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

May 4, 2017

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GEORGIA DEPARTMENT OF COMMUNITY HEALTH

DRUG UTILIZATION REVIEW BOARD MEETING
AGENDA

2 Peachtree Street - 5th Floor DCH Board Room
Atlanta, Georgia 30303
Thursday, May 4, 2017
11:00 a.m. to 2:00 p.m.

CALL TO ORDER	*Deborah Fincher, RPh, 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**
  - Spinraza
- **Supplemental Rebate Classes**

ADJOURNMENT OF OPEN SESSION	*Chair*
EXECUTIVE SESSION	*Steve Liles, PharmD, Senior Director, Change Healthcare*
RECONVENING OF OPEN SESSION	*Chair*
BOARD'S RECOMMENDATIONS AND VOTES	*Chair*
FUTURE AGENDA ITEMS	*Chair*
ADJOURNMENT OF MEETING	*Chair*

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Department of Community Health
Drug Utilization Review Board (DURB)
MINUTES
Tuesday, February 7, 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. Celeste Fowler, Pharm.D.
Glenda Wrenn Gordon, M.D.
Yolanda P. Graham, M.D.
Mary S. Harris, Ph.D.
Robyn Lorys, Pharm.D.
Osgood (Drew) A. Miller, R.Ph.
Brent L. Rollins, R.Ph., Ph.D.
Danny A. Toth, R.Ph.

MEMBERS ABSENT

Douglas Collins, M.D.
J. Russell May, 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
Cindy Nee, Pharm.D. Candidate (Mercer)
Karla Forbes, Pharm.D., Program Integrity

NorthStar HealthCare Consulting

Emily Baker, Pharm.D., BCPS, MHA, MBA, President
Afzal "Fez" Mistry, Pharm.D., Clinical Pharmacist
Chad Nicholson, Pharm.D., Clinical Pharmacist
Nekia Austin, Pharm.D., Esq., CFE, Program Compliance Director

OptumRx

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

Change Healthcare

Doug Martin, Pharm.D., Pharmacy Project Manager

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

Call to Order

The Drug Utilization Review Board (DURB/DUR Board/Board) held its first meeting for the calendar year on February 7, 2017. The Chair, Deborah Fincher, M.S., R.Ph., called the meeting to order at 9:33am.

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 December 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

External comments were presented to the Board from the following:

- Kathryn Pease – son has Muscular Dystrophy; spoke about coverage for Exondys 51 and their experience with it.
- Gretchen Agans – son has Muscular Dystrophy; spoke about experience with trial drug and coverage for Exondys 51 and future similar drugs.

Disclosure forms were completed by Kathryn Pease and Gretchen Agans 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
Duchenne Muscular Dystrophy	*Exondys 51*	Chad Nicholson, Pharm.D.
von Willebrand Factor Products	*Vonvendi*	Chad Nicholson, Pharm.D.
Ophthalmic Immunomodulators	*Xiidra*	Afzal Mistry, Pharm.D.
Gout Agents	*Zurampic*	Afzal Mistry, Pharm.D.

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

- Exondys 51
    - Guidelines to initiate therapy – when patients plateau or decline in muscular function; indefinite therapy
    - Costs – pricing structure is $700,000-$750,000/year
    - Increase in dystrophin but clinical outcomes were worse; two outliers but was an increase in 6 min. walk time; not a large enough patient sample size to say those functional endpoints are favorable but this is ongoing in Phase 3 trial

  - Study 2 (follow-up of Study 1)– twins that lost ambulatory function were included in the Study 2 group
  - Less drastic decline in motor function from data presented
  - Phase 3 trials will have more patients
  - Population in Georgia that could be treated – approximately 60 patients (35-40 potential FFS patients)
  - Other functional variables being looked at in the Phase 3 group: percentage of dystrophin positive fibers; ability to rise independently from floor; North Star Ambulatory Assessment; loss of ambulation and cardiac and pulmonary function
- Xiidra
  - Quite a few patients followed for a year for adverse events
  - In comparing Restasis/Xiidra – end result is the same, both decrease inflammation in Dry Eye Disease
  - No current feedback from physicians using it
- Zurampic
  - 3% or less experienced cardiovascular events
  - Used in combination with a Xanthine Oxidase Inhibitor (typically after XOI w/Probenecid)
  - no specific points in subpopulation

DCH Decisions

DCH Decisions from the December 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:

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

  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

  Thursday, March 30, 2017
  Thursday, June 29, 2017
  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 student, Cindy Nee, attended the closed session with Board members. A motion was made by Robyn Lorys, Pharm.D., and seconded by Danny 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 10:49am, at which time members took a break then reconvened for the executive (closed) session.

Executive Session

The Executive Session was held from 11:07am to 12:03pm.

Reconvening of Open Session

The DUR Board reconvened for the open session at 12:07pm.

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

Duchenne Muscular Dystrophy

The DUR Board provided ***No Recommendation at this time*** for ***Exondys 51 (Intravenous) Injection***.

von Willebrand Factor Products

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

Ophthalmic Immunomodulators

The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Xiidra (Ophthalmic) Solution***.

Gout Agents

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

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Future Agenda Items

The following future agenda items were noted:

- Epipen
- Onfi-utilization

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 12:11pm.

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

_____

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

Drug Utilization Review Board

Motions - Votes - **New Drugs**

FEBRUARY 7, 2017

New Drug	Drug	PDL Status	Motion - Recommendations	Additional Comments
Duchenne Muscular Dystrophy	Exondys 51 (Intravenous) Injection	Under Review	**None**	No recommendations at this time.

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
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	Gordon, Glenda Wrenn			√		
7	Graham, Yolanda, M.D.			√		
8	Harris, Mary, Ph.D.			√		
9	Lesnick, Burton, M.D. - **Vice**	√		√		
10	Lorys, Robyn Pharm.D.		√	√		
11	Miller, Osgood (Drew) A. R.Ph.			√		
12	Rollins, Brent L., R.Ph., Ph.D.			√		
13	Toth, Danny, R.Ph.			√		
			TOTAL	12	0	0

	Board Members - Absent
1	Collins, Douglas, M.D.
2	May, J. Russell (Rusty)

New Drug	Drug	PDL Status	Motion - Recommendations	Additional Comments
von Willebrand Factor Products	Vonvendi (Intravenous) Injection.	NPPA	NPPA	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
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	Gordon, Glenda Wrenn			√		
7	Graham, Yolanda, M.D.		√	√		
8	Harris, Mary, Ph.D.			√		
9	Lesnick, Burton, M.D. - **Vice**			√		
10	Lorys, Robyn Pharm.D.			√		
11	Miller, Osgood (Drew) A. R.Ph.	√		√		
12	Rollins, Brent L., R.Ph., Ph.D.			√		
13	Toth, Danny, R.Ph.			√		
			TOTAL	**12**	**0**	**0**

	Board Members - Absent
1	Collins, Douglas, M.D.
2	May, J. Russell (Rusty)

New Drug	**Drug**	**PDL Status**	**Motion - Recommendations**	**Additional Comments**
Ophthalmic Immunomodulators	Xiidra (Ophthalmic) Solution.	Under Review	NPPA	

	Board Members - Present (Strike out, when absent)	**Motion Maker (√)**	**Seconded By (√)**	**VOTES YES (√)**	**NO (√)**	**ABSTAIN (√)**
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	Gordon, Glenda Wrenn			√		
7	Graham, Yolanda, M.D.			√		

8	Harris, Mary, Ph.D.			√		
9	Lesnick, Burton, M.D. - **Vice**	√		√		
10	Lorys, Robyn Pharm.D.			√		
11	Miller, Osgood (Drew) A. R.Ph.			√		
12	Rollins, Brent L., R.Ph., Ph.D.			√		
13	Toth, Danny, R.Ph.			√		
			TOTAL	12	0	0

	Board Members - Absent
1	Collins, Douglas, M.D.
2	May, J. Russell (Rusty)

New Drug	Drug	PDL Status	Motion - Recommendations	Additional Comments
Gout Agents	Zurampic (Oral) Tablet	Under Review	NPPA	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
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	Gordon, Glenda Wrenn			√		
7	Graham, Yolanda, M.D.			√		
8	Harris, Mary, Ph.D.			√		
9	Lesnick, Burton, M.D. - **Vice**			√		
10	Lorys, Robyn Pharm.D.	√		√		
11	Miller, Osgood (Drew) A. R.Ph.			√		
12	Rollins, Brent L., R.Ph., Ph.D.		√	√		
13	Toth, Danny, R.Ph.			√		

Drug Utilization Review Board

Motions - Votes - **New Drugs**

FEBRUARY 7, 2017

		TOTAL	**12**	**0**	**0**

	Board Members - Absent
1	Collins, Douglas, M.D.
2	May, J. Russell (Rusty)

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Drug Utilization Review Board Meeting

February 7, 2017

Therapeutic Class	Drug Name	Current PDL/PIDL Status	DCH Decisions
Drug Reviews			
Duchenne Muscular Dystophy			
	Exondys 51 (Intravenous) Injection (PIDL-only)	Non-PIDL	Still Under Review
von Willebrand Factor Products			
	Vonvendi (Intravenous) Injection	NP/PA	NP/PA
Ophthalmic Immunomodulators			
	Xiidra (Ophthalmic) Solution	Non-PDL	NP/PA
Gout Agents			
	Zurampic (Oral) Tablet	Non-PDL	NP/PA

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

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GEORGIA DEPARTMENT OF COMMUNITY HEALTH

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, June 29, 2017, with an overflow day on Friday, June 30, 2017 ***only*** if needed.

Date: **Thursday, June 29, 2017 from 9am-5pm EST**
Friday, June 30, 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**.

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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.

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**.

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**

Questions not addressed in this document may be sent to NorthStar HealthCare Consulting by e-mail: GAMedicaid@nhc-llc.com

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2017

Upcoming Meetings

Drug Utilization Review Board Meeting

2 Peachtree Street, N.W.

5th Floor Board Room

Atlanta, Georgia 30303

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, June 29, 2017:	9:00am – 5:00pm
Tuesday, October 3, 2017:	9:00am – 5:00pm

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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	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