



GEORGIA DEPARTMENT
OF COMMUNITY HEALTH

Georgia Department of Community Health

DRUG UTILIZATION REVIEW BOARD MEETING

Department of Community Health

July 17, 2024



**DRUG UTILIZATION REVIEW BOARD MEETING
AGENDA**

*2 Martin Luther King Jr. Drive, S.E.
Atlanta, Georgia 30334*

*Department of Community Health Board Room - Room 470-A
East Tower, Balcony Level*

**Wednesday, July 17, 2024
10:00 a.m. to 2:00 p.m.**

CALL TO ORDER	<i>Celeste Fowler, PharmD, MBA, Chair</i>
MINUTES FROM PREVIOUS MEETING	<i>Chair</i>
EXTERNAL COMMENTS SESSION	<i>Chair</i>
CLINICAL REVIEWS	<i>Chad Nicholson, PharmD, NorthStar Mary-Beth Plum, PharmD, BCACP, NorthStar Emily Baker, PharmD, BCPS, NorthStar</i>
➤ New Drugs	
● Bimzelx	
● Omvoh	
● Velsipity	
● Casgevy	
● Lyfgenia	
ADJOURNMENT OF OPEN SESSION	<i>Chair</i>
EXECUTIVE SESSION	<i>Afzal Mistry, PharmD, Magellan Rx Management/Prime Therapeutics</i>
RECONVENING OF OPEN SESSION	<i>Chair</i>
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
Wednesday, April 17, 2024**

MEMBERS PRESENT

M. Celeste Fowler, Pharm.D., HCMBA, Chair
Doug Collins, M.D.
Glenda Wrenn Gordon, M.D., MSHP, FAPA
Burton L. Lesnick, M.D., FAAP
Robyn Lorys, Pharm.D.
J. Russell (Rusty) May, Pharm.D.
Osgood (Drew) A. Miller, R.Ph.
Matthew Perri, Pharm.D., R.Ph., Ph.D.
Suzanne Walton, Pharm.D., BCPS, BCOP

MEMBERS ABSENT

Gurinder Doad, M.D., Ph.D., Vice-Chair
Alton Condra, III, R.Ph.
Otto Goyco, M.D.
Torey Jones, Pharm.D.
Brent L. Rollins, R.Ph., Ph.D.
Danny A. Toth, R.Ph.

Staff

Gilletta Gray, R.Ph., Clinical Manager, Pharmacy Services
Ashlee Henry, MSHI, Pharmacy Operations Supervisor
Ashley Bellino, Pharmacy Operations Specialist, Pharmacy Services
Rose 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
Chad Nicholson, Pharm.D., Clinical Programs Director

OptumRx

Talmahjia "Tami" Sweat, Pharm.D., Clinical Consulting

Magellan Rx Management/Prime Therapeutics

Afzal "Fez" Mistry, Pharm.D., Pharmacist Account Manager

Care Management Organizations

Cassandra Tancil, Pharm.D., BCPS, Amerigroup

Pharmacy Students

Cherith Blair, Pharm.D. Candidate, University of Georgia
Garrett Brown, Pharm.D. Candidate, University of Georgia
Ciana Wallace, Pharm.D. Candidate, University of Georgia
William Bowen, Pharm.D. Candidate, University of Georgia

Department of Community Health
 Drug Utilization Review Board (DURB)
 MINUTES
 Wednesday, April 17, 2024
Call to Order

The Drug Utilization Review Board (DURB/DUR Board/Board) held its second meeting for the calendar year on April 17, 2024. The Chair, M. Celeste Fowler, Pharm.D., HCMBBA, called the meeting to order at 10:10am before Board members introduced themselves.

Minutes from the Previous Meeting

Chair Fowler asked for corrections or changes to the minutes from the January 17, 2024 meeting. A motion was made (Burton L. Lesnick, M.D., FAAP) and seconded (J. Russell (Rusty) May, Pharm.D.) and carried to approve the minutes as written.

External Comments Session

The following external comment was presented to the Board:

- L. Joy Baker, M.D., FACOG, PMH-C, C-EFM, MT (ASCP) (private practice) – spoke in favor of coverage for zuranolone (Zurzuvae) and shared her clinical experience on treating patients with the drug. When asked about the drowsiness associated with the drug, she indicated it is recommended for patients to have about 12 hours of downtime before they are ready to go out.
- Toby D. Smith, M.D. (Director, Women’s Mental Health Program, PEACE for Moms, Assistant Professor of Psychiatry and Distinguished Physician) – submitted written comments read by Chad Nicholson, Pharm.D. on postpartum depression, treatments, and impact of requiring failure of one to two SSRI or SNRI treatments before zuranolone (Zurzuvae). Dr. Smith also offered assistance with developing protocols for coverage.

Disclosure forms were completed by Dr. Baker and Dr. Smith and were reviewed by the Department.

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
Macular Degeneration Agents	<i>Izervay</i>	Chad Nicholson, Pharm.D.
Biologic Immunomodulators	<i>Litfulo</i>	Chad Nicholson, Pharm.D.
Ophthalmics, Anti-Inflammatory/ Immunomodulator	<i>Miebo</i>	Chad Nicholson, Pharm.D.
Antidepressants, Other	<i>Zurzuvae</i>	Chad Nicholson, Pharm.D.

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

- Izervay
 - No data past 24 months looking at visual acuity; primary endpoints looked at size of geographic atrophy; a lot of evidence still outstanding on how these products will be used
- Litfulo
 - Indication is for >50% hair loss (severe Alopecia Areata); same for baricitinib
- Miebo
 - Corneal fluorescein staining difference – statistically significant
 - Since dry eyes may have multifactorial etiologies, how is it best determined if patients would benefit from this drug – probably not anything to build in criteria, clinical practice may determine what’s reasonable (physical examination)
 - Patient satisfaction not looked at in clinical trials regarding dosing frequency, didn’t see any review of compliance (since applied four times a day)
 - Cyclosporine/Restasis – other second line options, used when more inflammation
- Zurzuvae
 - Has black box warning, typical with SSRIs, but this has a different mechanism of action
 - Excluded people with suicidal ideation – may have been from a med safety standpoint; most with post-partum depression may have other protective factors as to why they aren’t having suicidal ideation; more likely to be prescribed by OB/GYN so want them to be comfortable with it
 - Age cut off 18 years – was part of clinical inclusion criteria
 - Sedation – due to GABA effects
 - Nothing pharmacologic that would preclude any licensed practitioner from prescribing; requiring consultation with a psychiatrist would limit access
 - Make readily accessible for treatment so if not working, can move to other care options
 - Placebo – did well; over time may have had some down regulation of receptors and normalization of GABA signaling
 - Concomitant drug interactions – would want to be careful with other drugs with sedative properties

DCH Decisions

DCH Decisions from the January 2024 DUR Board meeting were provided in the DCH Decision section of the DUR Board binder.

Upcoming Meetings

The following upcoming meetings were announced:

- Drug Utilization Review Board
2 Martin Luther King Jr. Drive, SE
East Tower
Atlanta, Georgia 30334

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

Wednesday, April 17, 2024

Wednesday, July 17, 2024: 10:00am – 2:00pm

Wednesday, October 16, 2024: 10:00am – 2:00pm

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 have the Executive Session pursuant to the Open Meetings 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, OptumRx, and UGA pharmacy students. A motion was made by J. Russell (Rusty) May, Pharm.D. and seconded (Osgood (Drew) A. Miller, R.Ph.) to approve the closed session. There was a unanimous vote approving the closed session. The Chair, M. Celeste Fowler, Pharm.D., HCMBA, adjourned the open session at approximately 11:51am, at which time members took a break then reconvened for the executive (closed) session.

Executive Session

The Executive Session was held from 12:09pm to 1:02pm.

Reconvening of Open Session

The DUR Board reconvened for the open session at 1:04pm.

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.

Future Agenda Items

The following future agenda item was noted: look at Zurzuvae utilization in 6 months.

Conclusion

At the conclusion of the open session and no other business for discussion, Chair Fowler adjourned the meeting at 1:09pm.

THESE MINUTES ARE HEREBY APPROVED AND ADOPTED, THIS THE _____ DAY
OF _____, 2024.

M. Celeste Fowler, Pharm.D., HCMBA, Chair

Drug Utilization Review Board
Motions - Votes - New Drugs
April 17, 2024

New Drug	Drug	PDL Status	Motion - Recommendations	Additional Comments	
Macular Degenerations Agents	Izervay	N/A	NP/PA on PADL		
Board Members - Present <i>(Strike out, when absent)</i>	Motion Maker (v)	Seconded By (v)	VOTES		
			YES (v)	NO (v)	ABSTAIN (v)
1 Collins, Douglas, M.D.			√		
2 Condra III, Alton, R.Ph.					
3 Doad, Gurinder J.S., M.D., Ph.D.- Vice-Chair					
4 Fowler, M. Celeste, Pharm.D., HCMA- Chair					
5 Gordon, Glenda Wrenn, M.D., MSHP, FAPA			√		
6 Goyco, Otto, M.D.					
7 Jones, Torey, Pharm.D.					
8 Lesnick, Burton, M.D., FAAP	√		√		
9 Lorys, Robyn, Pharm.D.			√		
10 May, J. Russell (Rusty), Pharm.D.			√		
11 Miller, Osgood (Drew) A., R.Ph.		√	√		
12 Perri, Matthew, R.Ph., Pharm.D., Ph.D.			√		
13 Rollins, Brent L., R.Ph., Ph.D.					
14 Toth, Danny, R.Ph.					
15 Walton, Suzanne, Pharm.D., BCPS, BCOP			√		
TOTAL			8	0	0
New Drug	Drug	PDL Status	Motion - Recommendations	Additional Comments	
Biologic Immunomodulators	Litfulo	N/A	NP/PA		
Board Members - Present <i>(Strike out, when absent)</i>	Motion Maker (v)	Seconded By (v)	VOTES		
			YES (v)	NO (v)	ABSTAIN (v)
1 Collins, Douglas, M.D.			√		
2 Condra III, Alton, R.Ph.					
3 Doad, Gurinder J.S., M.D., Ph.D.- Vice-Chair					
4 Fowler, M. Celeste, Pharm.D., HCMA- Chair					
5 Gordon, Glenda Wrenn, M.D., MSHP, FAPA			√		
6 Goyco, Otto, M.D.					
7 Jones, Torey, Pharm.D.					
8 Lesnick, Burton, M.D., FAAP			√		
9 Lorys, Robyn, Pharm.D.	√		√		
10 May, J. Russell (Rusty), Pharm.D.		√	√		
11 Miller, Osgood (Drew) A., R.Ph.			√		
12 Perri, Matthew, R.Ph., Pharm.D., Ph.D.			√		
13 Rollins, Brent L., R.Ph., Ph.D.					
14 Toth, Danny, R.Ph.					
15 Walton, Suzanne, Pharm.D., BCPS, BCOP			√		
TOTAL			8	0	0
New Drug	Drug	PDL Status	Motion - Recommendations	Additional Comments	

Drug Utilization Review Board
Motions - Votes - New Drugs
April 17, 2024

Ophthalmics, Anti-Inflammatory/ Immunomodulator		Miebo	N/A	NP/PA	VOTES	
Board Members - Present <i>(Strike out, when absent)</i>		Motion Maker (v)	Seconded By (v)	YES (v)	NO (v)	ABSTAIN (v)
1	Collins, Douglas, M.D.			√		
2	Condra III, Alton, R.Ph.					
3	Doad, Gurinder J.S., M.D., Ph.D.- Vice-Chair					
4	Fowler, M. Celeste, Pharm.D., HCMBBA-Chair					
5	Gordon, Glenda Wrenn, M.D., MSHP, FAPA			√		
6	Goyco, Otto, M.D.					
7	Jones, Torey, Pharm.D.					
8	Lesnick, Burton, M.D., FAAP	√		√		
9	Lorys, Robyn, Pharm.D.			√		
10	May, J. Russell (Rusty), Pharm.D.			√		
11	Miller,Osgood (Drew) A., R.Ph.		√	√		
12	Perri, Matthew, R.Ph., Pharm.D., Ph.D.			√		
13	Rollins, Brent L., R.Ph., Ph.D.					
14	Toth, Danny, R.Ph.					
15	Walton, Suzanne, Pharm.D., BCPS, BCOP			√		
			TOTAL	8	0	0
New Drug		Drug	PDL Status	Motion - Recommendations	Additional Comments	
Antidepressants, Other		Zurzuvae	N/A	NP/PA	VOTES	
Board Members - Present <i>(Strike out, when absent)</i>		Motion Maker (v)	Seconded By (v)	YES (v)	NO (v)	ABSTAIN (v)
1	Collins, Douglas, M.D.			√		
2	Condra III, Alton, R.Ph.					
3	Doad, Gurinder J.S., M.D., Ph.D.- Vice-Chair					
4	Fowler, M. Celeste, Pharm.D., HCMBBA-Chair					
5	Gordon, Glenda Wrenn, M.D., MSHP, FAPA	√		√		
6	Goyco, Otto, M.D.					
7	Jones, Torey, Pharm.D.					
8	Lesnick, Burton, M.D., FAAP			√		
9	Lorys, Robyn, Pharm.D.		√	√		
10	May, J. Russell (Rusty), Pharm.D.			√		
11	Miller,Osgood (Drew) A., R.Ph.			√		
12	Perri, Matthew, R.Ph., Pharm.D., Ph.D.			√		
13	Rollins, Brent L., R.Ph., Ph.D.					
14	Toth, Danny, R.Ph.					
15	Walton, Suzanne, Pharm.D., BCPS, BCOP			√		
			TOTAL	8	0	0

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

Effective July 1, 2024 (see chart below)*

DCH rebate vendor, Magellan Medicaid Administration (MMA), has reviewed specific drugs at the April 2024 DURB meeting and corresponding supplemental rebate offers. The Preferred Drug List (PDL)/Providers' Administered Drug List (PADL) decisions/changes for categories reviewed are outlined below. For a full listing of our PDL, go to www.dch.georgia.gov/pharmacy and select the "Preferred Drug Lists" option; for the PADL, go to <https://www.mmis.georgia.gov/portal/> and select "Provider Information", "Fee Schedule", then "Providers' Administered Drug List."

PREFERRED AGENTS	NON-PREFERRED AGENTS
ANTIDEPRESSANTS, OTHER	
	ZURZUVAE (ORAL) – PA
BIOLOGIC IMMUNOMODULATORS	
	LITFULO (ORAL) – PA
MACULAR DEGENERATION AGENTS	
	IZERVAY (INTRAOCULAR)* – PA
OPHTHALMICS, ANTI-INFLAMMATORY/IMMUNOMODULATOR	
	MIEBO (OPHTHALMIC) – PA

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



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: New 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.

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 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

2024

Upcoming Meetings

Drug Utilization Review Board Meeting

2 Martin Luther King Jr. Drive, S.E.

Atlanta, Georgia 30334

Department of Community Health Board Room - Room 470-A

East Tower, Balcony Level

Wednesday, October 16, 2024:

10:00am – 2:00pm

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Drug Utilization Review Board

Board Member	Credentials	Specialty/Area of Expertise	Company Name
M. Celeste Fowler, Chair	Pharm.D., HCMBBA	340B Pharmacy	Piedmont Henry Hospital
Gurinder J.S. Doad, Vice-Chair	M.D., Ph.D.	Family Practice	Southwest Georgia Family Medicine and Mercer University School of Medicine
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
Otto C. Goyco	M.D., FACP	Internal Medicine	Otto C. Goyco Internal Medicine, LLC
Torey A. Jones	Pharm.D., MBA	340B Pharmacy	Phoebe Putney Health System, Bizzell Group, LLC,
Burton L. Lesnick	M.D., FAAP	Pediatrics/Pediatric Pulmonology	Children's Healthcare of Atlanta
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
Suzanne M. Walton	Pharm.D., BCPS, BCOF	Hematology/Oncology	Grady Health System
Glenda Wrenn	M.D.	Psychiatry, Academia - Professor	Morehouse School of Medicine