Utah Department of Health & Human Services

Drug Utilization Review Board

Meeting Minutes

Thursday, September 14, 2023
7:15 a.m. to 8:30 a.m.
Google Meet

Board Members Present:

Susan Siegfreid, MD
James Keddington, DDS
Judith Turner, DVM, PharmD
Colby Hancock, PharmD
Neal Catalano, PharmD
Sharon Weinstein, MD
Jennifer Brinton, MD
Kumar Shah, MSc, PEng

Board Members Excused:

Eric Cannon, PharmD, FAMCP, Board Chair
Katherine Smith, PharmD
Michelle Hofmann, MD

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

Jennifer Strohecker, PharmD, Medicaid Director
Yoon Kim-Butterfield, MD, Medical Director
Lisa Angelos, PharmD, Pharmacy Director
Andrea Rico, CPhT, CPC
Bryan Larson, PharmD
Luis Moreno, PharmD
Ngan Huynh, PharmD
Stephanie Byrne, PharmD

University of Utah Drug Regimen Review Center Staff Presenter:

Monet Luloh, PharmD

Other Individuals Present:

Jason Bott, Eli Lilly
Cheryl Donahue, Takeda
Rick Kegler, BioMarin
Deborah Speranzo, BioMarin
Lauren Heath, University of Utah DRRC
Monet Luloh, University of Utah DRRC
Aimee Redhair, Astellas Pharma
Marit Sivertson, Law Office of Sivertson & Barrett, P.A.
Michael Zarob, Alkermes
Amy Hale, Johnson & Johnson
Miles Rooney, Change Healthcare/Optum
Jason Smith, HHCRx
Chris Johnson, BioMarin
Russell Butterfield, MD, PhD, University of Utah
Jessi Bennett, Biocryst
Kathleen Ogden, Sarepta
Melissa Abbott, Syneos
Stephanie Kennedy, Sarepta
Laura Britton, Healthy U

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Robert Novahec, Healthy U
Rusty
Lori Amels, Sarepta
Joan Schindler, Genentech
Joe Panek, Purdue Pharma
Chris Johnson, Alexion Pharma
Northwest AMCP Affiliate
Brian Denger, Parent Project Muscular Dystrophy

Meeting conducted by: Ngan Huynh, PharmD

1. **Welcome:** Ngan Huynh opened the meeting and reminded everyone in attendance 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 August Minutes:** Judith Turner motioned to approve the minutes with corrections noted, from August. Sharon Weinstein seconded the motion. Unanimous approval.

3. **Housekeeping:**
   Jennifer Strohecker shared the following housekeeping items:
   a) Yoon Kim-Butterfield, MD, has been hired as the new Medical Director. She will have oversight of the Pharmacy Team and Medical Consultants team.
   b) Lisa Angelos, PharmD, BCSCP, CAPP, has stepped down as Pharmacy Director and will stay on as a pharmacist with the pharmacy team. Recruitment will be opening for the Pharmacy Director position.
   c) A study is being completed on carving the pharmacy service back to Fee-For-Service Medicaid.
   d) We anticipate the Medicaid Pharmacy Point Of Sale Request For Proposal will be posted next week

4. **Review:**
   a. **Insulin Pumps presented by Monet Luloh, PharmD**
      1. Information
         See Slide Presentation
      2. Public Comment
         None

3. Board Discussion
   None
4. Board Action
   None

b. Elevidys Prior Authorization Discussion

1. Public Comment
   a. Russell Butterfield, MD, PhD, spoke in favor of covering Elevidys for pediatric patients with Duchenne Muscular Dystrophy. He stated agreement with current draft prior authorization criteria. His clinic has been involved in the clinical trials of this therapy, as well as clinical trials for Zolgensma.
   b. Marit Sivertson, Law Office of Sivertson & Barrett, P.A., shared the experience of her son who has benefitted from the use of gene therapy as a participant in the clinical trial at the Nationwide Children's Hospital.
   c. Brian Denger from Parent Project Muscular Dystrophy organization shared the experience of his son who is 29 years old and living with Duchenne Muscular Dystrophy.
   d. Stephanie Kennedy, Sarepta Therapeutics, Inc., relinquished her time after thanking the Medicaid Pharmacy Team for adherence to drug labeling for prior authorization criteria.
2. Elevidys Prior Authorization Draft presented by Stephanie Byrne, PharmD
3. Board Discussion
   a. Jennifer Brinton shared her gratitude for all the public comments.
   b. Neal Catalano asked Russell Butterfield if there are Elevidys studies being conducted for patients older than 5 years of age. Russell Butterfield confirmed studies are being conducted in patients up to 7 years old.
   c. Russell Butterfield asked about the exon exclusion criterion on mutation that must be contained between exons 18 and 58. He stated that per the prescribing information, the

medication is only contraindicated if a patient has deletion in exon 8 and/or exon 9 in the DMD gene. He asked for consideration of dropping the prior authorization criterion that the mutation must be between exons 18 and 58.

d. Sharon Weinstein, MD, shared her gratitude for the public comments and asked for verification on the criterion on the prior authorization draft stated as "mutation must be contained between exons 18 and 58". She further made the motion to approve the prior authorization with modification made by expert opinion.
e. Ngan Huynh, PharmD, asked the board if there were any recommendations on how to restate this criterion.
f. Stephanie Kennedy shared that outside of the exclusions of deletion of exons 8-9, the other genetic exclusions are listed in labeling as a warning, which should be discussed with the provider and patient's family but should not be an exclusion criterion on the prior authorization for Elevidys.
g. James Keddington seconded the motion to approve the prior authorization, pending the expert opinion on the prior authorization criterion.

4. Board Action
   a. Unanimous Approval from the board for prior authorization approval with the additional edits recommended by experts.

c. Roctavian Prior Authorization Discussion:

1. Public Comment
   a. Rick Kegler with BioMarin shared information on Roctavian's utilization for patients with Hemophilia A.
   b. A written comment from the Hemophilia Federation of America, Utah Hemophilia Foundation, and National Bleeding Disorders Foundation, was shared by Ngan Huynh. The comments expressed concern about coverage exclusion for patients who have recently received Hemlibra.
   c. Ngan Huynh presented the Roctavian prior authorization draft. Based on the feedback from the Hemophilia Federation of America and National Bleeding Disorder

Foundation, the exclusion for patients who have received Hemlibra was removed. Due to the recent updates to the prior authorization draft, the draft will be reshared with the Hemophilia Treatment Centers of Utah for their review and comment.

2. Board Discussion
   None
3. Board Action:
   a. Judith Turner, DVM, PharmD, moved to approve Roctavian prior authorization draft, with amendments.
   b. Jennifer Brinton, MD, seconded.
   Unanimous Approval

5. **Meeting Chat Transcript:**

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00:07:10.150,00:07:13.150
Amy Hale: Amy Hale, Johnson and Johnson

00:07:24.613,00:07:27.613
Lisa Angelos (DHHS): Thank you, Amy!

00:07:43.830,00:07:46.830
Jennifer Brinton: Welcome, Dr. Kim Butterfield!

00:35:32.131,00:35:35.131
Neal A Catalano: Thank you Dr. Luloh for a great presentation and to
the DRRC Team for providing us with such a thorough DUR report.

00:46:18.821,00:46:21.821
Russell Butterfield: quick question on exclusion of mutations
outside of deletion 8-9

00:54:46.219,00:54:49.219
Russell Butterfield: than k you for letting me participate.  I have
to run to see a patient.

00:55:00.029,00:55:03.029
Sharon M Weinstein MD: Thank you all

00:55:25.012,00:55:28.012
Marit Sivertson: Thank you for allowing me to share my family's
perspective.

00:55:57.142,00:56:00.142
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Ngan Huynh (DHHS): Thank you for attending and share your story with us

6. **The next meeting is scheduled for Thursday, October 12, 2023** when Sickle Cell Disease will be the topic of discussion.

7. **Public Meeting Adjourned:** Sharon Weinstein, MD, moved to adjourn the meeting. Neal Catalano, PharmD, seconded the motion. Unanimous approval.

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