



GEORGIA DEPARTMENT
OF COMMUNITY HEALTH

Georgia Department of Community Health

DRUG UTILIZATION REVIEW BOARD MEETING

Department of Community Health
Zoom Teleconference

May 5, 2020



**DRUG UTILIZATION REVIEW BOARD MEETING
AGENDA**

Virtual Meeting Link:

https://magellanhealth.zoom.us/webinar/register/WN_prm6agmqSsmclvdEC858Dw

Tuesday, May 5, 2020

10:00 a.m. to 2:00 p.m.

EXECUTIVE SESSION	<i>Nina Bandali, PharmD, Pharmacist Account Manager, Magellan Rx Management</i>
CONVENING OF OPEN SESSION AND CALL TO ORDER	<i>Burton L. Lesnick, M.D., FAAP, Chair</i>
MINUTES FROM PREVIOUS MEETING	<i>Chair</i>
CLINICAL REVIEWS	<i>Afzal Mistry, PharmD, NorthStar Chad Nicholson, PharmD, NorthStar Emily Baker, PharmD, BCPS, NorthStar</i>
➤ New Drugs	
● Akliel	
● Anovera	
● Beovu	
● Nourianz	
● Rinvoq	
● Vumerity	
● Xenleta	
BOARD'S RECOMMENDATIONS AND VOTES	<i>Chair</i>
FUTURE AGENDA ITEMS	<i>Chair</i>
ADJOURNMENT OF MEETING	<i>Chair</i>

**Department of Community Health
Drug Utilization Review Board (DURB)
MINUTES
Tuesday, February 4, 2020**

MEMBERS PRESENT

Burton L. Lesnick, M.D., FAAP, Chair
M. Celeste Fowler, Pharm.D., Vice-Chair
Doug Collins, M.D.
Alton Condra III, R.Ph.
Gurinder Doad, M.D.
Robyn Lorys, Pharm.D.
Osgood (Drew) A. Miller, R.Ph.
Matthew Perri, R.Ph., Ph.D.
Brent L. Rollins, R.Ph., Ph.D.

MEMBERS ABSENT

Rod M. Duraski, M.D., FACP, MBA
Glenda Wrenn Gordon, M.D.
J. Russell May, Pharm.D.
Danny A. Toth, R.Ph.

Staff

Peter D'Alba, Pharm.D., Pharmacy Director, Pharmacy Services
Gilletta Gray, R.Ph., Clinical Manager, Pharmacy Services
Rebecca Morrison, Pharmacy Operations Manager, Pharmacy Services
Maria Lucas, Pharmacy Program Specialist, Pharmacy Services
Rose Marie Duncan, MBA, Operations Analyst-Drug Rebate Program, Pharmacy Services
Lori Garner, MHS, MBA, R.Ph., Pharmacist, SHBP
Judy Braich, Pharmacy Intern

NorthStar HealthCare Consulting

Afzal "Fez" Mistry, Pharm.D., Clinical Programs Director
Chad Nicholson, Pharm.D., Clinical Pharmacist

OptumRx

Mark Hall, MBA, PMP, Assoc. Director, Government and Public Sector Markets
Talmahjia "Tami" Sweat, Pharm.D., Director, Clinical Management

Magellan Rx Management

Nina Bandali, Pharm.D., Pharmacist Account Manager

Care Management Organizations

Turkesia Robertson-Jones, Pharm.D., CareSource

Call to Order

The Drug Utilization Review Board (DURB/DUR Board/Board) held its first meeting for the calendar year on February 4, 2020. The Chair, Burton L. Lesnick, M.D., FAAP, called the meeting to order at 10:02am. Board members introduced themselves and commented on any conflicts of interest (there were none).

Minutes from the Previous Meeting

Chair Lesnick asked for corrections or changes to the minutes from the November 5, 2019 meeting. A motion was made (Osgood (Drew) A. Miller, R.Ph.), seconded (Brent L. Rollins, R.Ph., Ph.D.), and carried to approve the minutes as written.

External Comments Session

There were no external comments.

New Drug Reviews

Clinical information for the following new drugs, in the market six months or more, was presented for discussion and recommendations. The complete detailed drug summary is in the New Drugs for Review section of the DUR Board binder.

Therapeutic Class	Drugs	Presenter
Sickle Cell Anemia Treatments	<i>Adakveo</i> <i>Oxbryta</i>	Afzal “Fez” Mistry, Pharm.D.

The Board discussed the drug information, provided comments, and raised questions and Dr. Collins provided comments on SCD, Oxbryta, Adakveo and prior authorization requirements:

- Adakveo-for vasocclusive crisis, had to be admitted to be treated
- Vasocclusive crises occur at random; not precipitated by things you might think
- Multiple differences between patients in terms of severity
- Four well documented separate genes for SCA (ex. Northern African gene (patients may not know they have it until come in for treatment), Central African gene (most patients don't survive because they die young)
- In this country, a merge of all 4 genes come together; so in the same family, you can have different levels of severity because of different combinations of genes (ex. crisis every week or a crisis every 3 or 4 years)
- Severity of crisis is not related to the genetic background but the frequency of the crisis is related to the genetic background
- Majority of crises are managed at home, so a person may have 20 crises a year but medical records may only show 2 that were treated
- Dr. Collins has attempted to put 30 patients on Oxbryta; only successful with getting 1 on it
- Step of hydroxyurea-most have been exposed or have had some objection to it; usually had it as a pediatric patient; probably 100% of patients can probably say they've had it or it didn't work (even if they didn't take it); don't want to penalize a patient from a new treatment if they have some moral or medical objection to an older treatment they have concerns about
- Hydroxyurea studies-adds 8.5 years to a SC patient's life, so has long-term benefit; currently too early to tell if Oxbryta has this benefit
- 3 years from now, most patients will be on gene therapy trials

Department of Community Health
Drug Utilization Review Board (DURB)
MINUTES

Tuesday, February 4, 2020

- Only a few prescribers treat SCD, so the easier to make it (PA criteria), the better; requiring a letter (form letter) would be fine; step of hydroxyurea not realistic as most patients will say they've had it
- Patient candidates for Adakveo or Oxbryta – Per Dr. Collins' practice: Jehovah witness population (~40 patients) would be candidates for Oxbryta since no transfusion option; Elderly patients (~50 patients)-don't tolerate hemoglobin around 7 or 8, transfusion dependent in terms of quality of life, do red cell exchange transfusion, relatively asymptomatic (go years without crisis), it would be a hard sell to put them on newer drugs; College students (~100 patients)-out of town and away from their red cell transfusion, these are the kids we want to try and modify, most are on Endari, they would be candidates for Oxbryta
- Adakveo candidates-probably require more screening; would have failed hydroxyurea, Endari, and maybe Oxbryta, so would be reserved for patients who did not respond to the other 3 treatments and need letter of medical necessity
- Use of Oxbryta or Adakveo in any SC patient-appears they would be beneficial; all patients should be eligible (so that's why no hydroxyurea step), but don't know if it will prevent end organ injury, no research outside of the trial; theoretically, it should help end organ injury; drug should be available to all patients whether they have been on hydroxyurea or not; number of crisis in criteria based on ER visits/hospitalizations but most patients having pain every day and if you can stop that pain, decrease narcotic use/requirements, then the drug is worth it; it should be moved close to how hydroxyurea is used in the patient population
- Hydroxyurea-cheap medicine, can prolong mortality but patients don't want to take; data for hydroxyurea is impressive but patients still don't want to take it; potentially leave step but add language about refusal to take hydroxyurea in criteria
- Majority of the patients Oxbryta has been requested for are Medicaid patients
- Have not seen both used/requested in combination
- Side effects from Oxbryta-doesn't necessarily alter oxygen delivery but more so alters (prolongs) gelation time (thus decreasing sickling); venous saturation remains the same
- Back pain/arthralgia with Adakveo-similar to placebo, hard to distinguish with disease
- Oxbryta-allow patients on the lower end of the hemoglobin range to get drug (whether having a crisis or not); an increase in hemoglobin will improve quality of life; for patients with higher hemoglobin, may decrease end organ injury (theoretically)
- Currently can't limit prescribers by specialty to not require PA
- Adakveo-therapy will probably replace some of the people being transfused; will look at those that fail all other therapy; if on it and still having 3-4 crises a year, then not worth to continue it
- Success of transfusion therapy-depends on age; elderly does well, no crises for years; younger people have a degree of 'learned behavior', who frequently visit the ER although may not be in crisis (this can screw up studies); this problem should be handled at the State level due to the use of resources.
- Newborn genetic testing doesn't capture the subtype of SCD; molecular testing done at Augusta University Health; Dr. Collins can clinically subtype patients.
- Gene therapy will hopefully address the world wide problem
- 100,000 Americans with SCD, 6000 patients in Georgia

Tuesday, February 4, 2020

DCH Decisions

DCH Decisions from the November 2019 DUR Board meeting were provided in the DCH Decision section of the DUR Board binder.

Upcoming Meetings

The following upcoming meetings were published in the DURB binder:

- Drug Utilization Review Board
2 Peachtree Street NW
5th Floor Board Room
Atlanta, Georgia 30303

Tuesday, May 5, 2020

Tuesday, August 4, 2020

Tuesday, November 3, 2020

Disclosure Forms

Disclosure forms were received and reviewed by the Department for completeness for all Board members attending the meeting.

Adjournment of Open Session

The DUR Board voted to close the open meeting pursuant to the Open Meeting Act of Georgia Section 50-14-1 – 50-14-6 and pursuant to Federal Law Section 1396R-8B3D. The individuals recorded in attendance with the Board members were from the Department of Community Health, Magellan Rx Management, NorthStar HealthCare Consulting, and OptumRx. CMO representative, Turkesia Robertson-Jones, Pharm.D. (CareSource), Clinical Pharmacy Specialist, Suzanne Waton, Pharm.D. (Grady Health Systems) and pharmacy students, Lilytte Tagala (PCOM), Zerika Armand (PCOM), Arash Zare (PCOM), Jackson Usher (PCOM), Taylor Shumake (PCOM), Jipal Patel (PCOM) and Stephanie Watson (UGA) also attended the closed session with Board members. A motion was made by Robyn Lorys, Pharm.D. and seconded (Osgood (Drew) A. Miller, R.Ph.), to adjourn the open session and approve the closed session. There was a unanimous vote approving the closed session. The Chairman, Burton L. Lesnick, M.D., FAAP, adjourned the open session at approximately 11:12am, at which time members took a break then reconvened for the executive (closed) session.

Executive Session

The Executive Session was held from 11:20am to 12:00pm.

Reconvening of Open Session

The DUR Board reconvened for the open session at 12:02pm.

Board's Recommendations to the Department

After all clinical and financial evaluations and discussions, the DUR Board voted and presented the Department with the following recommendations for changes to the Preferred Drug List (PDL) or Physician Administered Drug List (PADL) as noted in Attachment A. All motions and votes are noted in Attachment B.

Department of Community Health
Drug Utilization Review Board (DURB)

MINUTES

Tuesday, February 4, 2020

Future Agenda Items

There were no future agenda items noted.

Conclusion

At the conclusion of the reconvened open session and no other business for discussion, there was a unanimous decision to adjourn the meeting (motion made by Osgood (Drew) A. Miller, R.Ph. and seconded by Brent L. Rollins, R.Ph., Ph.D.). Chair Lesnick adjourned the meeting at 12:04pm.

THESE MINUTES ARE HEREBY APPROVED AND ADOPTED, THIS THE _____
DAY OF _____, 2020.

Burton L. Lesnick, M.D., FAAP, Chair

DRAFT



**The Drug Utilization Review (DUR) Board Reviewed
the Following New Drugs/Classes on
February 4, 2020**

Therapeutic Class	Drug Name	DURB Recommendations
Sickle Cell Anemia Treatments		
	<i>Adakveo (Intravenous) Injection</i>	NP/PA (for coverage on the PADL)
	<i>Oxbryta (Oral) Tablet</i>	NP/PA

DURB=Drug Utilization Review Board; P=preferred; NP=non-preferred; PA=prior authorization; PDL=Preferred Drug List; PADL=Providers' Administered Drug List

Drug Utilization Review Board

Motions - Votes - **New Drugs**

February 4, 2020

New Drug		Drug	PDL Status	Motion - Recommendations	Additional Comments	
Sickle Cell Anemia Treatments		Adakveo	N/A	PADL-NP/PA		
Board Members - Present		Motion Maker (v)	Seconded By (v)	VOTES		
(Strike out, when absent)				YES (v)	NO (v)	ABSTAIN (v)
1	Collins, Douglas, M.D.			√		
2	Condra III, Alton, R.Ph.			√		
3	Doad, Gurinder J.S., M.D.			√		
4	Duraski, Rod, M.D.					
5	Fowler, M. Celeste, Pharm.D. - Vice-Chair			√		
6	Gordon, Glenda Wrenn, M.D.					
7	Lesnick, Burton, M.D. - Chair					
8	Lorys, Robyn Pharm.D.		√	√		
9	May, J. Russell (Rusty)					
10	Miller, Osgood (Drew) A., R.Ph.			√		
11	Perri, Matthew, R.Ph., Ph.D.	√		√		
12	Rollins, Brent L., R.Ph., Ph.D.			√		
13	Toth, Danny, R.Ph.					
		TOTAL		8	0	0

Drug Utilization Review Board

Motions - Votes - **New Drugs**

February 4, 2020

	Drug	PDL Status	Motion - Recommendations	Additional Comments	
New Drug					
Sickle Cell Anemia Treatments					
	Oxbryta	N/A	NP/PA		
Board Members - Present	Motion Maker (v)	Seconded By (v)	VOTES		
<i>(Strike out when absent)</i>			YES (v)	NO (v)	ABSTAIN (v)
1 Collins, Douglas, M.D.			√		
2 Condra III, Alton, R.Ph.			√		
3 Doad, Gurinder J.S., M.D.			√		
4 Duraski, Rod, M.D.					
5 Fowler, M. Celeste, Pharm.D. - Vice-Chair			√		
6 Gordon, Glenda Wrenn, M.D.					
7 Lesnick, Burton, M.D. - Chair					
8 Lorys, Robyn Pharm.D.		√	√		
9 May, J. Russell (Rusty)					
10 Miller, Osgood (Drew) A., R.Ph.			√		
11 Perri, Matthew, R.Ph., Ph.D.	√		√		
12 Rollins, Brent L., R.Ph., Ph.D.			√		
13 Toth, Danny, R.Ph.					
		TOTAL	8	0	0

Important Update DCH Decision Document

Listed below are Preferred Drug List changes for the State of Georgia Fee-For-Service Medicaid and PeachCare for Kids Programs

Effective April 1, 2020 (see chart below)*

DCH rebate vendor Magellan Medicaid Administration (MMA) has reviewed 2020 supplemental rebate offers with DCH and also reviewed specific drug categories at the February 2020 DURB meeting. The PDL/PADL decisions or changes for new drugs or categories reviewed are outlined below. **Those drugs highlighted in red indicate a change from current PDL status.** For a full listing of our PDL, go to www.dch.georgia.gov/pharmacy and select the “preferred product list” option.

PREFERRED AGENTS	NON-PREFERRED AGENTS
SICKLE CELL ANEMIA TREATMENT	
	ADAKVEO
	OXBRYTA

**Georgia Department of Community Health (GDCH)
Opportunities for Pharmaceutical Manufacturer Input on Clinical
Recommendations and Clinical Management Strategies by the
Drug Utilization Review Board**

Clinical Information and Clinical Management Strategies relevant to the GDCH Medicaid Fee-For-Service program will be presented to the Drug Utilization Review Board (DURB) at each meeting through OptumRx by its vendor NorthStar HealthCare Consulting (NHC). Manufacturer input on new and existing drugs is welcomed and appreciated using these opportunities. **Please note that new drug entities are generally not reviewed by the DURB until the drug has been on the market for at least 6 months.**

Ongoing Opportunity:

DUR Board Meeting Process: Drugs, therapeutic classes and/or supplemental rebate classes under review will be posted to the DCH website at <http://dch.georgia.gov/durb-meeting-information> approximately 30 days prior to the Manufacturers' Forum. Input specific to the drugs under review from manufacturers are made directly to NHC via GAMedicaid@nhc-llc.com and reported as appropriate by NHC at subsequent DURB meetings. NHC will pass relevant manufacturer-submitted electronic materials to the DURB members via a secure FTP site.

Upon review of information, and based on its expertise and discussions, the DURB makes recommendations to GDCH.

Opportunity to Appeal to GDCH:

GDCH Review Process: DURB recommendations are reviewed by GDCH for final decisions. Manufacturers may request an appeal meeting directly with GDCH after conclusion of each quarterly DURB meeting and **this appeal meeting must be conducted within 10 business days following the DURB meeting.** **Contact: Shirmary Hodges at (404) 656-4044 or shodges@dch.ga.gov**

Presentation Opportunity:

Manufacturers' Forum: A forum prior to each relevant DURB meeting whereby manufacturers may present:

- 1) Clinical information relevant to a new drug on the market or a drug that is part of a therapeutic or supplemental rebate class under review by the DURB at the next meeting.
- 2) Clinical information relevant to ongoing NHC/OptumRx clinical management strategies (e.g. review of drug benefit plan designs, new drugs coming to market, new indications, etc.) as deemed necessary by NHC/OptumRx.

Please see the Manufacturers' Forum Announcement at <http://dch.georgia.gov/durb-meeting-information>.

**Questions not addressed in this document may be sent to NorthStar
HealthCare Consulting by e-mail: GAMedicaid@nhc-llc.com**

2020

Upcoming Meetings

Drug Utilization Review Board Meeting

2 Peachtree Street, N.W.

5th Floor Board Room

Atlanta, Georgia 30303

Tuesday, August 4, 2020: 10:00am – 2:00pm

Tuesday, November 3, 2020: 10:00am – 2:00pm

Drug Utilization Review Board

Board Member	Credentials	Specialty/Area of Expertise	Company Name
Burton L. Lesnick, Chair	M.D., FAAP	Pediatrics/Pediatric Pulmonology	Children's Healthcare of Atlanta
M. Celeste Fowler, Vice-Chair	Pharm.D., HCMBA	340B Pharmacy	Piedmont Henry Hospital
Douglas C. Collins	M.D.	Hematology/Oncology	Metro Hematology-Oncology, PC
Alton Condra III	R.Ph.	HIV/AIDS Pharmacy - Infectious Disease Program	Grady Memorial Hospital
Gurinder J.S. Doad	M.D., Ph.D.	Family Practice	Southwest Georgia Family Medicine and Mercer University School of Medicine
Rod M. Duraski	M.D., FACP, MBA	Internal Medicine	West Georgia Health
Glenda Gordon	M.D.	Psychiatry, Academia - Professor	Morehouse School of Medicine
Robyn Lorys	Pharm.D.	Academia - Professor	Mercer University College of Pharmacy
J. Russell May	Pharm.D.	Academia - Professor	University of Georgia College of Pharmacy
Drew A. Miller	R.Ph.	Retail Pharmacy	Wynn's Pharmacy
Matthew Perri III	Ph.D., R.Ph.	Academia - Professor	University of Georgia College of Pharmacy
Brent L. Rollins	R.Ph., Ph.D.	Academia - Professor	Philadelphia College of Osteopathic Medicine School of Pharmacy
Danny A. Toth	R.Ph.	Pharmacy Benefit Plans	Timber Ridge Consultants, LLC