



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 7, 2017

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DRUG UTILIZATION REVIEW BOARD MEETING

AGENDA

2 Peachtree Street - 5th Floor DCH Board Room

Atlanta, Georgia 30303

Tuesday, November 7, 2017

10:00 a.m. to 2:00 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	
● Dupixent	
● Ingrezza	
● Mavyret	
● Trulance	
● Tymlos	
● Utibron	
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
Thursday, August 3, 2017**

MEMBERS PRESENT

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

MEMBERS ABSENT

Doug Collins, M.D.
Yolanda P. Graham, M.D.
Glenda Wrenn Gordon, M.D.
Mary S. Harris, Ph.D.
Danny A. Toth, R.Ph.

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

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

Call to Order

The Drug Utilization Review Board (DURB/DUR Board/Board) held its third meeting for the calendar year on August 3, 2017. The Chair, Deborah Fincher, M.S., R.Ph., called the meeting to order at 10:00am.

Comments from the Department

There were no comments from the Department.

Thursday, August 3, 2017

Minutes from the Previous Meeting

Chair Fincher asked for corrections or changes to the minutes from the May 4, 2017 meeting. A motion was made (Osgood (Drew) A. Miller, R.Ph.), seconded (Rod M. Duraski, M.D., FACP, MBA), and carried to approve the minutes as written.

External Comments Session

- There were no external comments.

Acknowledgements

The following students were recognized: Regina Gim (UGA), Shelby Callaway (UGA), Angie Amado (PCOM), and Tibin Titus (Mercer).

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
Antidiabetics, Non-Insulin	<i>Adlyxin Soliqua</i>	Afzal “Fez” Mistry, Pharm.D.
Bronchodilators, Anticholinergics	<i>Bevespi</i>	Afzal “Fez” Mistry, Pharm.D.
Duchenne Muscular Dystrophy Steroids	<i>Emflaza</i>	Afzal “Fez” Mistry, Pharm.D.
Dermatologics, Atopic Dermatitis	<i>Eucria</i>	Afzal “Fez” Mistry, Pharm.D.
Multiple Sclerosis Agents	<i>Ocrevus</i>	Chad Nicholson, Pharm.D.
Vitamin D Analogs	<i>Royaldee</i>	Chad Nicholson, Pharm.D.
Antibacterial Monoclonal Antibody	<i>Zinplava</i>	Chad Nicholson, Pharm.D.

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

- Adlyxin/Soliqua – weight loss is class effect; recommend using in patients with weight issue; no one better than the other
- Bevespi – evidence comparing ease of administration - mechanics are the same as other MDIs, has advantage over Spiriva handihaler (dry capsule) which is tricky; spacer use important; Pinnacle study showed some improvement in FEV.
- Emflaza – patients can go through Care Place; there is also a bridge program to ensure patients continue on medication until insurance takes over; high price; evidence is not strong; no different than Prednisone; benefits – a few cases seen from CHOA and hard to assess if any value; weight gain – children are growing; can level off; Level C evidence-

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Thursday, August 3, 2017

subject to bias; PA Criteria – tie weight gain to BMI; look at history of prednisone use; be tighter with poor tolerance of prednisone; Canada – Emflaza commonly used.

- Eucrisa – novel mechanism of action, no malignancies shown in clinical trials; if safer, give consideration in stepping through other products; consideration for allergic component.
- Ocrevus – on Provider Administered Drug List; primary progressive MS vs relapsing-remitting MS – approximately 30% vs. 70%
- Rayaldee – prodrug converted to calcitriol; no huge advantage
- Zinplava – on Provider Administered Drug List; criteria would be beneficial for patients with relapsing patients; binds toxin, not indicated for treatment; PA criteria – put time frame in criteria, current draft criteria states within previous 6 months; table to next meeting for PA criteria review.

DCH Decisions

DCH Decisions from the May 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

Tuesday, November 7, 2017

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

Tuesday, October 3, 2017

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, Regina Gim (UGA), Shelby Callaway (UGA), Angie Amado (PCOM), and Tibin Titus (Mercer), attended the closed session with Board members. A motion was made by Robyn

Thursday, August 3, 2017

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, Deborah Fincher, M.S., R.Ph., adjourned the open session at approximately 12:21pm, at which time members took a break then reconvened for the executive (closed) session.

Executive Session

The Executive Session was held from 12:28pm to 1:10pm.

Reconvening of Open Session

The DUR Board reconvened for the open session at 1:13pm.

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

Antidiabetics, Non-Insulin, GLP-1 Receptor Agonists

The DUR Board recommended *Non-Preferred* status with *Prior Authorization* for *Adlyxin (Subcutaneous) Pen* and *Soliqua (Subcutaneous) Pen* with no additional changes in the class and the intention to discuss this class for changes at a future meeting.

Bronchodilators, Anticholinergics

The DUR Board recommended *Preferred* status for *Bevespi Aerosphere (Inhalation) Aerosol* with no additional changes in this class.

Duchenne Muscular Dystrophy Steroids

The DUR Board recommended *Non-Preferred* status with *Prior Authorization* for *Emflaza (Oral) Tablet*. The DUR Board further recommended reviewing each *Emflaza* request on a case-by-case basis.

Dermatologic, Atopic Dermatitis

The DUR Board recommended *Preferred* status with *Prior Authorization* for *Eucrisa (Topical) Ointment* contingent upon the Department of Community Health reviewing the recent supplemental rebate offer.

Vitamin D Analogs

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

Provider Administered Drugs

Ocrevus will be added to the Provider Administered Drug List with the PA as described in the open session. Zinplava will be deferred to the next DUR Board meeting with further consideration for prior authorization.

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 Fincher adjourned the meeting at 1:17pm.

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

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

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Drug Utilization Review Board

Motions - Votes - **New Drugs**

August 3, 2017

New Drug	Drug	PDL Status	Motion - Recommendations	Additional Comments	
Antidiabetics, Non-Insulin, GLP-1 Receptor Agonists	Adlyxin (Subcutaneous) Pen	N/A	NPPA	Discuss changes within this class at future meetings	
	Soliqua (Subcutaneous) Pen	N/A	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 Doad, Gurinder J.S., M.D.-	√		√		
3 Duraski, Rod, M.D.			√		
4 Fincher, Deborah W., M.S., R.Ph. - Chair					
5 Fowler, M. Celeste, Pharm.D.			√		
6 Lesnick, Burton, M.D. - Vice			√		
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.			√		
TOTAL			9	0	0
Board Members - Absent					
1 Collins, Douglas, M.D.					
2 Gordon, Glenda Wrenn					
3 Graham, Yolanda, M.D.					
4 Harris, Mary, Ph.D.					
5 Toth, Danny, R.Ph.					

Drug Utilization Review Board

Motions - Votes - **New Drugs**

August 3, 2017

New Drug	Drug	PDL Status	Motion - Recommendations	Additional Comments	
Bronchodilators, Anticholinergics	Bevespi Aerosphere (Inhalation) Aerosol	N/A	P		
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 Doad, Gurinder J.S., M.D.-			√		
3 Duraski, Rod, M.D.			√		
4 Fincher, Deborah W., M.S., R.Ph. - Chair					
5 Fowler, M. Celeste, Pharm.D.			√		
6 Lesnick, Burton, M.D. - Vice	√		√		
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.		√	√		
TOTAL			9	0	0
Board Members - Absent					
1 Collins, Douglas, M.D.					
2 Gordon, Glenda Wrenn					
3 Graham, Yolanda, M.D.					
4 Harris, Mary, Ph.D.					
5 Toth, Danny, R.Ph.					

Drug Utilization Review Board

Motions - Votes - **New Drugs**

August 3, 2017

New Drug	Drug	PDL Status	Motion - Recommendations	Additional Comments	
Duchenne Muscular Dystrophy Steroids	Emflaza (Oral) Tablet	N/A	NPPA	DCH to review requests for Emflaza on a case-by-case basis	
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 Doad, Gurinder J.S., M.D.-			✓		
3 Duraski, Rod, M.D.			✓		
4 Fincher, Deborah W., M.S., R.Ph. - Chair					
5 Fowler, M. Celeste, Pharm.D.			✓		
6 Lesnick, Burton, M.D. - Vice			✓		
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.			✓		
TOTAL			9	0	0
Board Members - Absent					
1 Collins, Douglas, M.D.					
2 Gordon, Glenda Wrenn					
3 Graham, Yolanda, M.D.					
4 Harris, Mary, Ph.D.					
5 Toth, Danny, R.Ph.					

Drug Utilization Review Board

Motions - Votes - **New Drugs**

August 3, 2017

New Drug	Drug	PDL Status	Motion - Recommendations	Additional Comments	
Dermatologic, Atopic Dermatitis	Eucrisa (Topical) Ointment	N/A	PPA	Recommendation is contingent upon supplemental rebate offer	
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 Doad, Gurinder J.S., M.D.-			✓		
3 Duraski, Rod, M.D.			✓		
4 Fincher, Deborah W., M.S., R.Ph. - Chair					
5 Fowler, M. Celeste, Pharm.D.			✓		
6 Lesnick, Burton, M.D. - Vice			✓		
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.		✓	✓		
TOTAL			9	0	0
Board Members - Absent					
1 Collins, Douglas, M.D.					
2 Gordon, Glenda Wrenn					
3 Graham, Yolanda, M.D.					
4 Harris, Mary, Ph.D.					
5 Toth, Danny, R.Ph.					

Drug Utilization Review Board

Motions - Votes - **New Drugs**

August 3, 2017

New Drug	Drug	PDL Status	Motion - Recommendations	Additional Comments	
Vitamin D Analogs	Royaldee (Oral) Capsule	N/A	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 Doad, Gurinder J.S., M.D.-			√		
3 Duraski, Rod, M.D.			√		
4 Fincher, Deborah W., M.S., R.Ph. - Chair					
5 Fowler, M. Celeste, Pharm.D.			√		
6 Lesnick, Burton, M.D. - Vice			√		
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.			√		
TOTAL			9	0	0
Board Members - Absent					
1 Collins, Douglas, M.D.					
2 Gordon, Glenda Wrenn					
3 Graham, Yolanda, M.D.					
4 Harris, Mary, Ph.D.					
5 Toth, Danny, R.Ph.					

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Drug Utilization Review Board Meeting

August 3, 2017

Therapeutic Class	Drug Name	Current PDL Status	DCH Decisions
Drug Reviews			
Antidiabetics, Non-Insulin, GLP-1 Receptor Agonists			
	Adlyxin (Subcutaneous) Pen	Non-PDL	NP/PA
	Soliqua (Subcutaneous) Pen	Non-PDL	NP/PA
Bronchodilators, Anticholinergics			
	Bevespi Aerosphere (Inhalation) Aerosol	Non-PDL	P
Duchenne Muscular Dystrophy Steroids			
	Emflaza (Oral) Tablet	Non-PDL	NP/PA
Dermatologic, Atopic Dermatitis			
	Eucrisa (Topical) Ointment	Non-PDL	P
Vitamin D Analogs			
	Rayaldee (Oral) Capsule	Non-PDL	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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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	340B Pharmacy	Piedmont 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