

# 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 Siegfried, 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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# Drug Utilization Review Board

## 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](mailto: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 Siegfried 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

# Drug Utilization Review Board

## Meeting Minutes

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

# Drug Utilization Review Board

## Meeting Minutes

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:
  - o Approval considered for FDA-approved indications, doses, and dosing intervals **OR**
  - o 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 <i>Trial must be at maximum dose</i>	Details of Trial and Failure <i>Trial must be minimum of two months</i>	Chart Note Page #
<b>CGRP:</b> Dose:		
<b>Beta-blocker:</b> Dose:		
<b>Anti-epileptic:</b> Dose:		
<b>Tricyclic Antidepressant or Venlafaxine:</b> Dose:		

- Additionally for **concurrent therapy with a CGRP antagonist:** The patient is still experiencing  $\geq 15$  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

# Drug Utilization Review Board

## Meeting Minutes

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

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

**Acute Migraine Abortive Treatment Additional Criteria:**

- Trial and failure or contraindication to 2 triptans:

Medication/Dose	Details of Trial and Failure <i>Including Duration</i>	Chart Note Page #
<b>Triptan:</b> Dose:		
<b>Triptan:</b> Dose:		

**Episodic Cluster Headache Treatment Additional Criterion:**

- Trial and failure of Verapamil. Details: \_\_\_\_\_ Chart Note Page #: \_\_\_\_\_

Medication/Dose	Details of Trial and Failure <i>Including Duration</i>	Chart Note Page #
<b>Verapamil</b> 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 #
<b>Preferred CGRP:</b> 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

# Drug Utilization Review Board

## Meeting Minutes

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

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

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

<b>Botox* (8/31/21 to 9/6/22)</b>			
<b>Medication</b>	<b>Claims</b>	<b>Approved PAs</b>	<b>Denied PAs</b>
<u>Botox</u>	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 Siegfried and Sharon Weinstein inquired if tricyclic

# Drug Utilization Review Board

## Meeting Minutes

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.

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Audio recordings of DUR meetings are available online at:

<https://medicaid.utah.gov/pharmacy/drug-utilization-review-board?p=DUR%20Board%20Audio%20Recordings/>