



GEORGIA DEPARTMENT
OF COMMUNITY HEALTH

Georgia Department of Community Health

DRUG UTILIZATION REVIEW BOARD MEETING

Department of Community Health
2 Peachtree Street – 5th Floor Board Room
Atlanta, Georgia 30303

November 6, 2018

This page intentionally left blank



DRUG UTILIZATION REVIEW BOARD MEETING

AGENDA

2 Peachtree Street - 5th Floor DCH Board Room

Atlanta, Georgia 30303

Tuesday, November 6, 2018

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

CALL TO ORDER

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

MINUTES FROM PREVIOUS MEETING

Chair

EXTERNAL COMMENTS SESSION

Chair

CLINICAL REVIEWS

Afzal Mistry, PharmD, NorthStar

Chad Nicholson, PharmD, NorthStar

Emily Baker, PharmD, BCPS, NorthStar

➤ New Drugs

- Aimovig
- Crysvida
- Mircera
- Rhopressa
- Trogarzo
- Vyzulta

ADJOURNMENT OF OPEN SESSION

Chair

EXECUTIVE SESSION

*Nina Bandali, PharmD, Pharmacist Account
Manager, Magellan Rx Management*

➤ Supplemental Rebate Class Reviews

RECONVENING OF OPEN SESSION

Chair

BOARD'S RECOMMENDATIONS AND VOTES

Chair

FUTURE AGENDA ITEMS

Chair

ADJOURNMENT OF MEETING

Chair

This page intentionally left blank

**Department of Community Health
Drug Utilization Review Board (DURB)
MINUTES
Tuesday, August 7, 2018**

MEMBERS PRESENT

Burton L. Lesnick, M.D., FAAP, Chair
M. Celeste Fowler, Pharm.D., Vice-Chair
Mia Avery, Pharm.D.
Gurinder J.S. Doad, M.D.
Deborah Fincher, M.S., R.Ph
Robyn Lorys, Pharm.D.
J. Russell May, Pharm.D.
Osgood (Drew) A. Miller, R.Ph.
Brent L. Rollins, R.Ph., Ph.D.
Danny A. Toth, R.Ph.

MEMBERS ABSENT

Doug Collins, M.D.
Rod M. Duraski, M.D., FACP, MBA
Glenda Wrenn Gordon, M.D

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
Keri Rosenthal, Pharmacist, Pharmacy Services
Lori Garner, MHS, MBA, R.Ph., Pharmacist, SHBP
Karla Forbes, Pharm.D., Program Integrity

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

Mark Hall, MBA, PMP, Assoc. Director, Government Markets, Relations & Reform
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
Cassandra Tancil, Pharm.D., Amerigroup

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

Tuesday, August 7, 2018

Call to Order

The Drug Utilization Review Board (DURB/DUR Board/Board) held its third meeting for the calendar year on August 7, 2018. The Chair, Burton L. Lesnick, M.D., FAAP, called the meeting to order at 10:03am. Board members verbally disclosed their conflicts of interests.

Minutes from the Previous Meeting

Chair Lesnick asked for corrections or changes to the minutes from the May 1, 2018 meeting. A motion was made (Deborah Fincher, M.S., R.Ph.), seconded (Danny A. Toth, R.Ph.), and carried to approve the minutes as written.

External Comments Session

External comments were presented to the Board from the following noted below. Conflicts of interests were noted between the Cystic Fibrosis Foundation and Vertex Pharmaceuticals, who made a total contribution of \$5.8M to the foundation in 2017.

- Rebecca Penuel – spoke about her son with Cystic Fibrosis and being on Symdeko.
- A letter from Bruce Marshall, M.D. and Lisa Feng, DrPH (Cystic Fibrosis Foundation) – requested to include Symdeko on the Preferred Drug List.
- Pam Baker – wrote about the benefits her children have experienced on Symdeko and allowing coverage.
- Todd Baillie – wrote about his son with CF and the benefits of being on Symdeko.

Disclosure forms were completed by Rebecca Penuel, Dr. Bruce Marshall, Dr. Lisa Feng, Pam Baker, and Todd Baillie 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
Fluoroquinolones	<i>Baxdela</i>	Afzal “Fez” Mistry, Pharm.D.
HIV/AIDS	<i>Biktarvy</i>	Afzal “Fez” Mistry, Pharm.D.
Hypoglycemics, Incretin Mimetics/Enhancers	<i>Ozempic</i>	Afzal “Fez” Mistry, Pharm.D.
Hyperparathyroid Agents	<i>Parsabiv</i>	Chad Nicholson, Pharm.D.
Hypoglycemics, SGLT2	<i>Steglatro</i>	Afzal “Fez” Mistry, Pharm.D.
Cystic Fibrosis, Oral	<i>Symdeko</i>	Chad Nicholson, Pharm.D.

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

Tuesday, August 7, 2018

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

Symdeko – trial patients previously on standard of care, ex. Ivacaptor; CF life expectancy-30 years; ongoing studies in children < 12 (Orkambi and Kalydeco); overlapping indications with products; Symdeko-focused on more severe population of CF.

Parsabiv – trials looked at compliance improvement; no outcomes data yet.

Baxdela – number of patients being treated for MRSA was small; patients being treated were inpatient (MRSA probably community acquired but could have some hospital acquired); not much control in outpatient because most are started in hospital; outpatient needs step therapy to discourage first line use in community; possible step through other preferreds or alternatives; PA criteria-use of drug only for transition from inpatient to outpatient, failure of standard treatment.

Biktarvy – no need for a prior authorization.

Ozempic – If new indication received for cardiovascular disease, drug typically would not come back to the Board for review.

DCH Decisions

DCH Decisions from the February 2018 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, November 6, 2018

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, and NorthStar HealthCare Consulting. CMO representatives, Turkesia Robertson-Jones, Pharm.D. (CareSource) and Cassandra Tancil, Pharm.D. (Amerigroup), and pharmacy students Angel Flournoy (UGA), Kevin Philippart (UGA), Harsh Patel (PCOM), Katheryn Long (UGA), and Keenya Riggins (Mercer), also attended the closed session with Board members. A motion was made by Robyn Lorys, Pharm.D., and seconded by Mia Avery, Pharm.D.

, 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 11:31am, at which time members took a break then reconvened for the executive (closed) session.

Department of Community Health
Drug Utilization Review Board (DURB)
MINUTES
Tuesday, August 7, 2018
Executive Session

The Executive Session was held from 11:38am to 12:12pm.

Reconvening of Open Session

The DUR Board reconvened for the open session at 12:20pm.

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. Chair Lesnick adjourned the meeting at 12:23pm.

THESE MINUTES ARE HEREBY APPROVED AND ADOPTED, THIS THE _____
DAY OF _____, 2018.

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



**The Drug Utilization Review (DUR) Board Reviewed
the Following New Drugs/Classes on
August 7, 2018**

Therapeutic Class	Drug Name	DURB Recommendations
Fluoroquinolones		
	<i>Baxdela (Intravenous) Injection</i>	NP/PA
	<i>Baxdela (Oral) Tablet</i>	NP/PA
HIV/AIDS		
	<i>Biktarvy (Oral) Tablet</i>	P
Hypoglycemics, Incretin Mimetics/Enhancers		
	<i>Ozempic (Subcutaneous) Injection</i>	NP/PA
Hyperparathyroid Agents		
	<i>Parsabiv (Intravenous) Injection</i>	P/PA (for coverage on the PADL)
Hypoglycemics, SGLT2 Inhibitors		
	<i>Steglatro (Oral) Tablet</i>	NP/PA
Cystic Fibrosis		
	<i>Symdeko (Oral) Tablet</i>	P/PA

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

This page intentionally left blank

Drug Utilization Review Board

Motions - Votes - **New Drugs**

August 7, 2018

New Drugs		Drug	PDL Status	Motion - Recommendations	Additional Comments		
Cystic Fibrosis		Symdeko (Oral) Tablet Motion Maker (v)	N/A Seconded By (v)	P/PA			
Board Members - Present (Strike out, when absent)				VOTES			
				YES (v)	NO (v)	ABSTAIN (v)	
1	Avery, Mia, Pharm.D.		✓	✓			
2	Doad, Gurinder J.S., M.D.-			✓			
3	Fincher, Deborah W., M.S., R.Ph.			✓			
4	Fowler, M. Celeste, Pharm.D. - Vice			✓			
5	Graham, Yolanda, M.D.			✓			
6	Lesnick, Burton, M.D. - Chair			✓			
7	Lorys, Robyn Pharm.D.	✓		✓			
8	May, J. Russell (Rusty)			✓			
9	Miller, Osgood (Drew) A. R.Ph.			✓			
10	Rollins, Brent L., R.Ph., Ph.D.			✓			
11	Toth, Danny, R.Ph.			✓			
			TOTAL	11	0	0	
Board Members - Absent							
1	Collins, Douglas, M.D.						
2	Duraski, Rod, M.D.						
3	Gordon, Glenda Wrenn						

Drug Utilization Review Board

Motions - Votes - **New Drugs**

August 7, 2018

New Drug		Drug	PDL Status	MOTION - Recommendations	Additional Comments	
Fluoroquinolones		Baxdela (Intravenous) Injection	N/A	NP/PA		
		Baxdela (Oral) Tablet	N/A	NP/PA		
		VOTES				
Board Members - Present <small>(Strike out, when absent)</small>	Motion Maker (v)	Seconded By (v)	YES (v)	NO (v)	ABSTAIN (v)	
1 Avery, Mia, Pharm.D.			✓			
2 Doad, Gurinder J.S., M.D.-			✓			
3 Fincher, Deborah W., M.S., R.Ph.			✓			
4 Fowler, M. Celeste, Pharm.D. - Vice			✓			
5 Graham, Yolanda, M.D.			✓			
6 Lesnick, Burton, M.D. - Chair			✓			
7 Lorys, Robyn Pharm.D.			✓			
8 May, J. Russell (Rusty)	✓		✓			
9 Miller, Osgood (Drew) A. R.Ph.			✓			
10 Rollins, Brent L., R.Ph., Ph.D.			✓			
11 Toth, Danny, R.Ph.		✓	✓			
			TOTAL	11	0	0
Board Members - Absent						
1 Collins, Douglas, M.D.						
2 Duraski, Rod, M.D.						
3 Gordon, Glenda Wrenn						

Drug Utilization Review Board

Motions - Votes - **New Drugs**

August 7, 2018

New Drug		Drug	PDL Status	Motion - Recommendations	Additional Comments	
HIV/AIDS		Biktarvy (Oral) Tablet Motion Maker (v)	P Seconded By (v)	P	VOTES	
Board Members - Present				YES (v)	NO (v)	ABSTAIN (v)
(Strike out, when absent)						
1	Avery, Mia, Pharm.D.			✓		
2	Doad, Gurinder J.S., M.D.-			✓		
3	Fincher, Deborah W., M.S., R.Ph.	✓		✓		
4	Fowler, M. Celeste, Pharm.D. - Vice			✓		
5	Graham, Yolanda, M.D.			✓		
6	Lesnick, Burton, M.D. - Chair			✓		
7	Lorys, Robyn Pharm.D.			✓		
8	May, J. Russell (Rusty)			✓		
9	Miller, Osgood (Drew) A. R.Ph.			✓		
10	Rollins, Brent L., R.Ph., Ph.D.		✓	✓		
11	Toth, Danny, R.Ph.			✓		
			TOTAL	11	0	0
Board Members - Absent						
1	Collins, Douglas, M.D.					
2	Duraski, Rod, M.D.					
3	Gordon, Glenda Wrenn					

Drug Utilization Review Board

Motions - Votes - **New Drugs**

August 7, 2018

New Drug		Drug	PDL Status	Motion - Recommendations	Additional Comments	
Hyperparathyroid Agents		Parsabiv (Intravenous) Injection	N/A	P/PA (for coverage on the PADL		
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	Doad, Gurinder J.S., M.D.-			✓		
3	Fincher, Deborah W., M.S., R.Ph.			✓		
4	Fowler, M. Celeste, Pharm.D. - Vice			✓		
5	Graham, Yolanda, M.D.			✓		
6	Lesnick, Burton, M.D. - Chair			✓		
7	Lorys, Robyn Pharm.D.			✓		
8	May, J. Russell (Rusty)			✓		
9	Miller, Osgood (Drew) A. R.Ph.		✓	✓		
10	Rollins, Brent L., R.Ph., Ph.D.			✓		
11	Toth, Danny, R.Ph.			✓		
TOTAL				11	0	0
Board Members - Absent						
1	Collins, Douglas, M.D.					
2	Duraski, Rod, M.D.					
3	Gordon, Glenda Wrenn					

Drug Utilization Review Board

Motions - Votes - **New Drugs**

August 7, 2018

New Drug		Drug	PDL Status	Motion - Recommendations	Additional Comments	
Hypoglycemics, Incretin Mimetics/Enhancers		Ozempic (Subcutaneous) Injection Motion Maker (v)	N/A Seconded By (v)	NP/PA	VOTES	
Board Members - Present				YES (v)		
(Strike out, when absent)						
1	Avery, Mia, Pharm.D.			✓		
2	Doad, Gurinder J.S., M.D.-			✓		
3	Fincher, Deborah W., M.S., R.Ph.			✓		
4	Fowler, M. Celeste, Pharm.D. - Vice			✓		
5	Graham, Yolanda, M.D.			✓		
6	Lesnick, Burton, M.D. - Chair			✓		
7	Lorys, Robyn Pharm.D.			✓		
8	May, J. Russell (Rusty)			✓		
9	Miller, Osgood (Drew) A. R.Ph.			✓		
10	Rollins, Brent L., R.Ph., Ph.D.	✓		✓		
11	Toth, Danny, R.Ph.		✓	✓		
			TOTAL	11	0	0
Board Members - Absent						
1	Collins, Douglas, M.D.					
2	Duraski, Rod, M.D.					
3	Gordon, Glenda Wrenn					

Drug Utilization Review Board

Motions - Votes - **New Drugs**

August 7, 2018

New Drug		Drug	PDL Status	Motion - Recommendations	Additional Comments	
Hypoglycemics, SGLT2 Inhibitors		Steglatro (Oral) Tablet Motion Maker (v)	N/A Seconded By (v)	NP/PA		
Board Members - Present (Strike out, when absent)				VOTES		
				YES (v)	NO (v)	ABSTAIN (v)
1	Avery, Mia, Pharm.D.			✓		
2	Doad, Gurinder J.S., M.D.-	✓		✓		
3	Fincher, Deborah W., M.S., R.Ph.			✓		
4	Fowler, M. Celeste, Pharm.D. - Vice			✓		
5	Graham, Yolanda, M.D.			✓		
6	Lesnick, Burton, M.D. - Chair			✓		
7	Lorys, Robyn Pharm.D.		✓	✓		
8	May, J. Russell (Rusty)			✓		
9	Miller, Osgood (Drew) A. R.Ph.			✓		
10	Rollins, Brent L., R.Ph., Ph.D.			✓		
11	Toth, Danny, R.Ph.			✓		
			TOTAL	11	0	0
Board Members - Absent						
1	Collins, Douglas, M.D.					
2	Duraski, Rod, M.D.					
3	Gordon, Glenda Wrenn					

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 September 1, 2018 (see chart below)

DCH rebate vendor Magellan Medicaid Administration (MMA) has reviewed SFY2019 supplemental rebate offers with DCH and also reviewed specific drug categories at the August 2018 DURB meeting. The PDL/PADL decisions or PDL/PADL changes for new drugs or categories reviewed during the August DURB meeting 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
ONLY DRUGS reviewed during the August 2018 DURB meeting as either new to market or a change in PDL status are listed	
CYSTIC FIBROSIS, ORAL	
SYMDEKO	
FLUOROQUINOLONES, INJECTABLE	
	BAXDELA (IV)
FLUOROQUINOLONES, ORAL	
	BAXDELA (ORAL)
HIV / AIDS	
BIKTARVY	
HYPERPARATHYROID AGENTS	
PARSABIV	
HYPOGLYCEMICS, INCRETIN MIMETICS/ENHANCERS	
	OZEMPIC
HYPOGLYCEMICS, SGLT2	
	STEGLATRO

This page intentionally left blank

**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**

This page intentionally left blank

2019

Upcoming Meetings

Drug Utilization Review Board Meeting

2 Peachtree Street, N.W.

5th Floor Board Room

Atlanta, Georgia 30303

Tuesday, February 5, 2019: TBD

Thursday, May 2, 2019: TBD

Tuesday, August 6, 2019: TBD

Tuesday, November 5, 2019: TBD

This page intentionally left blank

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
Mia Avery	Pharm.D.	Oncology Pharmacy	Emory University Hospital Winship Cancer Institute
Douglas C. Collins	M.D.	Hematology/Oncology	Metro Hematology-Oncology, PC
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
Deborah W. Fincher	R.Ph., M.S.	HIV/AIDS Pharmacy	Pride Medical Pharmacy
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