PharmD
Kumar Shah, MSc, PEng
Neal Catalano, PharmD
Sharon Weinstein, MD
Susan Siegfreid, MD

Board Members Excused:

Michelle Hofmann, MD

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

Jennifer Strohecker, PharmD, Medicaid Director
Lisa Angelos, PharmD, Pharmacy Director
Bryan Larson, PharmD
Craig Hummel, MD
James Stamos, Office Director
Joe Busby, RPh, MBA
Julie Armstrong, CPhT
Luis Moreno, PharmD
Ngan Huynh, PharmD
Stephanie Byrne, PharmD

University of Utah Drug Regimen Review Center Staff Presenter:

Lauren Heath, PharmD U of U DRRC

Other Individuals Present:

Amy Hale, Johnson & Johnson
Eric Nowak, Geisinger
Gary Parenteau, Fargo-Moorhead
Heidi Goodrich, Molina Healthcare
Jason Smith, Gilead Sciences
John Aldridge, PharmD Provention Bio
Maddy Webb, AmeriHealth
Matthew Call, UUHP
Melissa Abbott, Emergent BioSolution
Miles Rooney, Change Healthcare
Monet Luloh, PharmD U of U DRRC
Sandee Merrick, Provention Bio
Shannon Gilreath, UUHP
Todd Dickerson, Jazz Pharmaceuticals

Meeting conducted by: Eric Cannon

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Meeting Minutes

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. Eric Cannon recognized and thanked the Department of Health and Human Services for running the Medicaid pharmacy benefit for the recipients in the state of Utah.

2. **Review and Approval of May Minutes:** Sharon Weinstein motioned to approve the minutes from May as drafted. Judith Turner seconded the motion. Unanimous approval. Kumar Shah was not present for vote.

3. **Housekeeping:**
   - **a.** Lisa Angelos informed the Drug Utilization Review Board that the state has received the CMS DUR Survey submissions from the Accountable Care Organizations. The state is to review and complete the FFS portion and will submit to CMS by the deadline.
   - **b.** Jennifer Strohecker will be presenting a report to the legislature next week reviewing the Dispense as Written (DAW) override on psychotropic medications. A meeting with stakeholders will be scheduled following the presentation.
   - **c.** Ngan Huynh provided updates on the gender dysphoria S.B. 16 that was signed into law on January 28, 2023, to enact provisions regarding transgender care treatments and procedures in minor patients who are under eighteen years of age. The law requires policy changes to be put in place by July 2023. Changes include requiring a provider who provides hormone treatment for minors to have a history of treating gender dysphoria for that minor for six months prior to providing any hormone therapy. The minor patient will be required to have a mental health evaluation completed by a separate mental health professional than the one providing the hormone therapy. Documentation will be required that the provider has discussed side effects, risks, and benefits of using hormone therapy for gender dysphoria with the patient. Consent must be obtained. The hormone therapy for gender dysphoria criteria will be updated to reflect the changes and requirements and published on July 1, 2023.

4. **Tzield (teplizumab-mzwv):**
    a. **Information:** Lauren Heath, PharmD from the University of Utah College of Pharmacy Drug Regimen Review Center (DRRC) presented peer-reviewed research regarding indications for use, safety and efficacy, treatment guidelines, and considerations for prior authorization criteria for Tzield (teplizumab-mzwv). Tzield (teplizumab-mzwv) is a first in class monoclonal antibody approved by the Food and Drug Administration (FDA) and designated as breakthrough therapy indicated to delay the onset of type I diabetes mellitus for patients eight years of age and older. Type I diabetes mellitus is caused by destruction of pancreatic beta cells by the immune system. Individuals with a family history of type I diabetes mellitus have an increased genetic risk. Onset may occur at any age. Diagnosis usually occurs when symptomatic. One-third of children present with diabetic ketoacidosis when diagnosed. Type I diabetes mellitus requires chronic insulin treatment and is associated with psychosocial distress and health complications. Type I diabetes mellitus is classified into three stages of progression. Stage I patients have the presence of two or more pancreatic islet autoantibodies. Stage II patients develop dysglycemia and are usually pre-symptomatic. Stage III patients develop hyperglycemia and are usually symptomatic. All patients with a diagnosis of type I diabetes mellitus will eventually reach stage III, however the rate of progression through the stages is variable from months to decades. Tzield (teplizumab-mzwv) is indicated for patients diagnosed with stage II type I diabetes mellitus to delay the progression to stage III type I diabetes mellitus. A phase III clinical trial is ongoing with results expected to be published by mid-2023. In the TN-10 pivotal trial Tzield (teplizumab-mzwv) delayed stage III type I diabetes mellitus onset by twenty-four to thirty-two months depending on the median follow up. Common adverse events included lymphopenia, rash, leukopenia, headache, neutropenia, increased alanine transaminase (ALT), nausea, diarrhea, and nasopharyngitis. Tzield (teplizumab-mzwv) is not recommended during pregnancy. The mechanism of action is not fully understood. Tzield (teplizumab-mzwv) is administered as an

intravenous (IV) infusion given once daily over fourteen days in an outpatient setting once per lifetime. Considerations for prior authorization criteria include consultation with an endocrinologist, confirmation of a diagnosis of stage II type I diabetes mellitus in age-appropriate patients confirmed by laboratory testing and clinical screening, requiring pre-treatment laboratory screenings and age-appropriate vaccinations prior to treatment, having no serious, chronic, or active infections, and restricting patients to a single course of treatment.

b. **Public Comment:** John Aldridge, PharmD from Provention Bio provided testimony on the clinical information for Tzield (teplizumab-mzwv). Eric Cannon inquired if there is a standard screening that is recommended. John Aldridge stated primary screening usually begins with a first degree relative with a diagnosis of type I diabetes mellitus. Programs are beginning to develop where endocrinology centers work with pediatric offices to do general population screening. Colby Hancock inquired where patients are receiving weekend infusions to complete the concurrent fourteen-day treatments. John Aldridge stated it depends on the payer requirements. Most clinicians feel more comfortable with the medication be administered in a clinical setting or infusion center. Susan Siegfreid inquired if any autoantibodies resulted in a poor or better outcome compared to others. John Aldridge stated the results were so small that they may not be relevant to the differences between the different autoantibodies. John Aldridge stated the PROTECT study results should be available in the next six weeks for additional information.
c. **Board Discussion:** Luis Moreno, PharmD presented the proposed prior authorization criteria for Tzield (teplizumab-mzwv).

Criteria for Approval: *(all the following criteria must be met)*

- ❑ Medication being prescribed by, or in consultation with, an endocrinologist to delay onset of stage 3 type 1 diabetes (clinical type 1 diabetes)
- ❑ Patient is 8-45 years of age and DOES NOT have stage 3 type 1 diabetes or type 2 diabetes
- ❑ Patient is not pregnant
- ❑ Confirmed diagnosis of stage 2 type 1 diabetes by documenting:
  - Presence of 2 or more pancreatic islet autoantibodies
  - Patient has a relative with Type 1 diabetes that meets the following:
    - If first degree relative (brother, sister, parent, offspring), patient must be between 8-45 years old OR
    - If second degree relative (niece, nephew, aunt, uncle, grandchild, cousin), patient must be between 8-20 years old
  - Presymptomatic (no overt symptoms of hyperglycemia)
  - Impaired glycemic response (2-h PG 140-199 mg/dL) to an oral glucose tolerance test
    - If an oral glucose tolerance test is not available, an alternate method for diagnosing dysglycemia without overt hyperglycemia may be appropriate such as FPG 100-125 mg/dL or A1C 5.7-6.4% within the last 3 months

  Chart Note Page #: _____
- ❑ Patient has not been previously treated with Tzield (teplizumab-mzwv)
- ❑ Treating provider will obtain a complete blood count and liver enzyme tests prior to/and during treatment as recommended by the Teplizumab prescribing information
- ❑ Treating provider documents administration of all age-appropriate vaccinations prior to/after treatment as recommended by the Teplizumab prescribing information
- ❑ Treating provider attests to counseling the patient regarding the need to complete 14 consecutive days of infusions without missing a dose

Initial Authorization: Teplizumab to be administered by intravenous infusion once daily for 14 consecutive days according to the recommended dosage and administration schedule in the prescribing information.
Re-authorization: Not applicable

Sharon Weinstein recommended modifying the requirement of the requesting provider administering the vaccinations to attest that age-appropriate vaccinations have been completed. Susan Siegfreid inquired if the requirement of a patient having to have a relative diagnosed with type I diabetes is relevant or would exclude patients who may not know their family history if all other criteria are met. Neal Catalano recommended clarifying the patient must have a family history or relative, and the patient must be between the certain age ranges. Lauren Heath inquired if a temporary interruption in therapy would be allowed if the authorization approval is only for a fourteen-day period. Eric Cannon and Bryan Larson inquired if there is any data that has been studied to show how a temporary interruption in therapy impacts efficacy of the treatment. John Aldridge confirmed there is no data in the prescribing information. The half-life of the drug is four days, so the decision is deferred to the clinician's

discretion if they are comfortable with restarting after missing a couple days. Neal Catalano inquired if there would be an impact to patient care if a decision on the prior authorization criteria is made after more study data is published. Ngan Huynh stated the prior authorization criteria has not been published and there are no restrictions to access the medication. Sharon Weinstein inquired if date ranges of approval could be adjusted if treatment is interrupted or delayed due to logistic and/or clinical interruptions. Ngan Huynh stated the provider can reach out to Utah Medicaid to request date adjustments.

d. **Board Action:** Sharon Weinstein motioned to wait until more study data is published in a few weeks to revise and reword the criteria for the board to review. Neal Catalano seconded the motion. Unanimous approval. Katherine Smith was not present for vote.

5. **Meeting Chat Transcript:**
   00:22:50.225,00:22:53.225
   Sharon M Weinstein MD: I was wondering that too - infusion centers?
   00:49:34.164,00:49:37.164
   Katherine Smith: I've got to run to another meeting. Sorry I can't stay. Great discussion!
   00:54:18.026,00:54:21.026
   Sharon M Weinstein MD: proposed wording amendment to documenting vaccinations have been given.

6. **The next meeting scheduled for Thursday, July 13, 2023** Sickle Cell Disease.

7. **Public Meeting Adjourned:** Kumar Shah motioned to adjourn the meeting. Neal Catalano seconded the motion. Unanimous approval. Katherine Smith was not present for vote.

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