Utah Department of Health & Human Services

Drug Utilization Review Board

Meeting Minutes

Thursday, January 11, 2024
7:15 a.m. to 8:30 a.m.
Google Meet

Board Members Present:

Judith Turner, DVM, PharmD
Neal Catalano, PharmD
Michelle Hoffman, MD
Sharon Weinstein, MD
James Keddington, DDS
Jennifer Brinton, MD
Eric Cannon, PharmD, FAMCP, Board Chair

Board Members Excused:

Susan Siegfried, MD
Katherine Smith, PharmD
Colby Hancock, PharmD

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

Bryan Larson, PharmD, P&T Manager
Lisa Angelos, PharmD, BCSCP, CAPP
Luis Moreno, PharmD, CDCES
Ngan Huynh, PharmD, DURB Manager
Stephanie Byrne, PharmD
Yoon Kim-Butterfield, MD, Medical Director, Interim Pharmacy Director
Craig Hummel, MD

University of Utah Drug Regimen Review Center Staff Presenter:

Monet Luloh, PharmD

Other Individuals Present:

Chad Duncan, Vertex
Miles Rooney, CHC, Optum
Matthew Call, University of Utah
Lauren Heath, Medicaid DRRC
Artia Solutions Representative
Heidi Goodrich, Molina Healthcare
Jeff White, Sumitomo Pharma
Joseph Bennett
Robert Pearce, Karuna Therapeutics

Utah Department of Health & Human Services

Drug Utilization Review Board

Meeting Minutes

Meeting conducted by: Ngan Huynh and Eric Cannon

1. Welcome: Ngan Huynh opened the meeting and announced a quorum.
2. Judith Turner motioned to approve the December 2023 DUR minutes. Michelle Hoffman seconded the motion. Unanimous approval.
3. Housekeeping:
   - Legislative Session starting this week (Yoon Kim-Butterfield, MD)
   - Full Carve Back to FFS Study results are expected in the next few weeks (Yoon Kim-Butterfield, MD)
4. P&T Committee Update: No update
5. Topic:
   a. Donislecel-jujn (Lantidra) for Type 1 Diabetes Mellitus presented by Monet Luloh
   b. Public Comment: None
   c. Board Discussion:
   - Eric Cannon asked for the definition of hypoglycemia unawareness. Monet Luloh responded that the Lantidra drug studies listed the following definition as their criteria for hypoglycemia unawareness: a self-reported lack of awareness of blood glucose symptoms when blood glucose falls below 54mg/dL.
   - Neal Catalano asked about the malignancy risk stated in the presentation; specifically what type of malignancies were associated with Lantidra use? Sharon Weinstein mentioned that she noticed that as well and asked to review the slide.
   - Monet Luloh said she would research the associated malignancies and report back.
   - Neal Catalano thanked Monet Luloh for the presentation.
   - Monet Luloh responded via meeting chat: “To answer the previous question regarding the malignancies in the donislecel clinical trials (UIH-001 and UIH-002), it is reported that malignancies included 12 skin cancers, 1 post-transplant lymphoproliferative disease, 1 breast cancer, and 1 thyroid cancer.”
   - Eric Cannon asked if there were other questions. He mentioned the drug durability is interesting and mentioned the differences seen between studies. He further queried, if the treatment is used, does

that preclude patients from future transplant options? Monet Luloh said the exclusion criteria in both studies did not allow for previous renal transplants.

- Eric Cannon asked if there is a proposed prior authorization for the board to review. Ngan Huynh confirmed a prior authorization draft was prepared for review.
- Eric Cannon asked if the prior authorization had been reviewed by community specialists and leaders. Ngan Huynh responded that the prior authorization has been reviewed by the Managed Care Entity partners and their suggestions are included in the prior authorization draft.

d. Lantidra Prior Authorization: Ngan Huynh presented the Lantidra prior authorization draft for board review.

Criteria for Approval: *(at least one of the following criteria must be met)*

- ❑ The patient is 18 years of age or older
- ❑ The patient has a diagnosis of Type 1 Diabetes
- ❑ The patient is unable to approach target HbA1c because of current repeated episodes of severe hypoglycemia despite intensive diabetes management and education
- ❑ Patient will receive concomitant immunosuppression
- ❑ The patient is up to date with all vaccinations, in accordance with current vaccination guidelines, prior to initiating therapy
- ❑ The patient does not have a history of liver disease or renal failure and has not been the recipient of a renal transplant

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

Initial Authorization: One (1) infusion
Re-authorization: A repeated infusion may be performed if the patient does not achieve independence from exogenous insulin within one year of infusion or within one year after losing independence from exogenous insulin after a previous infusion. **Maximum 3 lifetime infusions**.

- Eric Cannon posed a couple of questions on the Lantidra prior authorization draft: Is there a timeframe on the expectation for patients unable to achieve glucose control with an insulin pump and monitoring? Ngan Huynh responded that the prescribing information does not mention a timeframe and asked the board for their suggested time frames. Eric Cannon suggested leaning on the physicians in the group for that feedback but thinks an appropriate time frame would be at least 6-12 months.
- Eric Cannon then asked about the three (3) infusion limit max if there

is data to support reinfusion. Monet Luloh mentioned that in the drug trials patients were able to receive up to three (3) infusions. Clinical data is available to support reinfusion. Yoon Kim-Butterfield shared that she has seen studies where patients with the second infusion had better outcomes than patients with a single infusion.

- Monet Luloh then shared the percentages of study participants who received one (1) infusion (37%), two (2) infusions (40%), and three (3) infusions (24%).
- Sharon Weinstein commented on the prior authorization criteria requiring care to be provided by an endocrinologist with a specialty in islet cell transplantation, and assumes that along with that criterion, the timeframe for failure would likely be 12 months; we may not want to specify a specific timeframe on the prior authorization form if the patient is being seen by a specialist who is qualified to make that determination.
- Sharon Weinstein mentioned in the exclusion criteria, it is her understanding patients should not have received any transplantation other than an islet cell transplant. She then asked if we needed to modify that criterion. Ngan Huynh responded that the prescribing information only specifically calls out renal transplant as an exclusion.
- Eric Cannon asked if there is a callout in the prescribing information for concomitant immunosuppressive therapy. Ngan Huynh responded that the prescribing information does mention that patients must be able to receive concurrent immunosuppression therapy.
- Eric Cannon responded to Sharon Weinstein's comment regarding the timeframe required for treatment failure and said her suggestion to allow the treating specialist to determine that timeframe seems appropriate.
- Eric Cannon then asked about the criteria suggesting that the patient is unable to achieve target HbA1c despite intensive diabetes management, which assumes the patient is capable of participating in intensive diabetes management. Judith Turner responded that if the member is not capable of participating in intensive diabetes management using a CGM pump, etc. then it calls into question if the patient can maintain the fairly intensive management of the immunosuppressive therapy post-transplant.

- Judith Turner then asked if a history of malignancy is a contraindication. Ngan Huynh responded; that malignancy is not a listed contraindication.
- Jennifer Brinton mentioned there may be a demographic of patients who may not be able to manage their regimen alone but should still be considered for the treatment if care is managed by others.
- Eric Cannon asked if there were any specific recommended changes. There were no suggestions.
- Eric Cannon moved that we accept the criteria as proposed and asked that the group hear back on utilization, approvals, and denials since this is a new treatment. Ngan Huynh agreed to update the board if there are any requests as well as outcomes to be shared in 6-12 months based on utilization.

e. Board Action: Sharon Weinstein proposed to approve the Lantidra prior authorization form as presented. Neal Catalano seconded. Unanimous approval.

6. Topic:
   a. Vyjuvek (beremagene geperpavec-svdt) Presented by Luis Moreno
   b. Luis Moreno presented the updated changes to the prior authorization form based upon the ACO's feedback since the December 2023 DURB Meeting.

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

- ❑ The medication is being prescribed by or in consultation with a dermatologist.
- ❑ The patient is 6 months of age or older.
- ❑ The patient is not pregnant.
- ❑ If the patient is an individual of childbearing potential, the patient is on an effective method of contraception during treatment with Vyjuvek.
- ❑ The patient has a diagnosis of Dystrophic Epidermolysis Bullosa (DEB) with genetically confirmed mutation(s) in the *collagen type VII alpha 1 chain (COL7A1)* gene.
  Chart Note Page #: _____
- ❑ Documented baseline number and size of wounds. Chart Note Page #: _____
- ❑ The patient has at least one open wound meeting all of the following criteria:
  - No evidence of active infection
  - No current evidence or history of squamous-cell carcinoma

  Chart Note Page #: _____
- ❑ Vyjuvek will be applied to wounds once weekly by a healthcare professional who has been trained in proper application of Vyjuvek; and arrangements have been made to ensure the patient will be compliant with weekly dosing.
- ❑ The Vyjuvek dose will be determined by the patient's age, wound size & maximum weekly dose threshold per the United States Food and Drug Administration-approved labeling.
  Chart Note Page #: _____
- ❑ Requested dosing: _____

c. Public Comment: None
d. Board Discussion:
   - Eric Cannon asked for any questions or comments on the Vyjuvek prior authorization updated criteria. No comments.
e. Board Action:
   - Eric Cannon asked if the board approved the proposed Vyjuvek prior authorization form as presented.
   - Judith Turner moved to approve. James Keddington and Sharon Weinstein seconded. Unanimous approval.

7. Topic: Opioids and/or Opioid-Benzodiazepine Combination Prior Authorization Updates presented by Ngan Huynh

Is the intended use any of the following situations: ☐ Cancer pain ☐ End-of-life care ☐ Long term care ☐ Palliative care ☐ Sickle cell disease-related pain

Short-Acting Opioids: *Prior Authorization may not be required if patient has filled initial script of the same medication for a 7-day supply (or 3-day for dental providers).*

❑ Clinical rationale for patient not receiving initial 7-day prescription:
_____ Chart Note Page #: _____

Long-Acting Opioids: *Prior Authorization may not be required if patient has filled short acting opioid within 30 days of initiating therapy on a long-acting opioid.*

❑ Clinical rationale for patient not receiving short acting opioid in past 30 days:
_____ Chart Note Page #: _____

❑ Non-opioid pain medication history. Patient is using or has tried and failed at least two of the following: NSAIDs, non-opioid analgesics, antidepressants (SNRI or TCAs) or anticonvulsants (gabapentin or pregabalin).
Medication: _____ Chart Note Page #: _____
Details of failure (including duration): _____
Medication: _____ Chart Note Page #: _____
Details of failure (including duration): _____

Dose, Age, Pregnancy, MME and/or Quantity Limits Exception Criteria for Approval: *Taper plan must be provided for all limit exception requests.*

❑ Clinical rationale if patient under 18 years of age is receiving a long-acting opioid or more than 7-day supply of a short-acting opioid:
_____ Chart Note Page #: _____

❑ Clinical rationale if pregnant patient receiving a long-acting opioid or more than 7-day supply of a short-acting opioid:
_____ Chart Note Page #: _____

❑ Clinical rationale for exceeding Utah Medicaid Opioid Quantity Limit and / or Morphine Milligram Equivalent > 90 MME/day limit:
_____ Chart Note Page #: _____

❑ **Details of opioid taper plan** or rationale for the lack thereof:
_____ Chart Note Page #: _____

Opioid Use Disorder (OUD) Criteria for Approval:

❑ Clinical rationale for opioid use if patient received Medication Assisted Treatment (MAT) in last 45 days:
_____Chart Note Page #: _____

Opioid and Benzodiazepine Combination: FDA Boxed Warning

- ❑ Clinical rationale and diagnosis for patient receiving concomitant benzodiazepine and opioid within last 45 days: _____ Chart Note Page #: _____
- ❑ Most recent opioid prescription information: Date Prescribed: _____
  Medication Name and Strength: _____ Quantity/Day Supply: _____
- ❑ Most recent benzodiazepine prescription information: Date Prescribed: _____
  Medication Name and Strength: _____ Quantity/Day Supply: _____

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

- ❑ Trial and failure of preferred opioid in same Utah Medicaid PDL class with appropriate dose and duration:
  Medication(s): _____Chart Note Page #: _____
  Dates of therapy: _____ Details of Failure: _____
- ❑ Clinical rationale for non-preferred product: *(i.e. adverse reaction, allergy, or contraindication to preferred product)*
  Chart Note Page #: _____

Provider attests to all the following:

- ☐ Provider has a signed opioid treatment agreement with the patient.
- ☐ Provider has assessed opioid abuse risk with a validated risk assessment tool, such as Opioid Risk Tool (ORT), Current Opioid Misuse Measure (COMM) or Patient Medication Questionnaire (PMQ).
- ☐ Provider has checked the Utah Controlled Substance Database with each opioid prescription.
- ☐ Provider has discussed the medication's benefits and potential harms, including combining opioids with other CNS depressants with the patient.
- ☐ Provider has counseled patient with high-risk conditions (sleep apnea, pregnancy, mental health conditions, substance abuse disorders, or children) on the heightened risk of using opioids.
- ☐ Provider has completed a urine drug test for chronic opioid use (duration of > 3 months) excluding pain management related to sickle cell disease, cancer-related pain treatment, palliative care and end-of-life care.
- ☐ Patient has received naloxone education and prescription (if appropriate).

Initial authorization: Up to three (3) months
Re-authorization: Up to six (6) months
Authorization for use with MAT (suboxone, buprenorphine for OUD): Up to fourteen (14) days, no re-authorization

a. Public Comment: None
b. Board Discussion:
   - Eric Cannon asked for any questions or comments on the Opioid and/or Opioid-Benzodiazepines Combination Prior Authorization updated criteria. He commented that the updates seem appropriate.
   - Sharon Weinstein asked for clarification on patients utilizing opioids and MAT. Ngan Huynh responded that the pharmacy system is programmed to reject claims when a patient is on MAT therapy and there is a subsequent request for opioids for greater than 7-day supply. However, the system does allow

claim adjudication for patients currently taking opioids who begin MAT therapy.
- Eric Cannon asked if there were any other comments. No comments.

c. Board Action:
- Eric Cannon moved to approve the proposed Opioid and/or Opioid-Benzodiazepines Combination prior authorization form as presented. Judith Turner and Sharon Weinstein seconded. Unanimous approval.
- Sharon Weinstein asked that the Opioid and/or Opioid-Benzodiazepines Combination prior authorization be emailed to the board.
- Ngan Huynh agreed to email the approved prior authorization form.

8. Meeting Chat Transcript:
00:46:25.150,00:46:28.150
Monet Luloh (UofU CoP, DRRC): To answer the previous question regarding types of malignancies in the donislecel clinical trials (UIH-001 and UIH-002), it is reported that that malignancies included 12 skin cancers, 1 post-transplant lymphorproliferative disease, 1 breast cancer, and 1 thyroid cancer.
00:46:47.446,00:46:50.446
Eric Cannon: thank you!
00:47:10.030,00:47:13.030
Neal Catalano: Thank you Monet!
00:47:18.657,00:47:21.657
Sharon M Weinstein MD: thanks!
00:55:34.565,00:55:37.565
Sharon M Weinstein MD: thank you all
9. The next meeting is scheduled for February 8, 2024, Sublocade Adherence Retrospective Review
10. Neal Catalano motioned to adjourn the meeting. Sharon Weinstein 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/