Drug Utilization Review Board

Meeting Minutes

Thursday, September 9, 2021
7:15 a.m. to 8:30 a.m.
Google Hangouts Meet

Board Members Present:
Katherine Smith, PharmD, Board Chair
Elizabeth Gargaro, MD
Eric Cannon, PharmD, FAMCP
Judith Turner, DVM, PharmD
Kumar Shah, MSc, PEng
Kyle Kitchen, PharmD
Michelle Hofmann, MD
Neal Catalano, PharmD
Sharon Weinstein, MD
Susan Siegfreid, MD

Board Members Excused:
Jennifer Brinton, MD

Dept. of Health/Div. of Health Care Financing Staff Present:
Jennifer Strohecker, PharmD
Andrea Rico, CPhT, CPC
Bryan Larson, PharmD
Craig Hummel, MD
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:
Joanne LaFleur, PharmD U of U DRRC

Other Individuals Present:
Aimee Redhair, Biogen
Brandon Yip, PharmD Sanofi Genzyme
Caleb Ham, U of U College of Pharmacy
Cheryl Donahue, Takeda
Garth Wright
Heidi Goodrich, Molina Healthcare
Kelvin Yamashita, Sanofi Genzyme
Kenneth Berry, Alkermes
Lindsey Walter, Novartis
Lisa Angelos, Change Healthcare
Lisa Ashton
Matthew Call, UUHP
Michael Shepherd, RN Eli Lilly
Morgan Carter
Phil Wettestad, Novartis
Robert Booth, AbbVie
Rosalynde Finch, PhD Biogen

Meeting conducted by: Katherine Smith

1. **Welcome & Housekeeping:** 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.

2. **Review and Approval of July Minutes:** Susan Siegfreid proposed to change "there is" to "there are" on Pg.3. 6. C. Kumar Shah made a motion to approve the minutes with the amended changes from July. Susan Siegfreid seconded the motion. Unanimous approval.

3. **P&T Committee Update:** Bryan Larson stated the P&T Committee will meet next week in September to discuss wakefulness promoting agents (Nuvigil, Provigil, Sunosi, and Wakix). Utah Open Public Meeting Act Annual Training will be completed by the Assistant Attorney General. Annual board chair election will take place.

4. **Anti-asthmatic Monoclonal Antibodies:**
   a. **Information:** Ngan Huynh presented the proposed annual updates to the prior authorization criteria for Anti-asthmatic Monoclonal Antibodies. The updated form combines multiple medications and indications in a grid format that guides providers which medications are preferred and what parts of the form need to be completed.
   b. **Board Discussion:** Kumar Shah inquired if there were any major changes made to the criteria. Ngan Huynh stated Dupixent (dupilumab) was added and the formatting was changed. Katherine Smith and Susan Siegfreid recommended adding dermatologist and otolaryngologist to Part 1 "The prescriber is or has consulted with". Katherine Smith noted a typo under Criteria for Chronic Idiopathic Urticaria "H2 antagonists" should be changed to "H1 antagonists".

Circle the diagnosis and medication, then complete the appropriate criteria part(s).

Diagnosis and Age Limitations	Complete	CinQair Preferred	Dupixent *Non-preferred	Fasenra Preferred	Nucala *Non-preferred	Xolair Preferred
Severe asthma w/ eosinophilic phenotype	Part: 1, 2	18 yrs. or older	12 yrs. or older	12 yrs. or older	6 yrs. or older	
Hypereosinophilic syndrome	Part: 1, 2				12 yrs. or older	
Eosinophilic granulomatosis w/ polyangiitis	Part: 1, 2, 3				18 yrs. or older	
Moderate to severe persistent asthma	Part: 1, 2, 4					6 yrs. or older
Chronic idiopathic urticaria	Part: 1, 5					12 yrs. or older
Nasal polyps in adults (add-on therapy)	Part: 1, 6					18 yrs. or older
Chronic rhinosinusitis w/ nasal polyposis	Part: 1, 7		12 yrs. or older		18 yrs. or older	
Moderate-to-severe atopic dermatitis	Part: 1		6 yrs. or older			
Other FDA-Approved indication	Part: 1					

Part 1 *Criteria for Approval for all Indications:*

- ❑ The prescriber is or has consulted with: ❑ Allergist ❑ Pulmonologist ❑ Immunologist ❑ Dermatologist ❑ Otolaryngologist
- ❑ Documented diagnosis of requested indication. Chart Note Page #: _____
- ❑ Describe other treatment(s) the patient currently takes.
  Medication(s): _____ Chart Note Page #: _____
  Dates of therapy: _____

Part 2 *Additional Criteria for the Following Indications: Severe asthma/eosinophilic phenotype, Hypereosinophilic syndrome, Eosinophilic granulomatosis/polyangiitis, and Moderate to severe persistent asthma:*

- ❑ Minimum 3-month trial and failure or contraindication of at least one high dose inhaled corticosteroid / long acting beta agonist combination product.
  Medication(s): _____ Chart Note Page #: _____
  Dates of therapy: _____ Details of Failure: _____
- ❑ Trial and failure or contraindication of add-on tiotropium or leukotriene receptor antagonist therapy:
  Medication(s): _____ Chart Note Page #: _____
  Dates of therapy: _____ Details of Failure: _____
- ❑ Baseline eosinophil value has been obtained. Baseline value #: _____ Chart Note Page #: _____

Part 3 *Additional Criteria for Eosinophilic Granulomatosis with Polyangiitis (EGPA)*

- ❑ Trial and failure within the past year or contraindication to oral corticosteroid therapy:
  Medication(s): _____ Chart Note Page #: _____
  Dates of therapy: _____ Details of Failure: _____

Part 4 *Additional Criteria for Moderate to Severe Persistent Asthma:*

- ❑ Positive skin test or in vitro reactivity to a perennial aero-allergen. Chart Note Page #: _____
- ❑ For dosing, include the patient's baseline IgE value (30 – 1,300 IU/ml): _____
- ❑ Include the patient's baseline weight (20 – 150 kg): _____

Part 5 *Additional Criteria for Chronic Idiopathic Urticaria (CIU):*

- ❑ Minimum 2-month trial and failure of at least ONE of the following add on therapies:
  - H2 antagonist: _____ Chart Note Page #: _____
  - Dates of therapy: _____ Details of Failure: _____
  - Leukotriene receptor antagonist: _____ Chart Note Page #: _____
  - Dates of therapy: _____ Details of Failure: _____

Part 6 *Additional Criteria for Nasal Polyps in Adults: (Add-on therapy)*

- ❑ Minimum 2-month trial and failure of at least ONE nasal corticosteroid:
  - Medication(s): _____ Chart Note Page #: _____
  - Dates of therapy: _____

Part 7 *Additional Criteria for Chronic Rhinosinusitis with Nasal Polyposis:*

- ❑ Trial and failure of Both nasal corticosteroid and oral corticosteroid within the past year:
  - Medication(s): _____ Chart Note Page #: _____
  - Dates of therapy: _____
  - Medication(s): _____ Chart Note Page #: _____
  - Dates of therapy: _____

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

- ❑ Minimum 3-month trial and failure of at least one preferred Antiasthmatic Monoclonal Antibody, or prescriber must demonstrate medical necessity for non-preferred product.
  - Medication(s): _____ Chart Note Page #: _____
  - Dates of therapy: _____ Details of Failure: _____

Off Label or Compendia Use of FDA-Approved Drugs Additional Criterion:
Requests for any off-label indications must be supported by at least one (1) major multi-site study or three (3) smaller studies published in JAMA, NEJM, Lancet or other peer review specialty medical journals within the most recent five (5) years. Supporting documentation must be included. Compendia use must be recommended by generally-accepted compendia such as American Hospital Formulary Service Drug Information (AHFS), United States Pharmacopeia-Drug Information (USP-DI), and the DRUGDEX Information System.
Diagnosis: _____ Duration of treatment: _____

Re-authorization Criteria: *Please submit pre-treatment and current information*
Updated letter with medical justification or updated chart notes demonstrating positive clinical response.

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

c. **Board Action:** Sharon Weinstein motioned to approve the prior authorization criteria with the amended changes. Michelle Hofmann seconded the motion. Unanimous approval. Elizabeth Gargaro recommended re-evaluation of the prior authorization criteria in the future if additional indications are approved.

d. **Public Comment:** Brandon Yip from Sanofi Genzyme informed the board of an expected upcoming launch for asthma with publication of the manuscript study in the New England Journal of Medicine. Emerging indications for 2021-2022 include atopic dermatitis and eosinophilic esophagitis.

5. **Aduhelm (aducanumab):**

a. **Information:** Jennifer Strohecker presented the proposed prior authorization criteria for Aduhelm (aducanumab). The Fee for Service and Managed Care Entities prior authorization criteria form will mirror each other. Guidance was obtained from clinical practice literature, clinical practice studies and other states.

b. **Public Comment:** Rosalynde Finch from Biogen stated Aduhelm (aducanumab) is indicated for the treatment of Alzheimer's Disease. Treatment should be initiated in patients with mild cognitive impairment (MCI) or mild dementia stage of disease. There is no safety or efficacy data to support the use in earlier

or later disease stages. The indication has been approved under accelerated approval based on the reduction of amyloid plaques observed . Continued approval will be contingent upon verification of clinical benefit and confirmatory clinical trials. Titration is required for treatment initiation. It takes six months to titrate up to the goal dose of 10mg/kg where removal of amyloid plaque was observed. Cholinesterase inhibitors and memantine products are not approved by the Food and Drug Administration (FDA) for the indication of mild cognitive impairment (MCI) or mild dementia.

c. **Board Discussion:** Susan Siegfreid stated the potential requirement for using memantine would be off-label due to only being approved for indications of moderate to severe dementia. Susan Siegfreid suggested adding contraindication for diseases that would create central nervous system (CNS) iron accumulation which can be comorbid with Alzheimer's. Susan Siegfreid inquired if the Apolipoprotein E4 (APOE4) status should be considered when using Aduhelm (aducanumab). Rosalynde Finch stated the Apolipoprotein E4 is a receptor for Alzheimer's. Two thirds of the patients included in the trials were carriers of the Apolipoprotein E4 (APOE4) allele and have a higher risk of amyloid-related imaging abnormalities (ARIA). Dose titration reduced the incidents of amyloid-related imaging abnormalities (ARIA). Susan Siegfreid inquired if an informed consent that patients know their Apolipoprotein E (APOE) status should be required. Eric Cannon stated the Institute for Clinical and Economic Review (ICER) did not recommend a step requirement of trial and failure of a cholinesterase inhibitor or memantine even though they are used daily for the non-approved indications. Eric Cannon asked if the State of Utah covers amyloid positron emission tomography (PET) scans since The Centers for Medicare and Medicaid Services (CMS) does not cover amyloid positron emission tomography (PET) scans for Alzheimer's for Medicare. Jennifer Strohecker stated Utah Medicaid does not currently require prior authorization for amyloid positron emission tomography (PET) scans. Sharon Weinstein inquired if there would be potential access to care issues for patients being managed by a primary care provider having to be referred to a specialist. Eric Cannon and Susan Siegfreid stated that primary care providers would not have the training or understanding to complete the screening and interpretations required for using Aduhelm (aducanumab). Katherine Smith recommended changing neurologist or geriatrician to board-certified neurologist or geriatric specialist. Elizabeth Gargaro noted restricting the criteria to be prescribed by a board-certified neurologist or geriatric specialist differs from requirements on other prior authorization forms that only require consultation with a specialist. The board agreed that restricting the medication to be prescribed by a specialist is appropriate based on the package insert, testing, interpretation, and follow up required.

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

- ❑ The medication is prescribed by a board certified neurologist or geriatrician
- ❑ The member is between the ages of 50-85 years old
- ❑ The member has a diagnosis of Alzheimer's disease with mild dementia or mild cognitive impairment as evidenced by the following within the past 6 months:
  - ❑ Clinical Dementia Rating (CDR) global scale of ≤0.5 **AND**
  - ❑ Repeatable Battery for Assessment of Neuropsychological Status (RBANS) delayed memory index score ≤ 85 **AND**
  - ❑ Mini-Mental State Examination (MMSE) score of ≥ 24
- ❑ The request includes documentation of a brain MRI within the past year without evidence of the following:
  - ❑ Acute or sub-acute hemorrhage
  - ❑ Cortical infarct
  - ❑ >1 lacunar infarct
  - ❑ Prior microhemorrhage or prior subarachnoid microhemorrhage not due to underlying structural hemorrhage
  - ❑ Greater than 4 microhemorrhages
  - ❑ Superficial siderosis
  - ❑ History of diffuse white matter disease
- ❑ The request includes documentation showing presence of amyloid abnormalities as determined by positron emission tomography (PET) or lumbar puncture
- ❑ The member has documented 3-month trial and failure of the following:
  - ❑ Cholinesterase inhibitor (e.g. donepezil, rivastigmine)
  - ❑ Memantine
- ❑ The member has not experienced any of the following:
  - ❑ Alcohol or substance misuse in the past one year
  - ❑ Clinically significant or unstable psychiatric illness within the last 6 months
  - ❑ Contraindication to amyloid testing (e.g., PET or brain MRI)
  - ❑ History of other possible contributors to the symptoms of dementia (e.g., Huntington's Disease, HIV related cognitive impairment, frontotemporal lobar degeneration, hypothyroidism, Lewy body dementia, Parkinson's disease, prion disease, syphilis, traumatic brain injury, vitamin B12 deficiency)
  - ❑ History of significant cardiac disease (e.g., chronic heart failure, clinically significant conduction abnormalities, history of unstable angina, myocardial infarction, uncontrolled hypertension) within past one year
  - ❑ Impaired renal or liver function
  - ❑ Relevant brain hemorrhage, bleeding disorder, or cerebrovascular abnormalities
  - ❑ Use of antiplatelet or anticoagulant medications other than prophylactic aspirin, including warfarin, DOACs, and $P2Y_{12}$ inhibitors
- ❑ The requested dose follows FDA prescribing information

Re-authorization Criteria:

- ❑ Absence of amyloid-related imaging abnormalities with edema (ARIA-E) or hemosiderin deposition (ARIA-H) before the 4th, 7th, and 12th infusions as determined by brain MRI
- ❑ Continued evidence of mild cognitive impairment as evidenced by an updated CDR global scale score ≤0.5, RBANS delayed memory index score ≤85, and MMSE score ≥24
- ❑ Titration up to 10 mg/kg maintenance dose

Initial Authorization: Up to six (6) months
Re-authorization: 6 months

d. **Board Action:** Eric Cannon motioned to approve the prior authorization criteria with the amended change. Sharon Weinstein seconded the motion. Unanimous approval.

6. **Humulin U-500 (concentrated insulin human injection):**
   a. **Information:** Luis Moreno presented the proposed prior authorization criteria for Humulin R U-500 (concentrated insulin human injection). Patients prescribed the Humulin R U-500 vial must also be prescribed the U-500 insulin syringes to avoid medication errors.
   b. **Public Comment:** Michael Shepherd from Eli Lilly stated there is a Humulin U-500 KwikPen available in addition to the vial.
   c. **Board Discussion:** Susan Siegfreid recommended changing the title to Humulin R U-500 Products (concentrated insulin human injection).

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

- ❑ Member has diabetes mellitus and is being treated with a total daily insulin dose of 200 units or higher.
  Chart Note Page #: _____
- ❑ Humulin R U-500 will not be used in combination with other insulins.
  Chart Note Page #: _____
- ❑ The member and caregiver have been educated on safely administering this medication.
  Chart Note Page#: _____

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

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

Note:
- ❖ Patients using the HUMULIN R U-500 vial must be prescribed the U-500 insulin syringe to avoid medication errors.

d. Board Action: Elizabeth Gargaro motioned to approve the prior authorization criteria with the amended change. Susan Siegfreid seconded the motion. Unanimous approval.

7. **DUR Annual Report:**
   a. Information: Joe Busby presented a summary of the Drug Utilization Review (DUR) Report provided to Centers for Medicare and Medicaid Services (CMS). The Drug Utilization Review Annual Report is a federal mandate for all Medicaid programs and driven by SUPPORT Act requirements. The reporting period presented was from October 1, 2019 to September 30, 2020. The majority of the data shown reflects the Fee for Service population. The data reflects a significant improvement in customer service from a team effort to implement and manage changes.
   b. Board Discussion: Kumar Shah inquired if individuals could be counted under multiple reporting categories. Joe Busby stated Centers for Medicare and Medicaid (CMS) sets the ages and categories reported on. Jennifer Strohecker stated the tables presented were new requirements this year and the data analyst who prepared the tables could be invited to a future meeting to discuss in more detail. Joanne LaFleur, PharmD from the University of Utah DRRC presented a summary of the activities completed by the Drug Regimen Review Center in the prior year. The provider-level normative feedback interventions and educational interventions were a new activity. Topics for normative feedback were selected to maximize timeliness, evidence basis, construct validity, face validity, simplicity and comparability. Intervention materials included cover letters, normative feedback reports, provider report cards, brief surveys and patient lists. Providers were selected from Utah Medicaid claim data.

8. **Meeting Chat Transcript:**
00:01:17.982,00:01:20.982
Sharon Weinstein: Sharon M Weinstein MD present, good morning

00:43:40.582,00:43:43.582
Joe Busby: For the record I have a conflict of interest on this discussion topic.

00:48:51.587,00:48:54.587
Sharon Weinstein: Ha ha Joe!

00:50:16.603,00:50:19.603
Sharon Weinstein: I can

00:50:21.926,00:50:24.926
Lisa Angelos: I can see it.

00:50:47.031,00:50:50.031
Eric Cannon: Joe's hair is in the way - blocking the screen

00:51:15.770,00:51:18.770
Sharon Weinstein: Ha ha Eric!

00:51:37.186,00:51:40.186
Sharon Weinstein: Excellent work team!

00:52:34.804,00:52:37.804
Jennifer Strohecker: Recall also that mental health drugs are carved to FFS

00:53:06.345,00:53:09.345
Katherine Thom: Which antivirals are on that list? curious.

00:53:22.473,00:53:25.473
Jennifer Strohecker: Hep C drives this, Katherine

00:53:31.659,00:53:34.659
Katherine Thom: thanks!

00:53:49.573,00:53:52.573
Jennifer Strohecker: FFS fills more HCV claims that all the ACO's combined.

00:54:30.878,00:54:33.878
Sharon Weinstein: please remind me if naloxone kits are dispensed free to patient at this time

00:54:59.164,00:55:02.164
Jennifer Strohecker: Free = without a copay?

00:55:06.519,00:55:09.519
Sharon Weinstein: yes

00:55:15.295,00:55:18.295
Elizabeth Gargaro: fabulous job reducing high risk opiate use!

00:56:14.481,00:56:17.481
Jennifer Strohecker: Many places offer naloxone for free across the state.... and I need to verify copay status for naloxone (stay tuned, Dr. Weinstein(

00:56:15.530,00:56:18.530
Jennifer Strohecker:)

00:56:25.728,00:56:28.728
Sharon Weinstein: thank you

01:01:05.037,01:01:08.037
Sharon Weinstein: again - great work team!

01:02:50.309,01:02:53.309
Sharon Weinstein: our friends!!!

01:16:08.975,01:16:11.975
Judith Turner: Sorry, I need to drop off to get to another appointment

01:16:26.227,01:16:29.227
Sharon Weinstein: opioids = opioid agonist, correct?

01:16:58.401,01:17:01.401
Michelle Hofmann: Apologies...need to drop for another meeting.

01:17:40.826,01:17:43.826
Joanne Lafleur: Yes Sharon.

01:17:41.952,01:17:44.952
Ngan Huynh: Thank you everyone for joining

01:17:52.505,01:17:55.505
Lisa Angelos: Thanks!

01:18:00.727,01:18:03.727
Sharon Weinstein: thanks for a great meeting!

01:18:03.499,01:18:06.499
Neal Catalano: Thank you everyone!

9. **Public Meeting Adjourned:** Eric Cannon motioned to adjourn the meeting. Kumar Shah seconded the motion. Unanimous Approval. Judith Turner and Michelle Hofmann were not present for vote.

10. **The next meeting scheduled for Thursday, October 14, 2021** Topical Lidocaine for Pain.

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