Utah Department of Health & Human Services

Drug Utilization Review Board

Meeting Minutes

Thursday, September 8, 2022
7:15 a.m. to 8:15 a.m.
Google Meet

Board Members Present:

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

Board Members Excused:

Katherine Smith, PharmD
Neal Catalano, PharmD

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

Andrea Rico, CPhT, CPC
Bryan Larson, PharmD
James Stamos, Office Director
Joe Busby, RPh, MBA
Julie Armstrong, CPhT
Lisa Angelos, PharmD, Pharmacy Director
Luis Moreno, PharmD
Ngan Huynh, PharmD
Stephanie Byrne, PharmD

University of Utah Drug Regimen Review Center Staff Presenter:

Valerie Gonzales, PharmD U of U DRRC

Other Individuals Present:

Amy Hale, Janssen
Amy Breen, Teva
Artia Solutions
Carrie Johnson, PharmD Amgen
Charlie Lovan, PharmD AbbVie
David Large, Biohaven
David Testerman, Change Healthcare
Heidi Goodrich, Molina Healthcare
Jason Bott, Eli Lilly
Matthew Call, UUHP
Michael Shepherd, RN Eli Lilly
Monet Luloh, PharmD U of U DRRC
Natalie Rose, Gilead
Robert Booth, AbbVie
Robert Nohavec, UUHP
Rochelle Yang, PharmD Teva

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. Eric Cannon announced a quorum.

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

3. **Housekeeping:** Ngan Huynh announced the resignation of Elizabeth Gargaro from her position on the Drug Utilization Review Board. Utah Medicaid appreciates Dr. Gargaro's expertise and contributions provided during her time on the Drug Utilization Review Board. Joe Busby informed the board he has a conflict of interest with topics on the agenda and he has removed himself from preparatory discussions.

4. **Mounjaro (tirzepatide):**
    a. **Information:** Valerie Gonzales, 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, utilization data, and considerations for prior authorization criteria for Mounjaro (tirzepatide). Mounjaro (tirzepatide) is the first dual glucose-dependent insulinotropic polypeptide (GIP)/glucagon-like peptide 1 (GLP-1) receptor agonist approve for adults with type II diabetes mellitus. Mounjaro (tirzepatide) increases insulin sensitivity and secretion while decreasing fasting and postprandial glucose, glucagon secretion and appetite resulting in improved glycemic control and body weight. Mounjaro (tirzepatide) is administered as a single dose once weekly. Mounjaro (tirzepatide) has not been approved for use in pediatric or type I diabetes mellitus patients. Mounjaro (tirzepatide) is not currently labeled for cardiovascular risk reduction although it has shown to be highly effective for glycemic control. Metformin and lifestyle changes are recommended as first line therapy. Glucagon-like peptide 1 (GLP-1) receptor agonist are recommended prior to insulin

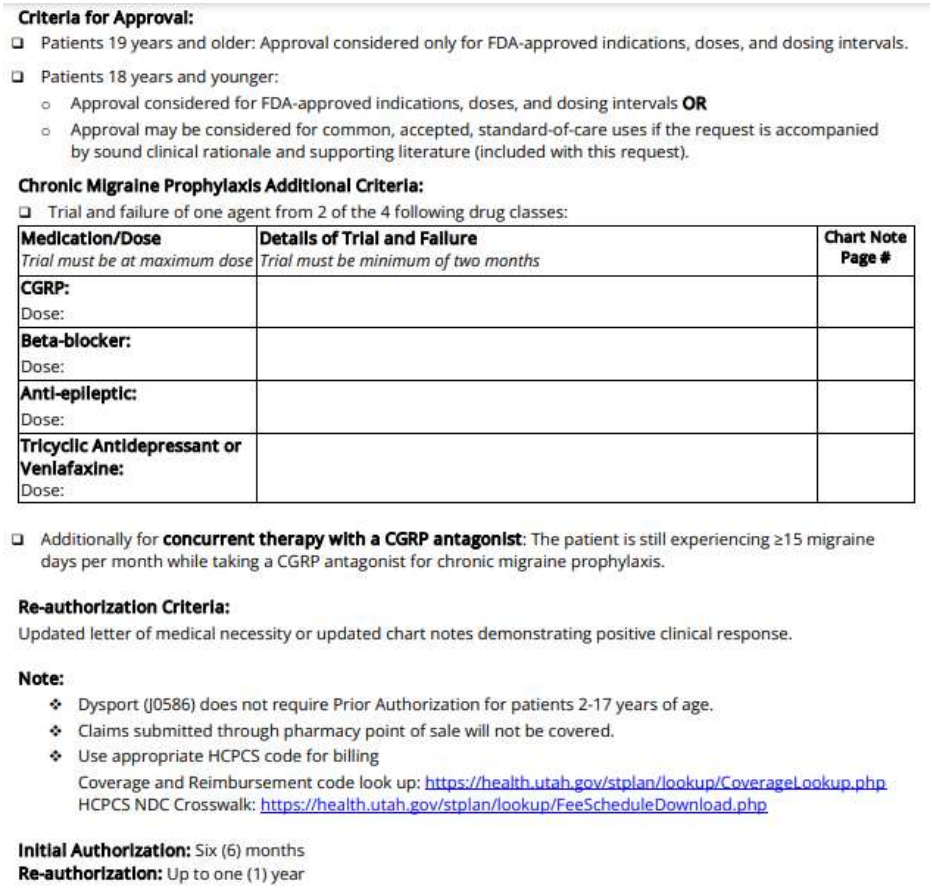
or in combination with insulin for greater efficacy. Mounjaro (tirzepatide) is safe and effective as monotherapy or as add-on therapy to oral antihyperglycemic agents or basal insulin according to the SURPASS clinical studies. Once weekly Trulicity (dulaglutide), Victoza (liraglutide) and Ozempic (semaglutide) are the recommended agents labeled for cardiovascular risk reduction while Bydureon (exenatide XR) and Victoza (liraglutide) are approved for use in pediatric patients. Phase 3 studies and clinical trials for Mounjaro (tirzepatide) are planned for to include additional indications for use. Common adverse reactions with Mounjaro (tirzepatide) include decreased appetite, diarrhea, dyspepsia, nausea/vomiting, constipation, and abdominal pain. Labeled warnings include hypersensitivity reactions and severe gastrointestinal reactions which can lead to dehydration and acute kidney injuries. Mounjaro (tirzepatide) is currently non-preferred on the Utah Medicaid Preferred Drug List (PDL). Criteria for approval requires one of the following: trial and failure of a preferred medication in the same drug class, continuation of care demonstrating member has been stable on Mounjaro (tirzepatide) for at least sixty days in the most recent ninety days, or appropriate clinical rationale. Considerations for drug specific prior authorization criteria could include meeting Food and Drug Administration (FDA) labeled indication of eighteen years of age or older with type II diabetes mellitus, step-therapy after a preferred agent used according to guideline recommendations, and indefinite approval once initial authorization approval to support adherence, limit disruptions in care, and lessen administrative burden.

b. **Public Comment:** Michael Shepherd, RN from Eli Lilly provided testimony on the clinical information for Mounjaro (tirzepatide).
c. **Board Discussion:** Ngan Huynh presented utilization data and current Preferred Drug List (PDL) placement for Utah Medicaid and surrounding states. Six prior authorization requests have been received and denied for Mounjaro (tirzepatide) due to not having sufficient trial and failure of a preferred product. Denial letters include denial information and criteria required for approval. Fee-for-Service has had zero paid claims for Mounjaro (tirzepatide). Preferred products on the Utah Medicaid Preferred Drug List (PDL) include

Bydureon, Trulicity, and Victoza. Surrounding states either do not have Mounjaro (tirzepatide) listed on their Preferred Drug List (PDL) yet or has it listed as non-preferred. Utah Medicaid proposes to keep Mounjaro (tirzepatide) as non-preferred status on the Preferred Drug List (PDL) and use the Medication Coverage Exception Criteria.

d. **Board Action:** Michelle Hofmann motioned to approve the states proposal to keep Mounjaro (tirzepatide) as non-preferred status on the Utah Medicaid Preferred Drug List (PDL) and use the Medication Coverage Exception Criteria. Judith Turner seconded the motion. Unanimous approval.

5. **Calcitonin Gene-Related Peptide (CGRP) Antagonists and Botox Prior Authorizations:**
   a. **Information:** Luis Moreno presented updated prior authorization criteria for Botulinum Toxins.



Criteria for Approval:

- ❑ Patients 19 years and older: Approval considered only for FDA-approved indications, doses, and dosing intervals.
- ❑ Patients 18 years and younger:
  - Approval considered for FDA-approved indications, doses, and dosing intervals **OR**
  - Approval may be considered for common, accepted, standard-of-care uses if the request is accompanied by sound clinical rationale and supporting literature (included with this request).

Chronic Migraine Prophylaxis Additional Criteria:

- ❑ Trial and failure of one agent from 2 of the 4 following drug classes:

Medication/Dose *Trial must be at maximum dose*	**Details of Trial and Failure** *Trial must be minimum of two months*	**Chart Note Page #**
CGRP: Dose:		
Beta-blocker: Dose:		
Anti-epileptic: Dose:		
Tricyclic Antidepressant or Venlafaxine: Dose:		

- ❑ Additionally for **concurrent therapy with a CGRP antagonist**: The patient is still experiencing ≥15 migraine days per month while taking a CGRP antagonist for chronic migraine prophylaxis.

Re-authorization Criteria:
Updated letter of medical necessity or updated chart notes demonstrating positive clinical response.

Note:

- ❖ Dysport (J0586) does not require Prior Authorization for patients 2-17 years of age.
- ❖ Claims submitted through pharmacy point of sale will not be covered.
- ❖ Use appropriate HCPCS code for billing

Coverage and Reimbursement code look up: https://health.utah.gov/stplan/lookup/CoverageLookup.php
HCPCS NDC Crosswalk: https://health.utah.gov/stplan/lookup/FeeScheduleDownload.php

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

Luis Moreno presented updated prior authorization criteria for

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Calcitonin Gene-Related Peptide (CGRP) Antagonists.

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

- ❑ Patient is 18 years or older.
- ❑ Diagnosis of one of the following, per Headache Guidelines (https://www.ihs-headache.org/ichd-guidelines):
  - Chronic Migraine
  - Episodic Migraine
  - Episodic Cluster Headache, for Emgality only.

Chronic Migraine Prophylaxis Additional Criteria:

- ❑ Trial and failure of one agent from 3 of the 4 following drug classes:

Medication/Dose *Trial must be at maximum dose*	**Details of Trial and Failure** *Trial must be minimum of two months*	**Chart Note Page #**
Botulinum toxin: Dose:		
Beta-blocker: Dose:		
Anti-epileptic: Dose:		
Tricyclic Antidepressant or Venlafaxine: Dose:		

- ❑ Additionally for concurrent therapy with CGRP antagonist: The patient is still experiencing ≥15 migraine days per month while taking a CGRP antagonist for chronic migraine prophylaxis.

Acute Migraine <u>Abortive</u> Treatment Additional Criteria:

- ❑ Trial and failure or contraindication to 2 triptans:

Medication/Dose	**Details of Trial and Failure** *Including Duration*	**Chart Note Page #**
Triptan: Dose:		
Triptan: Dose:		

Episodic Cluster Headache Treatment Additional Criterion:

- ❑ Trial and failure of Verapamil. Details: _____ Chart Note Page #: _____

Medication/Dose	**Details of Trial and Failure** *Including Duration*	**Chart Note Page #**
Verapamil Dose:		

Non-Preferred CGRP Product: *(Criteria above must also be met)*

- ❑ Trial and failure of preferred CGRP within same Utah Medicaid PDL class, or prescriber must demonstrate medical necessity for non-preferred product.

Medication/Dose	**Details**	**Chart Note Page #**
Preferred CGRP: Dose:		

Quantity Limits: Ubrelvy (ubrogepant): Max of 16 tablets per 30 days. **Nurtec** (rimegepant): Max of 8 tablets per 30 days (abortive treatment), 16 tablets per 30 days (prophylactic treatment)

Re-authorization Criteria: Updated letter of medical necessity or updated chart notes demonstrating positive clinical response with improvement in headache frequency (prophylaxis) or severity (abortive treatment).

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

Luis Moreno presented Fee-for-Service utilization data for Calcitonin Gene-Related Peptide (CGRP) Antagonists and Botox.

CGRP Antagonists for Abortive Treatment (8/31/21 to 9/6/22)			
Medication	**Claims**	**Approved PAs**	**Denied PAs**
Nurtec ODT (preferred)	117	71	72
Ubrelvy	28	13	40

CGRP Antagonists for Prophylactic Treatment (8/31/21 to 9/6/22)			
Medication	**Claims**	**Approved PAs**	**Denied PAs**
Ajovy (preferred)	250	60	52
Aimovig	126	25	35
Emgality	53	13	20
Vyepti		0	1
Qulipta	12	1	15

Botox* (8/31/21 to 9/6/22)			
Medication	**Claims**	**Approved PAs**	**Denied PAs**
Botox	277	148	33

*This data is not exclusive for migraine prophylaxis

b. **Public Comment:** Rochelle Yang, PharmD from Teva provided testimony on the clinical information for Ajovy (fremanezumab).

   Charlie Lovan, PharmD from AbbVie provided testimony on the clinical information for Botox (onabotulinumtoxinA).

   Carrie Johnson, PharmD from Amgen provided testimony on the clinical information for Aimovig (erenumab-aooe).

c. **Board Discussion:** Sharon Weinstein inquired why duloxetine or other selective serotonin reuptake inhibitors (SSRIs) were not included with venlafaxine. Luis Moreno stated duloxetine is not guideline recommended for migraine prophylaxis. Sharon Weinstein recommended removing “oral” from the acute migraine abortive treatment additional criteria due to not all triptans being an oral formulation. Susan Siegfreid and Sharon Weinstein inquired if tricyclic

antidepressants should be more defined or specified. Sharon Weinstein inquired if the current criteria require patients to be tapered from opioid therapy. Luis Moreno stated opioid tapering is not included in the criteria.

d. **Board Action:** Prior authorization updates provided by the state were informational only and no motions were needed. All prior authorization criteria recommendations made by the board will be considered.

6. **Meeting Chat Transcript:**
   00:43:12.609,00:43:15.609
   Michelle Hofmann (DHHS): Apologies need to drop early for another meeting
   00:43:22.946,00:43:25.946
   Ngan Huynh (DHHS): thank you Dr. Hofmann
   00:57:05.149,00:57:08.149
   Sharon M Weinstein MD: thanks all!

7. **The next meeting scheduled for Thursday, November 10, 2022** Topic TBD. A meeting will not be held in October.

8. **Public Meeting Adjourned:** Sharon Weinstein motioned to adjourn the meeting. Eric Cannon seconded the motion. Unanimous approval. Michelle Hofmann 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/