



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 6, 2018

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DRUG UTILIZATION REVIEW BOARD MEETING

AGENDA

2 Peachtree Street - 5th Floor DCH Board Room

Atlanta, Georgia 30303

Tuesday, February 6, 2018

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

CALL TO ORDER	<i>Burton L. Lesnick, M.D., FAAP, 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	
● Kevzara	
● Siliq	
● Tremfya	
● Vosevi	
● Xadago	
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>

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**Department of Community Health
Drug Utilization Review Board (DURB)
MINUTES
Tuesday, November 7, 2017**

MEMBERS PRESENT

Deborah Fincher, M.S., R.Ph., Chair
Burton L. Lesnick, M.D., FAAP, Vice-Chair
Mia Avery, Pharm.D.
Doug Collins, M.D.
Rod M. Duraski, M.D., FACP, MBA
M. Celeste Fowler, Pharm.D.
Yolanda P. Graham, M.D.
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

Gurinder J.S. Doad, M.D.
Glenda Wrenn Gordon, M.D.

Staff

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

NorthStar HealthCare Consulting

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

OptumRx

Talmahjia "Tami" Sweat, Pharm.D., Director, Clinical Management

Change Healthcare

Doug Martin, Pharm.D., Pharmacy Project Manager

Care Management Organizations

Turkesia Robertson-Jones, Pharm.D., CareSource
Cassandra Tancil, Pharm. D., Amerigroup

Call to Order

The Drug Utilization Review Board (DURB/DUR Board/Board) held its fourth meeting for the calendar year on November 7, 2017. The Chair, Deborah Fincher, M.S., R.Ph., called the meeting to order at 10:10am.

Comments from the Department

There were no comments from the Department.

Minutes from the Previous Meeting

Chair Fincher asked for corrections or changes to the minutes from the August 3, 2017 meeting. A motion was made (Burton L. Lesnick, M.D., FAAP, Vice-Chair), seconded (Rod M. Duraski, M.D., FACP, MBA), 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
Dermatologics, Atopic Dermatitis	<i>Dupixent</i>	Afzal "Fez" Mistry, Pharm.D.
Tardive Dyskinesia Agents	<i>Ingrezza</i>	Afzal "Fez" Mistry, Pharm.D.
Bronchodilators, Anticholinergics	<i>Utibron</i>	Afzal "Fez" Mistry, Pharm.D.
Antivirals, Hepatitis C Direct-Acting Agents	<i>Mavyret</i>	Chad Nicholson, Pharm.D.
Gastrointestinal Agents, Chronic Idiopathic Constipation (CIC)	<i>Trulance</i>	Chad Nicholson, Pharm.D.
Postmenopausal Osteoporosis, Parathyroid Hormone	<i>Tymlos</i>	Chad Nicholson, Pharm.D.

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

- Dupixent –concerns for immunocompromised patients-may want to consider phototherapy; length of therapy-indefinitely due to disease state; may be considered specialty-first dose in office, subsequent doses at home.
- Ingrezza – patient population treatment age-50-60 years; contraindications with other antipsychotics-possibly ziprasidone; clonidine, Seroquel-lower incidence of TD's;

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treatment may not be needed unless interfering with daily function; off label use; no restrictions for use in Parkinson's.

- Trulance – elderly safety concerns-not recommended in patients over 65; OIC-no ongoing trials.

Zinplava Follow-up

Follow up question from last DURB meeting regarding number needed to treat for reducing recurrence of C. Dificile – number needed to treat for overall population was 10 patients to prevent 1 recurrence of C. Dificile; patients with previous experience with recurrence or patients over 65 goes down to 6 needed to treat to prevent 1 recurrence. PA criteria was reviewed.

Acknowledgements

DCH Pharmacy Intern, Nathaniel Williams, Pharm.D. Candidate (Mercer), was thanked for his contributions to the Department during his rotation.

DCH Decisions

DCH Decisions from the August 2017 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

TBD

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

TBD

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, Change Healthcare, NorthStar HealthCare Consulting, and OptumRx. Pharmacy students, Kineta Naida (PCOM), Annie Lee (Mercer), and Nathaniel Williams (Mercer), and

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CMO representatives, Turkesia Robertson-Jones, Pharm.D. (CareSource) and Cassandra Tancil, Pharm.D. (Amerigroup), attended the closed session with Board members. A motion was made by Robyn Lorys, Pharm.D., and seconded by Danny A. Toth, R.Ph., to adjourn the open session and approve the closed session. There was a unanimous vote approving the closed session. The Chairman, Deborah Fincher, M.S., R.Ph., adjourned the open session at approximately 11:23am, at which time members took a break then reconvened for the executive (closed) session.

Executive Session

The Executive Session was held from 11:32pm to 11:57am.

Reconvening of Open Session

The DUR Board reconvened for the open session at 12:03pm.

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 A.

New Drugs Classes

Dermatologics, Atopic Dermatitis

The DUR Board recommended *Non-Preferred* status with *Prior Authorization* for *Dupixent (Subcutaneous) Injection*.

Movement Disorder Drug Therapy

The DUR Board recommended *Non-Preferred* status with *Prior Authorization* for *Ingrezza (Oral) Capsule* and to revisit once guidelines are updated.

Antivirals, Hepatitis C Direct-Acting Agents

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

Gastrointestinal Agents, Chronic Idiopathic Constipation (CIC)

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

Postmenopausal Osteoporosis, Parathyroid Hormone

The DUR Board recommended *Non-Preferred* status with *Prior Authorization* for *Tymlos (Subcutaneous) Injection*.

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Bronchodilators. Anticholinergics

The DUR Board recommended *Non-Preferred* status with *Prior Authorization* for *Utibron (Inhalation) Powder*. The DUR Board also recommended *Non-Preferred* status with *Prior Authorization* for *Combivent (Inhalation) Solution*.

Future Agenda Items

There were no future agenda items noted.

Acknowledgements

Chair Deborah Fincher, M.S., R.Ph., was thanked for her service 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 Fincher adjourned the meeting at 12:08pm.

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

Deborah Fincher, M.S., R.Ph., Chair

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Drug Utilization Review Board

Motions - Votes - **New Drugs**

NOVEMBER 7, 2017

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

Drug Utilization Review Board

Motions - Votes - **New Drugs**

NOVEMBER 7, 2017

New Drug		Drug	PDL Status	Motion - Recommendations	Additional Comments	
Movement Disorder Drug Therapy		Ingrezza (Oral) Capsule	N/A	NPPA		
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	Duraski, Rod, M.D.			√		
4	Fincher, Deborah W., M.S., R.Ph. - Chair					
5	Fowler, M. Celeste, Pharm.D.			√		
6	Graham, Yolanda, M.D.	√		√		
7	Lesnick, Burton, M.D. - Vice			√		
8	Lorys, Robyn Pharm.D.			√		
9	May, J. Russell (Rusty)			√		
10	Miller, Osgood (Drew) A. R.Ph.			√		
11	Rollins, Brent L., R.Ph., Ph.D.		√	√		
12	Toth, Danny, R.Ph.			√		
			TOTAL	11	0	0
Board Members - Absent						
1	Doad, Gurinder J.S., M.D. -					
2	Gordon, Glenda Wrenn					

Drug Utilization Review Board

Motions - Votes - **New Drugs**

NOVEMBER 7, 2017

New Drug	Drug	PDL Status	Motion - Recommendations	Additional Comments	
Antivirals, Hepatitis C Direct-Acting Agents	Mavyret (Oral) Tablet	PPA	PPA		
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 Duraski, Rod, M.D.			√		
4 Fincher, Deborah W., M.S., R.Ph. - Chair					
5 Fowler, M. Celeste, Pharm.D.			√		
6 Graham, Yolanda, M.D.			√		
7 Lesnick, Burton, M.D. - Vice			√		
8 Lorys, Robyn Pharm.D.			√		
9 May, J. Russell (Rusty)			√		
10 Miller, Osgood (Drew) A. R.Ph.		√	√		
11 Rollins, Brent L., R.Ph., Ph.D.	√		√		
12 Toth, Danny, R.Ph.			√		
TOTAL			11	0	0
Board Members - Absent					
1 Doad, Gurinder J.S., M.D. -					
2 Gordon, Glenda Wrenn					

Drug Utilization Review Board

Motions - Votes - **New Drugs**

NOVEMBER 7, 2017

New Drug	Drug	PDL Status	Motion - Recommendations	Additional Comments	
Gastrointestinal Agents, Chronic Idiopathic Constipation (CIC)	Trulance (Oral) Tablet	N/A	NPPA		
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 Duraski, Rod, M.D.			√		
4 Fincher, Deborah W., M.S., R.Ph. - Chair					
5 Fowler, M. Celeste, Pharm.D.		√	√		
6 Graham, Yolanda, M.D.			√		
7 Lesnick, Burton, M.D. - Vice			√		
8 Lorys, Robyn Pharm.D.			√		
9 May, J. Russell (Rusty)	√		√		
10 Miller, Osgood (Drew) A. R.Ph.			√		
11 Rollins, Brent L., R.Ph., Ph.D.			√		
12 Toth, Danny, R.Ph.			√		
TOTAL			11	0	0
Board Members - Absent					
1 Doad, Gurinder J.S., M.D. -					
2 Gordon, Glenda Wrenn					

Drug Utilization Review Board

Motions - Votes - **New Drugs**

NOVEMBER 7, 2017

New Drug	Drug	PDL Status	Motion - Recommendations	Additional Comments	
Postmenopausal Osteoporosis - Parathyroid Hormone	Tymlos (Sub-Q) Pen Injection	N/A	NPPA		
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 Duraski, Rod, M.D.			√		
4 Fincher, Deborah W., M.S., R.Ph. - Chair					
5 Fowler, M. Celeste, Pharm.D.			√		
6 Graham, Yolanda, M.D.	√		√		
7 Lesnick, Burton, M.D. - Vice			√		
8 Lorys, Robyn Pharm.D.			√		
9 May, J. Russell (Rusty)			√		
10 Miller, Osgood (Drew) A. R.Ph.			√		
11 Rollins, Brent L., R.Ph., Ph.D.			√		
12 Toth, Danny, R.Ph.			√		
TOTAL			11	0	0
Board Members - Absent					
1 Doad, Gurinder J.S., M.D. -					
2 Gordon, Glenda Wrenn					

Drug Utilization Review Board

Motions - Votes - **New Drugs**

NOVEMBER 7, 2017

New Drug	Drug	PDL Status	Motion - Recommendations	Additional Comments	
Bronchodilators, Anticholinergics	Utibron Neohaler (Inhalation) Powder	N/A	NPPA		
	Combivent Respimat (Inhalation) Solution	P	NPPA		
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 Duraski, Rod, M.D.			√		
4 Fincher, Deborah W., M.S., R.Ph. - Chair					
5 Fowler, M. Celeste, Pharm.D.			√		
6 Graham, Yolanda, M.D.			√		
7 Lesnick, Burton, M.D. - Vice	√		√		
8 Lorys, Robyn Pharm.D.			√		
9 May, J. Russell (Rusty)			√		
10 Miller, Osgood (Drew) A. R.Ph.		√	√		
11 Rollins, Brent L., R.Ph., Ph.D.			√		
12 Toth, Danny, R.Ph.			√		
TOTAL			11	0	0
Board Members - Absent					
1 Doad, Gurinder J.S., M.D.-					
2 Gordon, Glenda Wrenn					

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Drug Utilization Review Board Meeting

November 7, 2017

Therapeutic Class	Drug Name	Current PDL Status	DCH Decisions
Drug Reviews			
Dermatologics, Atopic Dermatitis			
	Dupixent (Subcutaneous) Injection	Non-PDL	NP/PA
Movement Disorder Drug Therapy			
	Ingrezza (Oral) Capsule	Non-PDL	NP/PA
Antivirals, Hepatitis C Direct-Acting Agents			
	Mavyret (Oral) Tablet	P/PA	P/PA
Gastrointestinal Agents, Chronic Idiopathic Constipation (CIC)			
	Trulance (Oral) Tablet	Non-PDL	NP/PA
Postmenopausal Osteoporosis, Parathyroid Hormone			
	Tymlos (Subcutaneous) Injection	Non-PDL	NP/PA
Bronchodilators, Anticholinergics			
	Utibron (Inhalation) Powder	Non-PDL	NP/PA
	Combivent (Inhalation) Solution	P	NP/PA

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

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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 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**

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2018

Upcoming Meetings

Drug Utilization Review Board Meeting

2 Peachtree Street, N.W.

5th Floor Board Room

Atlanta, Georgia 30303

Tuesday, May 1, 2018: 9:30am – 1:30pm

Tuesday, August 7, 2018: 9:30am – 1:30pm

Tuesday, November 6, 2018: 9:30am – 1:30pm

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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
Yolanda P. Graham	M.D.	Child and Adolescent Psychiatry	Devereux Georgia Treatment Network
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