Drug Utilization Review Board (DURB)

Friday, October 13, 2023

9:00 a.m.
Approved[1]
Virtual: Teams Meeting Platform
In Person Meeting Site: Robert D. Bernstein Building, Building K, K-100,
1100 W. 49th Street, Austin, TX 78756

Agenda Item 1: Call to order, roll call, and welcoming remarks

Dr. Alejandro Kudisch, Chair, called the Drug Utilization Review Board (DURB) meeting to order at 9:00 a.m.

Ms. Jacqueline Thompson, Advisory Committee Coordination Office (ACCO), Health and Human Services Commission (HHSC) read the logistical announcements and stated the meeting was being conducted in accordance with the Texas Open Meetings Act. Ms. Thompson conducted a roll call and announced the presence of a quorum.

Table 1: Drug Utilization Review Board member attendance at the Friday, October 13, 2023, meeting.

Member name	Attended	Member name	Attended
Dr. Scott Blaszczyk	N	Dr. Sarah Kubes	Y
Mr. Dennis Borel	N	Dr. Alejandro Kudisch	Y
Dr. Marlo Brawner	N	Dr. Jill Lester	Y
Dr. Dominique Brewster	Y	Dr. Brigetta Martinez	Y
Dr. Deborah Briggs	N	Dr. Richard Noel	Y
Dr. Salil Deshpande	Y	Dr. Kim Pham	Y
Dr. Jennifer Fix	Y	Dr. Lisa Sprenger	Y
Dr. Robert Hogue	N	Dr. Natalie Vanek	N
Dr. Heather Holmes	Y	Dr. Kathryn Velasquez	Y
Dr. Joshua Tonche-Johns	N	Dr. Carlos Omar Viesca	N

[1] These minutes were revised and re-approved at the Friday, April 26, 2024 DUR Board meeting. The revision reflects the motion made regarding agenda item 4j as passing.

Agenda Item 2: 88th Texas Legislature, Regular Session (2023), Legislative Update

Dr. Alejandro Kudisch, Chair, turned the floor to Dr. Justin Luong, Vendor Drug Program Drug Utilization Review and Formulary Management Director, to provide the 88th Texas Legislature, Regular Session (2023), Legislative Update related to House Bill (HB) 3286 and HB 1283.

- Member discussion included confirmation from Dr. Luong that:
    - a recipient who was discharged from an inpatient facility on a non-preferred drug, including long-acting injectables (LAIs), and is stable would be enough alone to continue that medication as an outpatient as described in HB 3286
    - a 24-hour turnaround time, including weekends, on manual prior authorization requests if not first automatically approved through claim data mining
    - a temporary non-preferred status for any new drugs available but not yet reviewed by DURB
    - HB 3286 was not the legislative bill that prohibited coverage of medications for weight loss
    - physician calls to obtain prior authorization (PA) will get a determination at the end of the call

Ms. Thompson, Advisory Committee Coordination Office (ACCO), Health and Human Services Commission (HHSC) read the logistical announcements for providing public comments.

Agenda Item 3: Retrospective drug use criteria for outpatient use in Vendor Drug Program: The University of Texas at Austin College of Pharmacy

Dr. Justin Pedigo, Pharm. D, The University of Texas at Austin College of Pharmacy referenced PowerPoint, *Texas Medicaid Vendor Drug Program Drug Utilization Review Board Meeting-Retrospective Drug Use Criteria Proposals October 13, 2023.*

- Oral Public comment – Kenneth Berry, Alkermes, yielded his time back to the DUR Board to make himself available to the DUR Board for questions.
- Dr. Pedigo stated he will add to Table 1 of the Antipsychotics (Oral) criteria set, the indication of agitation associated with dementia due to Alzheimer's disease the Rexulti (brexpiprazole).

- **Motion:** Dr. Richard Noel moved to approve revisions with the noted addition by Dr. Justin Pedigo. Dr. Jennifer Fix seconded the motion. Following roll call votes, the motion passed with a majority vote with 10 yeas (Brewster, Fix, Holmes, Kubes, Kudisch, Lester, Martinez, Noel, Pham, Velasquez), 0 nays, 0 abstentions.

Agenda Item 4: Prospective prior authorization proposal (clinical edits): KEPRO, LLC.

Dr. Christina Faulkner, Kepro, referenced the PowerPoint, *Texas HHSC DUR Board Meeting Prospective Prior Authorization Proposals October 13, 2023.*

a. Antipsychotics (ASY) Agents – Revisions

- Oral Public comment – Kenneth Berry, Alkermes, provided drug information
- Member discussion included:
  - use of check insomnia diagnosis
  - how antidepressant agents are identified in check for use of other antidepressants and used for the managed care required PMUR
  - age check for under 18 years
  - no impact on clinical PA criteria from HB 3286
- Member discussion resulted in recommendations for:
  - removing insomnia diagnosis check
  - updating the duplicate therapy check to 2 or more antipsychotics with unique active pharmaceutical agents
- **Motion:** Dr. Sarah Kubes moved to approve the revised criteria for clinical prior authorization (CPA) for Antipsychotics (ASY) Agents as amended above. Dr. Jennifer Fix seconded the motion. Following a roll call vote, the motion passed by a majority vote with 10 yeas (Brewster, Fix, Holmes, Kubes, Kudisch, Lester, Martinez, Noel, Pham, Velasquez), 0 nays, 0 abstentions.

b. Anxiolytics and Sedative-Hypnotics (ASH) Agents – Revisions

- Member discussion for Rozerem (ramelteon) included:
  - what drugs are included in the check for concurrent therapy agents
  - confirmation that check for substance abuse is going away
- Member discussion resulted in no recommended changes to CPA criteria for Rozerem (ramelteon) as presented.
- **Motion:** Dr. Richard Noel moved to approve the CPA criteria for Rozerem (ramelteon) of the ASH as presented. Dr. Sarah Kubes seconded the motion. Following a roll call vote the motion passed by a

majority vote with 10 yeas (Brewster, Fix, Holmes, Kubes, Kudisch, Lester, Martinez, Noel, Pham, Velasquez), 0 nays, 0 abstentions.

c. Cytokine and CAM Antagonists – New Criteria for Litfulo (Ritlecitinib)

- Member discussion included:
  - what diagnoses are used to identify severe hepatic impairment found in the last 365 days
  - confirmation of the list of diagnoses to identify severe hepatic impairment is listed in the criteria
  - typical duration of therapy of these agents
- Member discussion resulted in no recommended changes to CPA criteria for Litfulo (Ritlecitinib) as presented.
- **Motion:** Dr. Kim Pham moved to approve the proposed new CPA for Litfulo (Ritlecitinib) as presented. Dr. Richard Noel seconded the motion. Following a roll call vote the motion passed by a majority vote with 10 yeas (Brewster, Fix, Holmes, Kubes, Kudisch, Lester, Martinez, Noel, Pham, Velasquez), 0 nays, 0 abstentions.

d. Calcitonin Gene-Related Peptide Receptor (CGRP) - New criteria for Zavzpret (Zavegepant)

- Member discussion included:
  - the process to handle if a member reaches the eight-quantity max
  - ensure other chronic baseline management agents and stabilized monoclonal drugs are included in the check history use step
  - the need for longer approval for chronic use and shorter approval for acute use
- Member discussion resulted in recommendations for:
  - a check for routine prophylactic therapy and if found, approve for 365 days otherwise, if not found, approve for 90 days.
- **Motion:** Dr. Sarah Kubes moved to approve new CPA criteria for Zavzpret (Zavegepant) of CGRP guide as amended above. Dr. Jennifer Fix and Dr. Kim Pham seconded the motion. Following a roll call vote, the motion passed by a majority vote with 10 yeas (Brewster, Fix, Holmes, Kubes, Kudisch, Lester, Martinez, Noel, Pham, Velasquez), 0 nays, 0 abstentions.

e. Filspari (Sparsentan) – New Criteria

- Oral public comment:
  - John Omick, Trevere Therapeutics, discussed the use of Filspari (Sparsentan) and questioned the proposed lookback period

- Written public comment was received from the following organizations/associations:
    - South Texas Renal Care Group
    - IGA Nephropathy Foundation
- Member discussion included the possible limited distribution of Filspari (Sparsentan)
- Member discussion resulted in no recommended changes to the new CPA criteria for Filspari (Sparsentan)
- **Motion:** Dr. Jennifer Fix moved to approve the proposed new criteria for Filspari (Sparsentan) CPA as presented. Dr. Sarah Kubes seconded the motion. Following a roll call vote, the motion passed by a majority vote with 10 yeas (Brewster, Fix, Holmes, Kubes, Kudisch, Lester, Martinez, Noel, Pham, Velasquez), 0 nays, 0 abstentions.

f. Imcivree (Setmelanotide) – New Criteria

- Member discussion included:
    - the lookback period for the genetic testing
    - the weight check on renewal criteria for patients with continued growth potential
    - verification of the step numbering in the criteria document
    - impact of this criteria on the speaker from the DURB meeting the day before
    - reclassification of this drug to the drug class of melanocortin receptor agonist which allows for Medicaid coverage
    - no indication for Chung Jansen syndrome
- Oral public comment:
    - Jordan Smelley, self
    - Codey Gerber, Rhythm Pharmaceuticals, discussed the needed criteria step renumbering, requested the addition of ICD10 Code Q87.83, the reclassification of Imcivree (Setmelanotide) as to drug class of melanocortin receptor agonist, and responded to member question confirming no indication for Chung Jansen Syndrome and only the indications in Dr. Faulkner's presentation.
- Written public comment was received from the following organizations/associations:
    - Rhythm Pharmaceuticals
- Member discussion resulted in recommendations for:
    - updating step 4 to go to step 6 if the answer to step 4 is "yes"
    - adding ICD10 Code Q87.83 for Bardet-Biedl syndrome for Imcivree
- **Motion:** Dr. Sarah Kubes moved to approve new CPA criteria for Imcivree (Setmelanotide) as amended above. Dr. Jennifer Fix

seconded the motion. Following a roll call vote the motion passed by a majority vote with 10 yeas (Brewster, Fix, Holmes, Kubes, Kudisch, Lester, Martinez, Noel, Pham, Velasquez), 0 nays, 0 abstentions.

10 Minute Break

The Drug Utilization Review Board took a short break from 11:00 a.m. until 11:10 a.m. Dr. Alex Kudisch, chair called the meeting to order. Ms. Jacqueline Thompson, ACCO Facilitator, HHSC called roll and confirmed a quorum was present.

Agenda 4g continued:

g. Rezurock (Belumosudil) – New Criteria

- Member discussion included:
  - appropriate PA approval duration to address effectiveness
  - safety parameters
- Members discussion resulted in recommendations for:
  - not requiring a prior systemic therapy for renewal requests
  - initial requests, approval for 90 days, and renewal requests approval for 365 days
- **Motion:** Dr. Sarah Kubes moved to approve new CPA criteria for Rezurock (Belumosudil) as amended above. Dr. Jennifer Fix seconded the motion. Following a roll call vote the motion passed by a majority vote with 10 yeas (Brewster, Fix, Holmes, Kubes, Kudisch, Lester, Martinez, Noel, Pham, Velasquez), 0 nays, 0 abstentions.

h. Skyclarys (Omaveloxolone) – New Criteria

- Member discussed lab limits in the last 90 days which resulted in no recommended changes.
- **Motion**: Dr. Bridgetta Martinez moved to approve new CPA criteria for Skyclarys (Omaveloxolone) as presented. Dr. Heather Holmes seconded the motion. Following a roll call vote the motion passed by a majority vote with 10 yeas (Brewster, Fix, Holmes, Kubes, Kudisch, Lester, Martinez, Noel, Pham, Velasquez), 0 nays, 0 abstentions.

i. Vesicular Monoamine Transporter 2 (VMAT2) Inhibitors – Revision of current criteria

- Member discussion included:
  - adding dopamine-blocking agents to check for prior antipsychotic therapy
  - processes to use these agents for rare diseases as last-line therapy for those under 18 years of age
  - educating DURB members of the PA processes with timeframes

- Member discussion resulted in recommendations for:
    - changing the check for prior antipsychotic therapy to a check for prior dopamine-blocking therapy
    - adding Generic Code Numbers (GCNs) for metoclopramide to the table
- **Motion:** Dr. Sarah Kubes moved to approve new CPA criteria for VMAT2 with amended above. Dr. Jennifer Fix seconded the motion. Following a roll call vote the motion passed by a majority vote with 10 yeas (Brewster, Fix, Holmes, Kubes, Kudisch, Lester, Martinez, Noel, Pham, Velasquez), 0 nays, 0 abstentions.

j. Hormonal Therapy Agents – New Criteria

- Member discussion included:
    - changing lookback period for diagnosis of gender dysphoria
    - understanding the rationale behind the proposed criteria
    - providing members with more information, any relevant legislation, or historical information related to any expected action of the DURB on an agenda item
- Members' discussion resulted in the recommendation to change look back period from 365 to one day.
- **Motion:** Dr. Sarah Kubes moved to approve new CPA criteria for Hormonal Therapy Agents as amended above. Dr. Jennifer Fix seconded the motion. Following a roll call vote the motion did pass by a majority vote with 2 yeas (Kubes, Pham), 0 nays, and 8 abstentions (Brewster, Fix, Holmes, Kudisch, Lester, Martinez, Noel, Velasquez).

Agenda Item 5: Review of action items for the next meeting

- Dr. Alejandro Kudisch, Chair, announced the next meeting DURB meeting scheduled for January 26, 2024, at 9:00 a.m. at the site to be determined.

Agenda Item 6: Adjournment and Thank You

- Dr. Alejandro Kudisch, Chair, thanked board members and members of the public for their attendance and adjourned the meeting at 12:09 p.m.

Below is the link to the archived video of the October 13, 2023, Drug Utilization Review Board meeting to view and listen for approximately, two years from the date of the meeting is posted in accordance with the HHS records retention schedule.

Drug Utilization Review Board