



GEORGIA DEPARTMENT  
OF COMMUNITY HEALTH

## Georgia Department of Community Health

# DRUG UTILIZATION REVIEW BOARD MEETING

Department of Community Health  
2 Peachtree Street – **5<sup>th</sup> Floor Board Room**  
Atlanta, Georgia 30303

**November 5, 2019**

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## DRUG UTILIZATION REVIEW BOARD MEETING

### AGENDA

*2 Peachtree Street - 5<sup>th</sup> Floor DCH Board Room*

*Atlanta, Georgia 30303*

**Tuesday, November 5, 2019**

**10:00 a.m. to 3:00 p.m.**

<b>CALL TO ORDER</b>	<i>Burton L. Lesnick, M.D., FAAP, Chair</i>
<b>MINUTES FROM PREVIOUS MEETING</b>	<i>Chair</i>
<b>EXTERNAL COMMENTS SESSION</b>	<i>Chair</i>
<b>EXONDYS 51 PRESENTATION</b>	<i>Chad Nicholson, PharmD, NorthStar</i>
<b>CLINICAL REVIEWS</b>	<i>Afzal Mistry, PharmD, NorthStar</i> <i>Chad Nicholson, PharmD, NorthStar</i> <i>Emily Baker, PharmD, BCPS, NorthStar</i>
➤ <b>New Drugs</b>	
● Bevyxxa	
● Evenity	
● Inbrija	
● Mavenclad	
● Mayzent	
● Motegrity	
● Skyrizi	
● Spravato	
<b>ADJOURNMENT OF OPEN SESSION</b>	<i>Chair</i>
<b>EXECUTIVE SESSION</b>	<i>Nina Bandali, PharmD, Pharmacist Account Manager, Magellan Rx Management</i>
<b>RECONVENING OF OPEN SESSION</b>	<i>Chair</i>
<b>BOARD'S RECOMMENDATIONS AND VOTES</b>	<i>Chair</i>
<b>FUTURE AGENDA ITEMS</b>	<i>Chair</i>
<b>ADJOURNMENT OF MEETING</b>	<i>Chair</i>

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**Department of Community Health  
Drug Utilization Review Board (DURB)  
MINUTES  
Tuesday, August 6, 2019**

**MEMBERS PRESENT**

M. Celeste Fowler, Pharm.D., Vice-Chair  
Mia Avery, Pharm.D.  
Doug Collins, M.D.  
Alton Condra III, R.Ph.  
Gurinder Doad, M.D.  
Rod M. Duraski, M.D., FACP, MBA  
Glenda Wrenn Gordon, M.D.  
Robyn Lorys, Pharm.D.  
J. Russell May, Pharm.D.  
Osgood (Drew) A. Miller, R.Ph.  
Matthew Perri, R.Ph., Ph.D.  
Brent L. Rollins, R.Ph., Ph.D.  
Danny A. Toth, R.Ph.

**MEMBERS ABSENT**

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

**Staff**

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

**NorthStar HealthCare Consulting**

Emily Baker, Pharm.D., BCPS, MHA, MBA, President  
Afzal "Fez" Mistry, Pharm.D., Clinical Programs Director  
Chad Nicholson, Pharm.D., Clinical Pharmacist

**OptumRx**

Susan McCreight, VP, Government Markets, Relations & Reform, Account Management  
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  
Heather Brown

**Care Management Organizations**

Turkesia Robertson-Jones, Pharm.D., CareSource  
Charles Kim, Pharm.D., PeachState  
Cassandra Tancil, Pharm.D., BCPS Amerigroup

### **Call to Order**

The Drug Utilization Review Board (DURB/DUR Board/Board) held its third meeting for the calendar year on August 6, 2019. The Vice-Chair, M. Celeste Fowler, Pharm.D., called the meeting to order at 10:00am.

### **Minutes from the Previous Meeting**

Vice-Chair Fowler asked for corrections or changes to the minutes from the May 7, 2019 meeting. A motion was made (Osgood (Drew) A. Miller, R.Ph.), seconded (J. Russell May, Pharm.D.), and carried to approve the minutes as written.

### **External Comments Session**

There were no external comments presented to the Board.

### **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
<b>Tetracyclines</b>	<i>Nuzyra</i>	Chad Nicholson, Pharm.D.
<b>COPD Agents</b>	<i>Yupelri</i>	Chad Nicholson, Pharm.D.
<b>Spinal Muscular Atrophy</b>	<i>Zolgensma</i>	Chad Nicholson, Pharm.D.

The Board discussed the drug information, provided comments, and raised questions on the following:

- Nuzyra - PA criteria would require oral loading dose for only ABSSI; incidence of nausea significant higher with oral loading dose than IV loading dose (22% vs. 4%); C. Diff less likely but short trial duration may limit definitive conclusions.
- Zolgensma – Reason for ongoing clinical trial is looking at durability; durability should be lifelong but only 5-6 years of data; approval of Zolgensma would require stop of Spinraza; no data using Zolgensma and Spinraza together.

### **DCH Decisions**

DCH Decisions from the May 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  
5<sup>th</sup> Floor Board Room  
Atlanta, Georgia 30303

Tuesday, November 5, 2019

### **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 representatives, Turkesia Robertson-Jones, Pharm.D. (CareSource), Charles Kim, Pharm.D., (PeachState), Cassandra Tancil, Pharm.D., BCPS (Amerigroup), and pharmacy students, Amanda Wolfe (UGA), Kirty Patel (UGA), Ariel Dyches (UGA), Connor Lockridge (Mercer), Pierce Skersick (PCOM), Ononuju Ume (PCOM), and Tuong Huynh (Mercer), also attended the closed session with Board members. A motion was made by Robyn Lorys, Pharm.D. and seconded by Alton Condra III, R.Ph. to adjourn the open session and approve the closed session. There was a unanimous vote approving the closed session. The Vice-Chair, M. Celeste Fowler, Pharm.D., adjourned the open session at approximately 10:47am, at which time members took a break then reconvened for the executive (closed) session.

### **Executive Session**

The Executive Session was held from 11:00am to 11:25am.

### **Reconvening of Open Session**

The DUR Board reconvened for the open session at 11:30am.

### **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) as noted in Attachment A. All motions and votes are noted in Attachment B.

### **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 Mia Avery, Pharm.D.). Vice-Chair Fowler adjourned the meeting at 11:33am.

THESE MINUTES ARE HEREBY APPROVED AND ADOPTED, THIS THE \_\_\_\_\_  
DAY OF \_\_\_\_\_, 2019.

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M. Celeste Fowler, Pharm.D., Vice-Chair

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**The Drug Utilization Review (DUR) Board Reviewed  
the Following New Drugs/Classes on  
August 6, 2019**

<b>Therapeutic Class</b>	<b>Drug Name</b>	<b>DURB Recommendations</b>
<b>Tetracyclines</b>		
	<i>Nuzyra (Oral) Tablet</i> <i>Nuzyra (Intravenous) Injection</i>	NP/PA
<b>COPD Agents</b>		
	<i>Yupelri (Inhalation) Solution</i>	NP/PA
<b>Spinal Muscular Atrophy</b>		
	<i>Zolgensma (Intravenous) Injection</i>	Add to PADL with PA and defer decision to future DURB meeting

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

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# Drug Utilization Review Board

Motions - Votes - **New Drugs**

**August 6, 2019**

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

# Drug Utilization Review Board

Motions - Votes - **New Drugs**

**August 6, 2019**

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

# Drug Utilization Review Board

Motions - Votes - **New Drugs**

**August 6, 2019**

New Drug		Drug	PDL Status	Motion - Recommendations	Additional Comments	
<b>Spinal Muscular Atrophy</b>		Zolgensma (Intravenous) Injection	N/A	PA-PADL	Handle on a case by case basis pending further DURB review	
<b>Board Members - Present</b>		<b>Motion</b>	<b>Seconded</b>	<b>VOTES</b>		
<i>(Strike out, when absent)</i>		<b>Maker (v)</b>	<b>By (v)</b>	<b>YES (v)</b>	<b>NO (v)</b>	<b>ABSTAIN (v)</b>
1	Avery, Mia, Pharm.D.			√		
2	Collins, Douglas, M.D.			√		
3	Condra III, Alton, R.Ph.			√		
4	Doad, Gurinder J.S., M.D.			√		
5	Duraski, Rod, M.D.			√		
6	Fowler, M. Celeste, Pharm.D. - <b>Vice-Chair</b>					
7	Gordon, Glenda Wrenn, M.D.			√		
8	Lesnick, Burton, M.D. - <b>Chair</b>					
9	Lorys, Robyn Pharm.D.			√		
10	May, J. Russell (Rusty)			√		
11	Miller, Osgood (Drew) A., R.Ph.			√		
12	Perri, Matthew, R.Ph., Ph.D.	√		√		
13	Rollins, Brent L., R.Ph., Ph.D.		√	√		
14	Toth, Danny, R.Ph.			√		
			<b>TOTAL</b>	<b>12</b>	<b>0</b>	<b>0</b>

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## 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 October 1, 2019 (see chart below)\*

DCH rebate vendor Magellan Medicaid Administration (MMA) has reviewed SFY2020 supplemental rebate offers with DCH and also reviewed specific drug categories at the August 2019 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](http://www.dch.georgia.gov/pharmacy) and select the “preferred product list” option.

PREFERRED AGENTS	NON-PREFERRED AGENTS
<b>COPD AGENTS</b>	
	YUPELRI
<b>SPINAL MUSCULAR ATROPHY</b>	
ZOLGENSMA (PADL) – decision deferred	
<b>TETRACYCLINES</b>	
	NUZYRA

\*PADL drugs may be subject to a different effective date.

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**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](mailto: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](mailto: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](mailto:GAMedicaid@nhc-llc.com)**

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**2020**

## **Upcoming Meetings**

### **Drug Utilization Review Board Meeting**

2 Peachtree Street, N.W.

5<sup>th</sup> Floor Board Room

Atlanta, Georgia 30303

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

Tuesday, May 5, 2020: 10:00am – 2:00pm

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

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

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### Drug Utilization Review Board

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