



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

February 7, 2017



**GEORGIA DEPARTMENT
OF COMMUNITY HEALTH**

This page intentionally left blank



DRUG UTILIZATION REVIEW BOARD MEETING

AGENDA

2 Peachtree Street - 5th Floor DCH Board Room

Atlanta, Georgia 30303

Tuesday, February 7, 2017

9:30 a.m. to 1:30 p.m.

CALL TO ORDER	<i>Deborah Fincher, RPh, Chair</i>
COMMENTS FROM THE DEPARTMENT	<i>Peter D'Alba, RPh, Pharmacy Director, DCH</i>
MINUTES FROM PREVIOUS MEETING	<i>Chair</i>
EXTERNAL COMMENTS SESSION	<i>Chair</i>
CLINICAL REVIEWS	<i>Afzal Mistry, PharmD, NorthStar Chad Nicholson, PharmD, NorthStar Emily Baker, PharmD, BCPS, NorthStar</i>
➤ New Drugs	
● Exondys 51	
● Vonvendi	
● Xiidra	
● Zurampic	
ADJOURNMENT OF OPEN SESSION	<i>Chair</i>
EXECUTIVE SESSION	<i>Steve Liles, PharmD, Senior Director, Change Healthcare</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
Tuesday, December 13, 2016**

MEMBERS PRESENT

Gurinder J.S. Doad, M.D., Chair
Mia Avery, Pharm.D.
Douglas Collins, M.D.
Yolanda P. Graham, M.D.
Mary S. Harris, Ph.D.
Burton L. Lesnick, M.D., FAAP
Robyn Lorys, Pharm.D.
J. Russell May, Pharm.D.
Brent L. Rollins, R.Ph., Ph.D.
Danny A. Toth, R.Ph.

MEMBERS ABSENT

Deborah Fincher, M.S., R.Ph., Vice Chair
Rod M. Duraski, M.D., FACP, MBA
M. Celeste Fowler, Pharm.D.

Staff

Peter D'Alba, R.Ph., Pharmacy Director, Pharmacy Services
Turkesia Robertson-Jones, Pharm.D., Pharmacy Operations Manager, Pharmacy Services
Gilletta Gray, R.Ph., Clinical Manager, Pharmacy Services
Lori Garner, MHS, MBA, R.Ph., Pharmacist, Pharmacy Services
Rose Marie Duncan, MBA, Program Associate, Pharmacy Services

NorthStar HealthCare Consulting

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

OptumRx

Mark Hall, MBA, PMP, Assc. Director, Government Markets, Relations & Reform
Talmahjia "Tami" Sweat, Pharm.D., Director, Clinical Management

Goold Health Services

Steve Liles, Pharm.D., Sr. Director, Pharmacy Services
Doug Martin, Pharm.D., Pharmacy Project Manager

Amerigroup

Kelli W. Ferrell, R.Ph., MS

Call to Order

The Drug Utilization Review Board (DURB/DUR Board/Board) held its fourth meeting for the calendar year on December 13, 2016. Board member (and former Chair), Osgood (Drew) A. Miller, R.Ph., called the meeting to order at 9:45am.

Tuesday, December 13, 2016

Comments from the Department

Peter D'Alba, R.Ph., Pharmacy Director, Pharmacy Services, commented on the following items:

1. SFY 2016: Pharmacy Plan Snapshot - A presentation was given to provide an overview of Fee For Service (FFS) pharmacy expenditures/growth and 2017 pharmacy highlights (See Attachment A).
2. Thank you - Gurinder J.S. Doad, M.D., Chair and Deborah Fincher, M.S., R.Ph., Vice Chair, were thanked for their service to the Board.
3. 2017 Chair and Vice-Chair - Deborah Fincher, M.S., R.Ph., Chair, and Burton L. Lesnick, M.D., FAAP, Vice-Chair.
4. New Board Member – Glenda Wrenn Gordon, M.D., is a psychiatrist who will be joining the Board.

Hepatitis C Retreatment Strategy

Afzal “Fez” Mistry, Pharm.D., reviewed retreatment guidelines for Hepatitis C and costs associated with retreatment, discussed retreatment in Georgia Medicaid’s FFS Hepatitis C population, and presented retreatment strategies. The Board raised questions and provided comments on the following:

- Use patient form for initial treatment
- Most states don’t supply compliance data but claim increased compliance
- Would take out denial part of attestation form
- Patients should understand intermittent compliance can lead to resistance
- Take out part about expensive costs as the goal of the patient is to get better
- Noncompliance not based on cost if you are not the payer
- May need synonym for expensive
- Focus message on improvement of health
- Run through reading competency level
- Introduce attestation form for all patients
- Put motivators in form and not be punitive
- Offer supervised treatment for noncompliance

Centers for Medicare & Medicaid Services Methadone Guidance and Treatment Strategy

Afzal “Fez” Mistry, Pharm.D., reviewed the CMS best practices for methadone misuse and overdose and discussed potential strategies for Georgia Medicaid. Questions and comments were received on the following:

- Medicaid population has a lot of medical problems; methadone sometimes only choice for pain
- Require EKG prior to starting methadone
- Pain specialist should only prescribe methadone for pain
- From the data, don’t know how many are specialist vs. primary care
- Blurred lines – replacement therapy; look at indication of the medication
- Dr. Collins has not seen deaths due to methadone in his practice; many sickle cell patients are started on methadone; look at data for underlying causes, look at who is being treated; look at the dosing
- Long-term pain management – patients seen monthly, urine screen, utilize PDMP, get routine EKG
- Step-therapy guidelines – methadone not 1st line treatment
- For sickle cell patients, pediatric oncologists – methadone is used

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

Tuesday, December 13, 2016

- Get input from a clinician who is an expert in pain management, addiction, and pharmacy
- CDC website notes Georgia has prevalent deaths
- Address concurrent use of other drugs
- Drill down into data – demographics, concomitant therapy, dosing, etc.
- Utilize PDMP, can assign people (nurse) to log in
- PBM has capabilities to block concomitant therapy
- Look at experiences of other states who have implemented similar strategies in order to provide guidance
- CMS provides guidelines – states can make own decisions on what to do
- Look at codes for drug overdose associated with deaths and if any are attributed to medications

Minutes from the Previous Meeting

Chair Doad asked for corrections or changes to the minutes from the September 13, 2016 meeting. A motion was made (Burton L. Lesnick, M.D.), seconded (Osgood (Drew) A. Miller, R.Ph.), 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
Antivirals, Hepatitis C	<i>Epclusa</i>	Chad Nicholson, Pharm.D.
Parkinson's Disease Psychosis	<i>Nuplazid</i>	Chad Nicholson, Pharm.D.
Biologic Immunomodulators	<i>Taltz</i>	Chad Nicholson, Pharm.D.

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

- Nuplazid – three point reduction in score was clinically significant; why classified as an atypical antipsychotic since no dopaminergic activity; concern with its effect on mood; two previous trials failed but current trial had a different study design; use of Seroquel was probably off label for sleep; study design questionable

DCH Decisions

DCH Decisions from the September 2016 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:

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

Tuesday, December 13, 2016

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

Tuesday, February 7, 2017

Thursday, May 4, 2017

Thursday, August 3, 2017

Tuesday, November 7, 2017

- Manufacturers' Forum
NorthStar Healthcare Consulting
1121 Alderman Drive
Suite 112
Alpharetta, Georgia 30005

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, Amerigroup, Goold Health Services, NorthStar HealthCare Consulting, and OptumRx. Pharmacy student, David Book, attended the closed session with Board members. A motion was made by Robyn Lorys, Pharm.D., and seconded by 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, Gurinder J.S. Doad, M.D., adjourned the open session at approximately 11:49am, at which time members took a break then reconvened for the executive (closed) session.

Executive Session

The Executive Session was held from 12:00pm to 12:23pm.

Reconvening of Open Session

The DUR Board reconvened for the open session at 12:24pm.

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). All motions and votes are noted in Attachment B.

New Drugs Classes

Antivirals, Hepatitis C

The DUR Board recommended *Preferred* status with *Prior Authorization* for *Epclusa (Oral) Tablet* and *Non-Preferred* status with *Prior Authorization* for *Pegasys (Subcutaneous) Syringe/Autoinjector/Solution*.

Parkinson's Disease Psychosis Agents

The DUR Board recommended *Non-Preferred* status with *Prior Authorization* for *Nuplazid (Oral) Tablet*.

Biologic Immunomodulators, Antipsoriatics

The DUR Board recommended *Non-Preferred* status with *Prior Authorization* for *Taltz (Subcutaneous) Syringe/Autoinjector*.

Future Agenda Items

There were no future agenda items noted.

Dr. Doad expressed his gratitude for support during his term as Chair.

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 Doad adjourned the meeting at 12:28pm.

THESE MINUTES ARE HEREBY APPROVED AND ADOPTED, THIS THE _____
DAY OF _____, 2017.

Gurinder J.S. Doad, M.D., Chair

Drug Utilization Review Board

Motions - Votes - **New Drugs**

DECEMBER 13, 2016

New Drug	Drug	PDL Status	Motion - Recommendations	Additional Comments	
ANTIVIRALS, HEPATITIS C	Epclusa (Oral) Tablet	P/PA	P/PA		
	Pegasys (Subcutaneous) Syringe/Autoinjector/Solution	P	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 Doad, Gurinder J.S., M.D. - Chair					
4 Graham, Yolanda, M.D.			✓		
5 Harris, Mary, Ph.D.			✓		
6 Lesnick, Burton, M.D.		✓	✓		
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			10	0	0
Board Members - Absent					
1 Duraski, Rod, M.D.					
2 Fincher, Deborah W., M.S., R.Ph. - Vice					
3 Fowler, M. Celeste, Pharm.D.					

Drug Utilization Review Board

Motions - Votes - **New Drugs**

DECEMBER 13, 2016

New Drug		Drug	PDL Status	Motion - Recommendations	Additional Comments	
PARKINSON'S DISEASE PSYCHOSIS		Nuplazid (Oral) Tablet	UNDER REVIEW	NP/PA		
Board Members - Present <small>(Strike out, when absent)</small>		Motion Maker (v)	Seconded By (v)	VOTES		
				YES (v)	NO (v)	ABSTAIN (v)
1	Avery, Mia, Pharm.D.			√		
2	Collins, Douglas, M.D.			√		
3	Doad, Gurinder J.S., M.D. - Chair					
4	Graham, Yolanda, M.D.	√		√		
5	Harris, Mary, Ph.D.			√		
6	Lesnick, Burton, M.D.			√		
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	10	0	0
Board Members - Absent						
1	Duraski, Rod, M.D.					
2	Fincher, Deborah W., M.S., R.Ph. - Vice					
3	Fowler, M. Celeste, Pharm.D.					

Drug Utilization Review Board

Motions - Votes - **New Drugs**

DECEMBER 13, 2016

New Drug	Drug	PDL Status	Motion - Recommendations	Additional Comments	
BIOLOGIC IMMUNOMODULATORS	Taltz (Subcutaneous) Syringe/Autoinjector	UNDER REVIEW	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 Avery, Mia, Pharm.D.			✓		
2 Collins, Douglas, M.D.			✓		
3 Doad, Gurinder J.S., M.D. - Chair					
4 Graham, Yolanda, M.D.			✓		
5 Harris, Mary, Ph.D.			✓		
6 Lesnick, Burton, M.D.			✓		
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			10	0	0
Board Members - Absent					
1 Duraski, Rod, M.D.					
2 Fincher, Deborah W., M.S., R.Ph. - Vice					
3 Fowler, M. Celeste, Pharm.D.					

Drug Utilization Review Board Meeting

December 13, 2016

Therapeutic Class	Drug Name	Current PDL Status	DCH Decisions
Drug Reviews			
Antivirals, Hepatitis C			
	Epclusa (Oral) Tablet	P/PA	P/PA
	Pegasys (Subcutaneous) Syringe/Autoinjector/ Solution	P	P
Parkinson's Disease Psychosis Agents			
	Nuplazid (Oral) Tablet	Non-PDL	NP/PA
Biologic Immunomodulators, Antipsoriatics			
	Taltz (Subcutaneous) Syringe/Autoinjector	Non-PDL	NP/PA

PDL=Preferred Drug List; P=preferred; NP=non-preferred; PA=prior authorization



Manufacturers' Forum
ANNOUNCEMENT
NorthStar HealthCare Consulting
Georgia Department of Community Health

On behalf of the Georgia Department of Community Health (DCH) and in service to the Georgia Medicaid Fee-for-Service (FFS) Drug Utilization Review Board (DURB), NorthStar HealthCare Consulting (NHC), in conjunction with OptumRx, announces the Manufacturers' Forum occurring Thursday, March 30, 2017, with an overflow day on Friday, March 31, 2017 **only** if needed.

Date: Thursday, March 30, 2017 from 9am-5pm EST
Friday, March 31, 2017 from 9am-5pm EST (overflow day only if needed)

Location: NorthStar HealthCare Consulting
1121 Alderman Drive, Suite 112
Alpharetta, GA 30005

Appointments: *The Manufacturers' Forum is by appointment only.* Appointments may be requested and will be scheduled **after** the Drugs Under Review are posted to the DCH website at <http://dch.georgia.gov/2017-durb-meeting-information> approximately 30 days prior to the Forum. Manufacturers with drugs up for review at the current DURB meeting will be granted preference when seeking appointments. All requests for appointments must be made in writing to GAMedicaid@nhc-llc.com and include the drug name. New drug entities are generally not reviewed by the DURB until the drug has been on the market for at least 6 months.

Guidelines for Participation:

- To ensure equitable treatment of all manufacturers, individual manufacturer participation shall be limited to one 30-60 minute time segment per Forum. The presentation shall be limited to approximately 20-40 minutes with 10-20 minutes for questions and answers.
- Manufacturer presentations may be audio-recorded for review after the Forum.
- For new drugs, manufacturers are highly encouraged to present all clinical information pertinent and relevant to current NHC clinical presentations to the DURB, to DCH drug benefit plan design and to other drugs within the class.
- For existing drugs, manufacturers are highly encouraged to present *new* clinical information since the drug was last reviewed by the DURB, especially clinical information related to comparisons of other drugs within the class.
- An electronic **one-page** summary (front only, font 10, not including references) of each drug presentation, **factually based**, in a stand-alone, user-friendly document should be provided one week prior to the presentation via email to GAMedicaid@nhc-llc.com. Please include a pronunciation guide of the drug's brand and generic names. The one-page summary will be provided to the DURB members.

Comments and Inquiries:

- Manufacturers with comments or inquiries related to Georgia Medicaid FFS **Preferred Drug List, Prior Authorization Criteria, Manufacturers' Forum or DURB** should submit these in writing to GAMedicaid@nhc-llc.com.
- Manufacturers with comments or inquiries related to Georgia Medicaid FFS **supplemental rebates** should submit these in writing to pba_gaoffers@changehealthcare.com.
- Manufacturers with comments or inquiries related to Georgia Medicaid FFS **claims processing or drug benefit plan design** should submit these in writing to Tami.Sweat@optum.com.

**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**

2017

Upcoming Meetings

Drug Utilization Review Board Meeting

2 Peachtree Street, N.W.

5th Floor Board Room

Atlanta, Georgia 30303

Thursday, May 4, 2017: 9:30am – 4:30pm

Thursday, August 3, 2017: 9:30am – 1:30pm

Tuesday, November 7, 2017: 9:30am – 1:30pm

Manufacturers' Forum

NorthStar HealthCare Consulting

1121 Alderman Drive

Suite 112

Alpharetta, Georgia 30005

Thursday, March 30, 2017: 9:00am – 5:00pm

Thursday, June 29, 2017: 9:00am – 5:00pm

Tuesday, October 3, 2017: 9:00am – 5:00pm

Drug Utilization Review Board

Board Member	Credentials	Specialty/Area of Expertise	Company Name
Deborah W. Fincher, Chair	R.Ph., M.S.	HIV/AIDS Pharmacy	Pride Medical Pharmacy
Burton L. Lesnick, Vice-Chair	M.D., FAAP	Pediatrics/Pediatric Pulmonology	Children's Healthcare of Atlanta
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
M. Celeste Fowler	Pharm.D., HCMBA	Hospital Pharmacy	Piedmont Henry Hospital
Glenda Gordon	M.D.	Psychiatry, Academia - Professor	Morehouse School of Medicine
Yolanda P. Graham	M.D.	Child and Adolescent Psychiatry	Devereux Georgia Treatment Network
Mary S. Harris	Ph.D.	Health Care Information/Education Research	BioTechnical Communications, Inc
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
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