



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

August 3, 2017

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DRUG UTILIZATION REVIEW BOARD MEETING

AGENDA

2 Peachtree Street - 5th Floor DCH Board Room

Atlanta, Georgia 30303

Thursday, August 3, 2017

10:00 a.m. to 1:00 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	
● Adlyxin/Soliqua	
● Bevespi	
● Emflaza	
● Eucrisa	
● Ocrevus	
● Rayaldee	
● Zinplava	
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, May 4, 2017**

MEMBERS PRESENT

Deborah Fincher, M.S., R.Ph., Chair
Burton L. Lesnick, M.D., FAAP, Vice-Chair
Douglas Collins, M.D.
Gurinder J.S. Doad, M.D.
Rod M. Duraski, M.D., FACP, MBA
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

MEMBERS ABSENT

Mia Avery, Pharm.D.
M. Celeste Fowler, Pharm.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
Jalessa Jones, Pharm.D. Candidate (FAMU)

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

Susan McCreight, VP, Government Markets, Relations & Reform, Account Management
Talmahjia "Tami" Sweat, Pharm.D., Director, Clinical Management

Change Healthcare

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

Call to Order

The Drug Utilization Review Board (DURB/DUR Board/Board) held its second meeting for the calendar year on May 4, 2017. The Chair, Deborah Fincher, M.S., R.Ph., called the meeting to order at 11:05am.

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 February 7, 2017 meeting. A motion was made (Robyn Lorys, Pharm.D.), seconded (J. Russell May, Pharm.D.), and carried to approve the minutes as written.

External Comments Session

External comments were presented to the Board from the following:

- Kim Jones (NAMI of Georgia) – son has a mental health diagnosis; spoke about Crisis Intervention Team Training for law enforcement officers
- Rachael Carrington – son has Spinal Muscular Atrophy (SMA); spoke about FDA approval of Spinraza
- Bhagyashree Shastri, MD (Resident at Wellstar Atlanta Medical Center) – spoke about increasing coverage of antiretrovirals
- A letter from Cathalene Teahan, RN, MSN (GA AIDS Coalition) – requested inclusion of all single tablet regimens on formulary

Disclosure forms were completed by Kim Jones, Rachael Carrington, Dr. Bhagyashree Shastri, and Cathalene Teahan 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
Spinal Muscular Atrophy	<i>Spinraza</i>	Chad Nicholson, Pharm.D.

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

- Spinraza
 - Generally administered hospital outpatient setting (observed 22-23 hours and then released); categorized as hospital outpatient but cases the Department has seen have been inpatient
 - Number of patients in Fee-for-Service/Care Management Organizations – 33 with diagnosis of SMA
 - Cost of drug treatment – \$1.2 million per patient per year
 - Improvement of respiratory function or ability to swallow or prolong life span – unaware of mortality data; inclusion/exclusion may have limited the ability to determine any improvement; primary focus in studies was motor function
 - No insight on the methods used to inject medication
 - Number of patients in Phase 2 – ongoing analysis; cutoff at interim analysis
 - Respiratory complications – most are handled with normal pulmonary care/support

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

MINUTES

Thursday, May 4, 2017

- Respiratory support care – improve lungs; improve compliance; noninvasive ventilation; tracheostomy
- Adverse events – treatment emergent adverse events were less significant in the treatment population
- Reviewed medical policy criteria-discussed approval length; tracheostomy doesn't make patient ineligible for Spinraza

Supplemental Rebate Drugs – New Clinical Information Review

Clinical updates to the Supplemental Rebate categories were listed in the Supplemental Rebate section of the DURB binder and presented to the Board by Dr. Afzal “Fez” Mistry. The following therapeutic categories had updates:

Drug Class/Name
Antidiabetics, Insulin
Antidiabetics, Non-Insulin
Antihemophilic Factor VIIIs
Antivirals, Antiretrovirals
Attention Deficit Hyperactivity Disorder (ADHD) Agents
Cardiovascular, Angiotensin modulator/neprolysin inhibitor
Otic Antiinfective

DCH Decisions

DCH Decisions from the February 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

Thursday, August 3, 2017
Tuesday, November 7, 2017

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

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 residents and students, Paige Watkins (UGA), Matt Wallace (Mercer), Elenna Smalley (South), attended the closed session with Board members. A motion was made by Gurinder J.S. Doad, M.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 12:23pm, at which time members took a break then reconvened for the executive (closed) session.

Executive Session

The Executive Session was held from 12:32pm to 1:47pm.

Reconvening of Open Session

The DUR Board reconvened for the open session at 1:51pm.

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 and Supplemental Rebate Classes

Spinal Muscular Atrophy

The DUR Board recommended **Preferred** status with **Prior Authorization** for **Spinraza (Intrathecal) Injection** on the Physicians' Injectable Drug List (PIDL). The DUR Board urged the manufacturer to consider providing a supplemental rebate and requested reviewing the class at a future meeting.

Antidiabetics, Insulin

The DUR Board recommended **Non-Preferred** status with **Prior Authorization** for **all Humulin 100 U (Subcutaneous) products** with **grandfathering**, **Preferred** status with **Prior Authorization** for **Humalog U-200 (Subcutaneous) KwikPen**, **Preferred** status for **Lantus (Subcutaneous) Pen** and **Preferred** status for **Levemir (Subcutaneous) Pen**.

Antidiabetics, Non-Insulin, GLP-1 Receptor Agonists

The DUR Board recommended *Preferred* status with *Prior Authorization* for *Byetta (Subcutaneous) Pen* and *Victoza (Subcutaneous) Pen*. The DUR Board expressed willingness to revisit the class for removal of prior authorization criteria based on manufacturers' inclination to provide supplemental rebates in this category.

Antidiabetics, Non-Insulin, SGLT2 Inhibitors

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

Antihemophilic Factor VIII

The DUR Board recommended *Preferred* status for *Kogenate FS (Intravenous) Injection* and *Xyntha (Intravenous) Injection* and *Non-Preferred* status with *Prior Authorization* for *Advate (Intravenous) Injection*, *Helixate FS (Intravenous) Injection*, and *Novoeight (Intravenous) Injection*.

Antivirals, Antiretrovirals

The DUR Board recommended *Preferred* status for *Lamivudine (Oral) Tablet* and *Non-Preferred* status with *Prior Authorization* for *Lopinavir/Ritonavir (Oral) Solution*.

Attention Deficit Hyperactivity Disorder (ADHD) Agents

The DUR Board recommended deferral of decisions in this category until a comprehensive review of class, including revised financial offers, is conducted.

Cardiovascular, Angiotensin Modulator/Neprilysin Inhibitor

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

Hematopoietic, Colony Stimulating Factors

The DUR Board recommended *Preferred* status for *Granix (Subcutaneous) Injection*.

Ophthalmics, Antiallergics

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

Ophthalmics, Antibiotics, Quinolones

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

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Otic Antiinfectives

The DUR Board recommended *Preferred* status for *Ciprofloxacin (Otic) Solution* and *Non-Preferred* status with *Prior Authorization* for *Ofloxacin (Otic) Solution*.

Pulmonary Hypertension Drugs

The DUR Board recommended *Preferred* status for *Tracleer (Oral) Tablet*.

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 2:00pm.

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**

MAY 4, 2017

New Drug	Drug	PDL Status	Motion - Recommendations	Additional Comments	
Spinal Muscular Atrophy	Spinraza (Intrathecal) Injection	N/A	*PADL/PA	Reviewed for the *Providers' Administered Drug List (PADL).	
<p>The board members recommended that all requests to the Department for the use of Spinraza should be considered on a case by case basis due to cost. They further asked the manufacturer to consider supplemental rebate due to the overall cost of the drug. The board also requested future review of Spinraza with data on existing patients.</p>					
Board Members - Present <small>(Strike out, when absent)</small>	Motion Maker (v)	Seconded By (v)	VOTES		
			YES (v)	NO (v)	ABSTAIN (v)
1 Collins, Douglas, M.D.			✓		
2 Doad, Gurinder J.S., M.D. -			✓		
3 Duraski, Rod, M.D.			✓		
4 Fincher, Deborah W., M.S., R.Ph. - Chair					
5 Graham, Yolanda, M.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 Avery, Mia, Pharm.D.					
2 Fowler, M. Celeste, Pharm.D.					
3 Gordon, Glenda Wrenn					
4 Harris, Mary, Ph.D.					
5 Toth, Danny, R.Ph.					

Drug Utilization Review Board
 Motions - Votes - Supplemental Rebate Drugs
 MAY 4, 2017

Supplemental Rebate Class		Drug	PDL Status	Motion - Recommendations	Additional Comments	
Antidiabetics, Insulin		Humalog Kwikpen U-200 (Sub-Q) Insulin Pen	NPPA	PPA	The Board recommended Non-Preferred status with Prior Authorization for all Humulin 100 U (Subcutaneous) products with grandfathering.	
		Humulin N (Sub-Q) Vial	P	NPPA		
		Humulin N Kwikpen	PPA	NPPA		
		Humulin R (Injection) Vial	P	NPPA		
		Humulin 70/30 Kwikpen (Sub-Q) Insulin Pen	PPA	NPPA		
		Humulin 70-30 (Sub-Q) Vial	P	NPPA		
		Lantus Solostar (Sub-Q) Insulin Pen	PPA	P		
		Levemir Flex Touc (Sub-Q) Insulin Pen	PPA	P		
Board Members - Present <i>(Strike out, when absent)</i>		Motion Maker (v)	Seconded By (v)	VOTES		
				YES (v)	NO (v)	ABSTAIN (v)
1	Collins, Douglas, M.D.			√		
2	Doad, Gurinder J.S., M.D.-	√		√		
3	Duraski, Rod, M.D.			√		
4	Fincher, Deborah W., M.S., R.Ph. - Chair					
5	Graham, Yolanda, M.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	Avery, Mia, Pharm.D.					
2	Fowler, M. Celeste, Pharm.D.					
3	Gordon, Glenda Wrenn					
4	Harris, Mary, Ph.D.					
5	Toth, Danny, R.Ph.					

Drug Utilization Review Board
Motions - Votes - Supplemental Rebate Drugs
MAY 4, 2017

Supplemental Rebate Class		Drug	PDL Status	Motion - Recommendations	Additional Comments	
Antidiabetics, Non-Insulin GLP-1 Receptor Agonists		Byetta (Sub-q) Pen Injctr	NPPA	PPA	Board is opened to revisit this class for the removal of prior authorization.	
		Victoza (Sub-Q) Pen Injctr	NPPA	PPA		
Board Members - Present <i>(Strike out, when absent)</i>		Motion Maker (v)	Seconded By (v)	VOTES		
				YES (v)	NO (v)	ABSTAIN (v)
1	Collins, Douglas, M.D.			√		
2	Doad, Gurinder J.S., M.D.-			√		
3	Duraski, Rod, M.D.			√		
4	Fincher, Deborah W., M.S., R.Ph. - Chair					
5	Graham, Yolanda, M.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	Avery, Mia, Pharm.D.					
2	Fowler, M. Celeste, Pharm.D.					
3	Gordon, Glenda Wrenn					
4	Harris, Mary, Ph.D.					
5	Toth, Danny, R.Ph.					

Drug Utilization Review Board
 Motions - Votes - Supplemental Rebate Drugs
 MAY 4, 2017

Supplemental Rebate Class		Drug	PDL Status	Motion - Recommendations	Additional Comments	
Antidiabetics, Non-Insulin SGLT-2 Inhibitors		Invokana (Oral) Tablet	NPPA	PPA		
Board Members - Present <i>(Strike out, when absent)</i>		Motion Maker (✓)	Seconded By (✓)	VOTES		
				YES (✓)	NO (✓)	ABSTAIN (✓)
1	Collins, Douglas, M.D.			✓		
2	Doad, Gurinder J.S., M.D.-			✓		
3	Duraski, Rod, M.D.			✓		
4	Fincher, Deborah W., M.S., R.Ph. - Chair					
5	Graham, Yolanda, M.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	Avery, Mia, Pharm.D.					
2	Fowler, M. Celeste, Pharm.D.					
3	Gordon, Glenda Wrenn					
4	Harris, Mary, Ph.D.					
5	Toth, Danny, R.Ph.					

Drug Utilization Review Board
 Motions - Votes - Supplemental Rebate Drugs
 MAY 4, 2017

Supplemental Rebate Class		Drug	PDL Status	Motion - Recommendations	Additional Comments	
Antihemophilic Factor VIIIs		Advate (Intraven) Vial	P	NPPA		
		Helixate FS (Intraven) Vial	P	NPPA		
		Kogenate FS (Intraven) Vial (Helixate FS)	NPPA	P		
		Novoeight (Intraven) Vial	P	NPPA		
		Xyntha (Intraven) Syringe/Vial	NPPA	P		
Board Members - Present		Motion Maker (v)	Seconded By (v)	VOTES		
<i>(Strike out, when absent)</i>				YES (v)	NO (v)	ABSTAIN (v)
1	Collins, Douglas, M.D.			√		
2	Doad, Gurinder J.S., M.D.-			√		
3	Duraski, Rod, M.D.		√	√		
4	Fincher, Deborah W., M.S., R.Ph. - Chair					
5	Graham, Yolanda, M.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	Avery, Mia, Pharm.D.					
2	Fowler, M. Celeste, Pharm.D.					
3	Gordon, Glenda Wrenn					
4	Harris, Mary, Ph.D.					
5	Toth, Danny, R.Ph.					

Drug Utilization Review Board
 Motions - Votes - Supplemental Rebate Drugs
 MAY 4, 2017

Supplemental Rebate Class		Drug	PDL Status	Motion - Recommendations	Additional Comments	
Antivirals, Antiretrovirals		Lopinavir-Ritonavir (Oral) Solution	None	NPPA		
Board Members - Present <i>(Strike out, when absent)</i>		Motion Maker (√)	Seconded By (√)	VOTES		
				YES (√)	NO (√)	ABSTAIN (√)
1	Collins, Douglas, M.D.			√		
2	Doad, Gurinder J.S., M.D. -			√		
3	Duraski, Rod, M.D.			√		
4	Fincher, Deborah W., M.S., R.Ph. - Chair					
5	Graham, Yolanda, M.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	Avery, Mia, Pharm.D.					
2	Fowler, M. Celeste, Pharm.D.					
3	Gordon, Glenda Wrenn					
4	Harris, Mary, Ph.D.					
5	Toth, Danny, R.Ph.					

Drug Utilization Review Board
 Motions - Votes - Supplemental Rebate Drugs
 MAY 4, 2017

Supplemental Rebate Class		Drug	PDL Status	Motion - Recommendations	Additional Comments	
Attention Deficit Hyperactivity Disorder Agents		The Board deferred voting for a more comprehensive review. On June 5, 2017, the Department provided the members with additional rebate information via e-mail and requested that they render their voting decisions on this class, which generated the documented results.				
Board Members - Present <i>(Strike out, when absent)</i>		Motion Maker (v)	Seconded By (v)	VOTES		
				YES (v)	NO (v)	ABSTAIN (v)
1	Collins, Douglas, M.D.			√		
2	Doad, Gurinder J.S., M.D.-		√	√		
3	Duraski, Rod, M.D.			√		
4	Fincher, Deborah W., M.S., R.Ph. - Chair					
5	Graham, Yolanda, M.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					0	0
Board Members - Absent						
1	Avery, Mia, Pharm.D.					
2	Fowler, M. Celeste, Pharm.D.					
3	Gordon, Glenda Wrenn					
4	Harris, Mary, Ph.D.					
5	Toth, Danny, R.Ph.					

Drug Utilization Review Board
 Motions - Votes - Supplemental Rebate Drugs
 MAY 4, 2017

Supplemental Rebate Class		Drug	PDL Status	Motion - Recommendations	Additional Comments	
Attention Deficit Hyperactivity Disorder Agents		Methylphenidate ER	PPA	NPPA	These are the voting results requested via e-mail on June 5, 2017.	
		Methylphenidate LA	PPA	NPPA		
Board Members - Present					VOTES	
<i>(Strike out, when absent)</i>		Motion Maker (✓)	Seconded By (✓)	YES (✓)	NO (✓)	ABSTAIN (✓)
1	Collins, Douglas, M.D.			*N/A		
2	Doad, Gurinder J.S., M.D.-			*N/A		
3	Duraski, Rod, M.D.			✓		
4	Fincher, Deborah W., M.S., R.Ph. - Chair			**✓		
5	Graham, Yolanda, M.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				8	0	0
Board Members - Absent						
1	Avery, Mia, Pharm.D.	* Did not respond to the request submitted via e-mail ** Required grandfathering for members doing well on these agents				
2	Fowler, M. Celeste, Pharm.D.					
3	Gordon, Glenda Wrenn					
4	Harris, Mary, Ph.D.					
5	Toth, Danny, R.Ph.					

Drug Utilization Review Board
Motions - Votes - Supplemental Rebate Drugs
MAY 4, 2017

Supplemental Rebate Class		Drug	PDL Status	Motion - Recommendations	Additional Comments	
Cardiovascular, Angiotensin Modulator/Nepriylsin Inhibitor		Entresto (Oral) Tablet	NPPA	PPA		
Board Members - Present		Motion Maker (v)	Seconded By (v)	VOTES		
<i>(Strike out, when absent)</i>				YES (v)	NO (v)	ABSTAIN (v)
1	Collins, Douglas, M.D.			√		
2	Doad, Gurinder J.S., M.D.-			√		
3	Duraski, Rod, M.D.		√	√		
4	Fincher, Deborah W., M.S., R.Ph. - Chair					
5	Graham, Yolanda, M.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		
Board Members - Absent						
1	Avery, Mia, Pharm.D.					
2	Fowler, M. Celeste, Pharm.D.					
3	Gordon, Glenda Wrenn					
4	Harris, Mary, Ph.D.					
5	Toth, Danny, R.Ph.					

Drug Utilization Review Board
Motions - Votes - Supplemental Rebate Drugs
MAY 4, 2017

Supplemental Rebate Class		Drug	PDL Status	Motion - Recommendations	Additional Comments	
Hematopoietic, Colony Stimulation Factors		Granix (Sub-Q) Syringe	NPPA	P		
Board Members - Present <i>(Strike out, when absent)</i>		Motion Maker (✓)	Seconded By (✓)	VOTES		
				YES (✓)	NO (✓)	ABSTAIN (✓)
1	Collins, Douglas, M.D.	✓		✓		
2	Doad, Gurinder J.S., M.D.-			✓		
3	Duraski, Rod, M.D.			✓		
4	Fincher, Deborah W., M.S., R.Ph. - Chair					
5	Graham, Yolanda, M.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	Avery, Mia, Pharm.D.					
2	Fowler, M. Celeste, Pharm.D.					
3	Gordon, Glenda Wrenn					
4	Harris, Mary, Ph.D.					
5	Toth, Danny, R.Ph.					

Drug Utilization Review Board
 Motions - Votes - Supplemental Rebate Drugs
 MAY 4, 2017

Supplemental Rebate Class		Drug	PDL Status	Motion - Recommendations	Additional Comments	
Ophthalmics, Antiallergics		Pataday (Ophthalmic) Drops	P	NPPA		
Board Members - Present <i>(Strike out, when absent)</i>		Motion Maker (v)	Seconded By (v)	VOTES		
				YES (v)	NO (v)	ABSTAIN (v)
1	Collins, Douglas, M.D.			√		
2	Doad, Gurinder J.S., M.D.-			√		
3	Duraski, Rod, M.D.			√		
4	Fincher, Deborah W., M.S., R.Ph. - Chair					
5	Graham, Yolanda, M.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	Avery, Mia, Pharm.D.					
2	Fowler, M. Celeste, Pharm.D.					
3	Gordon, Glenda Wrenn					
4	Harris, Mary, Ph.D.					
5	Toth, Danny, R.Ph.					

Drug Utilization Review Board
 Motions - Votes - Supplemental Rebate Drugs
 MAY 4, 2017

Supplemental Rebate Class		Drug	PDL Status	Motion - Recommendations	Additional Comments	
Ophthalmic Quinolones		Ofloxacin (Ophthalmic) Drops	P	NPPA		
		Zymaxid (Ophthalmic) Drops	P	NPPA		
Board Members - Present <i>(Strike out, when absent)</i>		Motion Maker (✓)	Seconded By (✓)	VOTES		
				YES (✓)	NO (✓)	ABSTAIN (✓)
1	Collins, Douglas, M.D.			✓		
2	Doad, Gurinder J.S., M.D.-			✓		
3	Duraski, Rod, M.D.		✓	✓		
4	Fincher, Deborah W., M.S., R.Ph. - Chair					
5	Graham, Yolanda, M.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	Avery, Mia, Pharm.D.					
2	Fowler, M. Celeste, Pharm.D.					
3	Gordon, Glenda Wrenn					
4	Harris, Mary, Ph.D.					
5	Toth, Danny, R.Ph.					

Drug Utilization Review Board
 Motions - Votes - Supplemental Rebate Drugs
 MAY 4, 2017

Supplemental Rebate Class		Drug	PDL Status	Motion - Recommendations	Additional Comments	
Otic Anti-Infectives		Ciprofloxacin HCL (Otic) Droperette	NPPA	P		
		Ofloxacin (Otic) Drops	P	NPPA		
Board Members - Present <i>(Strike out, when absent)</i>		Motion Maker (✓)	Seconded By (✓)	VOTES		
				YES (✓)	NO (✓)	ABSTAIN (✓)
1	Collins, Douglas, M.D.			✓		
2	Doad, Gurinder J.S., M.D. -			✓		
3	Duraski, Rod, M.D.			✓		
4	Fincher, Deborah W., M.S., R.Ph. - Chair					
5	Graham, Yolanda, M.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	Avery, Mia, Pharm.D.					
2	Fowler, M. Celeste, Pharm.D.					
3	Gordon, Glenda Wrenn					
4	Harris, Mary, Ph.D.					
5	Toth, Danny, R.Ph.					

Drug Utilization Review Board
 Motions - Votes - Supplemental Rebate Drugs
 MAY 4, 2017

Supplemental Rebate Class		Drug	PDL Status	Motion - Recommendations	Additional Comments	
Pulmonary Antihypertension Drugs		Tracleer (Oral) Tablet	NPPA	P		
Board Members - Present <i>(Strike out, when absent)</i>		Motion Maker (v)	Seconded By (v)	VOTES		
				YES (v)	NO (v)	ABSTAIN (v)
1	Collins, Douglas, M.D.			√		
2	Doad, Gurinder J.S., M.D.-			√		
3	Duraski, Rod, M.D.			√		
4	Fincher, Deborah W., M.S., R.Ph. - Chair					
5	Graham, Yolanda, M.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	Avery, Mia, Pharm.D.					
2	Fowler, M. Celeste, Pharm.D.					
3	Gordon, Glenda Wrenn					
4	Harris, Mary, Ph.D.					
5	Toth, Danny, R.Ph.					

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 July 1, 2017 (see chart below)

DCH rebate vendor Change Healthcare (CHC) has reviewed SFY2018 supplemental rebate offers with DCH and also reviewed specific drug categories at the May 2017 DURB meeting. The PDL/PIDL decisions or PDL/PIDL changes for new drugs or categories reviewed during the May 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.

ONLY DRUGS with Supplemental Rebate Offer or reviewed during the March DURB as either new to market or a change in PDL status are listed	PREFERRED AGENTS	NON-PREFERRED AGENTS
AMINOGLYCOSIDES FOR CYSTIC FIBROSIS		
	BETHKIS	
	KITABIS	
ANAPHYLAXIS EPINEPHRINE PENS		
		EPIPEN, JR
		EPIPEN 2-PAK
ANDROGENS-ANABOLIC		
	ANDROGEL	
ANTICOAGULANTS		
	ELIQUIS	LOVENOX
	PRADAXA	
	XARELTO	
ANTICONVULSANTS		
	LYRICA CAPS	APTIOM
	OXTELLAR XR	FYCOMPA TAB, SUS
	VIMPAT	LYRICA SOLN
		TROKENDI XR
ANTIDEMENTIA AGENTS		
	EXELON	
ANTIDEPRESSANTS		
		FETZIMA
		VIIBRYD
ANTIDIABETICS – INSULIN		
	HUMALOG KWIKPEN U-100	HUMULIN 70/30 KWIKPEN
	HUMALOG MIX 50/50 KWIKPEN	HUMULIN 70-30
	HUMALOG MIX 75/25 KWIKPEN	HUMULIN N
	HUMALOG KWIKPEN U-200	HUMULIN R

ONLY DRUGS with Supplemental Rebate Offer or reviewed during the March DURB as either new to market or a change in PDL status are listed	PREFERRED AGENTS	NON-PREFERRED AGENTS
	HUMULIN R U-500 KWIKPEN	HUMULIN N KWIKPEN
	LANTUS	
	LEVIMIR	
ANTIDIABETICS - NON-INSULIN DPP-IV		
	JANUMET	
	JANUVIA	JANUMET XR
ANTIDIABETICS NON - INSULIN- GLP-1RA		
	BYETTA	TRULICITY
	BYDUREON	
	VICTOZA	
ANTIDIABETICS - NON-INSULIN SGLT2		
		FARXIGA
		GLYXAMBI
		INVOKAMET , XR
		INVOKANA
		JARDIANCE
		SYNJARDY , XR
		XIGDUO XR
ANTIEMETICS		
	DICLEGIS	
ANTIHEMOPHILIC Factor VIII PRODUCTS		
	KOGENATE FS	ADVATE
	XYNTHA	HELIXATE FS
		NUWIQ
		NOVOEIGHT
		KOVALTRY
		ELOCTATE
ANTIHEMOPHILIC Factor IX PRODUCTS		
	BENEFIX	ALPROLIX
ANTIHYPERLIPIDEMICS, PCSK9I		
		REPATHA
ANTIPSYCHOTICS, ORAL ATYPICALS		
	LATUDA	SAPHRIS
	REXULTI	VRAYLAR
ANTIPSYCHOTICS, LAI		
	ABILIFY MAINTENA	
	ARISTADA	
	INVEGA SUSTENNA	
	INVEGA TRINZA	
ANTIVIRALS, ANTIRETROVIRALS		
	DESCOVY	LOPINAVIR-RITONAVIR SOLN
	EVOTAZ	ODEFSEY
	GENVOYA	
	NORVIR	
	PREZCOBIX	
ANTIVIRALS, HEPATITIS C DAAS		
	EPCLUSA	DAKLINZA
	HARVONI	
	TECHNIVIE	

ONLY DRUGS with Supplemental Rebate Offer or reviewed during the March DURB as either new to market or a change in PDL status are listed	PREFERRED AGENTS	NON-PREFERRED AGENTS
	VIEKIRA PAK, XR	
	ZEPATIER	
	SOVALDI	
ATTENTION DEFICIT HYPERACTIVITY DISORDER (ADHD)		
	FOCALIN	ADDERALL XR
	FOCALIN XR	ADZENYS XR ODT
	QUILLICHEW ER	APTENSIO XR
	QUILLIVANT XR SUS	DYNAVEL XR SUSP
	VYVANSE	EVEKEO
	ZENZEDI	(effective 09.01.2017) METHYLPHENIDATE ER CPBP 50-50
		(effective 09.01.2017) METHYLPHENIDATE ER TAB
BIOLOGIC IMMUNOMODULATORS		
	ENBREL	XELJANZ, XR
	HUMIRA	
	COSENTYX	
BRONCHODIL, ANTICHOLINERGICS		
	COMBIVENT	ANORO ELLIPTA
		INCRUSE ELLIPTA
		SPIRIVA
		STIOLTO
BRONCHODIL, STEROID INHALANTS		
		ARNUIITY ELPT INH
BRONCHODILATOR SYMPATHOMIMETICS		
		ARCAPTA
		BREO ELLIPTA INH
		STRIVERDI
CV-ANGIOTENSIN MODULATOR/NEPRILYSIN INHIBITOR		
	ENTRESTO	
DERM, ANTI-INFLAMMATORY AGENTS		
		FLECTOR
DERM, SCABICIDES,PEDICULOCIDES		
	NATROBA	
	SKLICE	
GI- DIGESTIVE ENZYMES		
	CREON	PERTZYE
		ZENPEP
GI- INFLAMMATORY BOWEL AGENTS		
	APRISO	
	LIALDA	
	PENTASA	
GI- CONSTIPATION – IBS/OIC		
		LINZESS
		MOVANTIK
GI -IRRITABLE BOWEL SYNDROME -D		
		VIBERZI
GI- LAXATIVES		

ONLY DRUGS with Supplemental Rebate Offer or reviewed during the March DURB as either new to market or a change in PDL status are listed	PREFERRED AGENTS	NON-PREFERRED AGENTS
	PREPOPIK	
GROWTH HORMONE RELEASING HORMONE		
	EGRIFTA	
GROWTH HORMONE		
	GENOTROPIN	
	NORDITROPIN FLEXPRO	
	NUTROPIN AQ	
HEMATAPOIETIC GROWTH FACTOR		
		ARANESP
HEMATAPOIETIC GROWTH FACTOR -CSF		
	GRANIX	
	NEUPOGEN	
HEMATAPOIETIC MIXTURES		
	FUSION PAK SPRINKLE	TANDEM PLUS CAP
	FUSION PLUS CAP	
	HEMOCYTE PLS CAP	
	HEMOCYTE-F TAB	
	INTEGRA F CAP	
	INTEGRA PLUS CAP	
MIGRAINE PRODUCTS		
	RELPAK	
MS AGENTS		
	AUBAGIO	COPAXONE 40 MG/ML SYRINGE
	BETASERON	PLEGRIDY
	GILENYA	
	REBIF	
	TECFIDERA	
MULTIVITAMINS, PRENATAL DHA		
	CONCEPT DHA	
OPHTHALMICS, ADRENERGIC AGENTS		
	SIMBRINZA	
OPHTHALMICS ANTIALLERGICS		
	PAZEO	PATADAY
OPHTHALMIC ANTIBIOTICS - QUINOLONES		
	MOXEZA	OFLOXACIN
	VIGAMOX	ZYMAXID
OPHTHALMIC IMMUNOMODULATORS		
	RESTASIS	XIIDRA
OPHTHALMIC NSAIDS		
	ILEVRO	
OPHTHALMICS STEROID ANTIBIOTIC COMBINATIONS		
	TOBRADEX SUS	
OPHTHALMIC STEROIDS		
	DUREZOL	
OPHTHALMIC STEROIDS INTRAOCULAR		
	ILUVIEN	
OPIOID ABUSE ANALGESICS		
	SUBOXONE	BUNAVAIL

ONLY DRUGS with Supplemental Rebate Offer or reviewed during the March DURB as either new to market or a change in PDL status are listed	PREFERRED AGENTS	NON-PREFERRED AGENTS
		ZUBSOLV
OPIOID LONG ACTING ANALGESICS		
	EMBEDA	HYSINGLA ER
OPIOID-NSAID COMBINATIONS		
	IBUDONE	
OTIC ANTI-INFECTIVES		
	CIPRODEX	OTOVEL
	CIPROFLOXACIN	OFLOXACIN
PHOSPHATE BINDER AGENTS		
	RENAGEL	FOSRENOL
PLATELET AGGREGATION INHIBITORS		
	BRILINTA	
PROGESTINS		
	MAKENA	
PULMONARY HYPERTENSION DRUGS		
	LETAIRIS	OPSUMIT
	TRACLEER	ORENITRAM
SMOKING DETERRENENTS		
		CHANTIX
SPINAL MUSCULAR ATROPHY		
	SPINRAZA	
URINARY ANTISPASMODICS		
	TOVIAZ	MYRBETRIQ
VAGINAL ANTI-INFECTIVES		
	GYNAZOLE-1 CRE	

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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 Tuesday, October 3, 2017, with an overflow day on Wednesday, October 4, 2017 **only** if needed.

Date: Tuesday, October 3, 2017 from 9am-5pm EST
Wednesday, October 4, 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.

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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2017

Upcoming Meetings

Drug Utilization Review Board Meeting

2 Peachtree Street, N.W.

5th Floor Board Room

Atlanta, Georgia 30303

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

Manufacturers' Forum

NorthStar HealthCare Consulting

1121 Alderman Drive

Suite 112

Alpharetta, Georgia 30005

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