GEORGIA DEPARTMENT OF COMMUNITY HEALTH

Georgia Department of Community Health

DRUG UTILIZATION REVIEW BOARD MEETING

Department of Community Health

October 16, 2024

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GEORGIA DEPARTMENT OF COMMUNITY HEALTH

DRUG UTILIZATION REVIEW BOARD MEETING
AGENDA
2 Martin Luther King Jr. Drive, S.E.
Atlanta, Georgia 30334
Department of Community Health Board Room - Room 470-A
East Tower, Balcony Level
Wednesday, October 16, 2024
10:00 a.m. to 2:00 p.m.

CALL TO ORDER	*Celeste Fowler, PharmD, MBA, Chair*
MINUTES FROM PREVIOUS MEETING	*Chair*
EXTERNAL COMMENTS SESSION	*Chair*
CLINICAL REVIEWS	*Chad Nicholson, PharmD, NorthStar* *Mary-Beth Plum, PharmD, BCACP, NorthStar* *Emily Baker, PharmD, BCPS, NorthStar*

- **New Drugs**
  - Agamree
  - Rezdiffra
  - Voquezna
  - Xdemvy
  - Xphozah

ADJOURNMENT OF OPEN SESSION	*Chair*
EXECUTIVE SESSION	*Afzal Mistry, PharmD, Magellan Rx Management/Prime Therapeutics*
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
Wednesday, July 17, 2024

MEMBERS PRESENT
M. Celeste Fowler, Pharm.D., HCMBA, Chair
Gurinder Doad, M.D., Ph.D., Vice-Chair
Doug Collins, M.D.
Alton Condra, III, R.Ph.
Glenda Wrenn Gordon, M.D., MSHP, FAPA
Torey Jones, Pharm.D.
Burton L. Lesnick, M.D., FAAP
Robyn Lorys, Pharm.D.
J. Russell (Rusty) May, Pharm.D.
Osgood (Drew) A. Miller, R.Ph.
Brent L. Rollins, R.Ph., Ph.D.
Suzanne Walton, Pharm.D., BCPS, BCOP

MEMBERS ABSENT
Otto Goyco, M.D.
Matthew Perri, Pharm.D., R.Ph., Ph.D.
Danny A. Toth, R.Ph.

Staff
Peter D'Alba, Pharm.D., Pharmacy Director, Pharmacy Services
Gilletta Gray, R.Ph., Clinical Manager, Pharmacy Services
Ashlee Henry, MSHI, Pharmacy Operations Supervisor
Ashley Bellino, Pharmacy Operations Specialist, Pharmacy Services
Rose Duncan, MBA, Operations Analyst-Drug Rebate Program, Pharmacy Services
Lori Garner, MHS, MBA, R.Ph., Pharmacist, SHBP

NorthStar HealthCare Consulting
Emily Baker, Pharm.D., BCPS, MHA, MBA, President
Chad Nicholson, Pharm.D., Clinical Programs Director
Mary-Beth Plum, Pharm.D., BCACP, Clinical Pharmacist

OptumRx
Kelly Coleman, CPhT Account Manager
Talmahjia "Tami" Sweat, Pharm.D., Clinical Consulting

Magellan Rx Management/Prime Therapeutics
Afzal "Fez" Mistry, Pharm.D., Pharmacist Account Manager

Care Management Organizations
Turkesia Robertson-Jones, Pharm.D., CareSource

Pharmacy Students
Mary Grace Johnson, Pharm.D. Candidate, University of Georgia
Nareg Kaltakdjian, Pharm.D. Candidate, University of Georgia
Edith Fisk, Pharm.D. Candidate, University of Georgia
Alexandria Rakestraw, Pharm.D. Candidate, University of Georgia

Department of Community Health
Drug Utilization Review Board (DURB)
MINUTES
Wednesday, July 17, 2024

Hannah Walton, Pharm.D. Candidate, Medical University of South Carolina
Deondra Shipp, Pharm.D. Candidate, Philadelphia College of Osteopathic Medicine

Call to Order

The Drug Utilization Review Board (DURB/DUR Board/Board) held its third meeting for the calendar year on July 17, 2024. The Chair, M. Celeste Fowler, Pharm.D., HCMBA, called the meeting to order at 10:01am. Board members later introduced themselves.

Minutes from the Previous Meeting

Chair Fowler asked for corrections or changes to the minutes from the April 17, 2024 meeting. A motion was made (Burton L. Lesnick, M.D., FAAP) and seconded (J. Russell (Rusty) May, Pharm.D.) and carried to approve the minutes as written (one abstention- Brent L. Rollins, R.Ph., Ph.D.).

External Comments Session

The following external comment was presented to the Board:

- Mapillar Dahn (Founder/CEO of MTS Sickle Cell Foundation) – shared her family story and challenges faced with having three daughters with Sickle Cell; spoke in support of curative and therapeutic options so patients have full range of therapies.
- Domonique Friend (Founder, Sickle International Family Coalition) – a 54-year-old Sickle Cell patient advocating to improve care in ER departments; spoke in support of approving new drug therapies.
- Chad Nicholson, Pharm.D., summarized written comments received from the following advocating for open access to Lyfgenia and Casgevy:
    - Marc A. Registre, caregiver for Georgia resident treated with gene therapy for sickle cell disease
    - Cathalene Teahan, President of Georgia AIDS Coalition
    - Dr. Charles Wilmer, Medical Association of Georgia President
    - Dr. Samuel L. Church, Georgia Academy of Family Physicians President
    - Dr. Beatrice E. Gee, Director of Aflac Sickle Cell Disease Program at Children's Healthcare of Atlanta
    - State Representatives Gloria Frazier (District 126), Carolyn Hugley (District 141), and Al Williams (District 168)

Disclosure forms were completed by Mapillar Dahn, Domonique Friend, Marc Registre, Cathalene Teahan, Dr. Charles Wilmer, Dr. Samuel Church, Dr. Beatrice Gee, and State Representatives Gloria Frazier and Carolyn Hugley and were reviewed by the Department.

Peter D'Alba, Pharm.D., Pharmacy Director, Department of Community Health commented:
DCH has been working diligently with both manufacturers of Casgey and Lyfgenia (Vertex and Bluebird Bio) to partner with them, since these medications are very expensive. Medicaid (FFS and CMOs) has over 10,000 members who suffer with Sickle Cell Anemia. It is estimated around 1000 FFS members could be eligible for these medications. The job of DCH and the Board is to be good stewards of taxpayers' dollars. Many thanks to the manufacturers who are willing to work with DCH to make access to care available for these products. DCH is still in active negotiations with manufacturers. Access to care for these medications will be made available to our community. Thanks to the manufacturers, the Board, DCH team, NorthStar, Magellan, and Optum.

Department of Community Health
Drug Utilization Review Board (DURB)
MINUTES
Wednesday, July 17, 2024

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
Sickle Cell Agents	***Casgevy***	Chad Nicholson, Pharm.D.
Sickle Cell Agents	***Lyfgenia***	Chad Nicholson, Pharm.D.
Biologic Immunomodulators	***Bimzelx***	Mary-Beth Plum, Pharm.D., BCACP
Biologic Immunomodulators	***Omvoh***	Mary-Beth Plum, Pharm.D., BCACP
Biologic Immunomodulators	***Velsipity***	Mary-Beth Plum, Pharm.D., BCACP

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

- Casjevy
    - Durability data – Fetal Hbg at 65% (3 months), 90% (6 months), stable after that with no evidence of decline; longest duration data-48 months
    - Pharmacoeconomic analysis – ICER gave $1.62-2M range of what would be cost effective

    Comments from
    - Need input from an Ethicist-how to make decision of who gets treatment and when; childhood disease doesn't predict how someone will do as an adult
    - Criteria to use in selecting curative treatments – can't use mortality (1% mortality rate in children); could use other criteria for severity (like with stem cell transplants) but patients with stroke were excluded in these studies, along with children; cognitive injuries can occur so curative treatments should be started earlier in life; studies primarily treated healthy patients; to affect the quality of life at 18 years, you have to start treating children at 2 and 3 years of age; FDA approval criteria is not sufficient to address what's going on because it addresses what the insurance companies will require to pay for these drugs; can't let insurance company requirements determine ethically how to administer these drugs; it comes down to do patients have the right to ask for curative treatment regardless of criteria, which is where we may go ethically (but not financially); if we really want to address the disease, we have to address the issues at a time when it will really make a difference

  - Haplo Identical Stem Cell Transplant-2 year results shown to be 96% curative; doesn't work as well in kids; this can be an option and only around $800,00; there are already hundreds of stem cell transplant centers across the country
  - Patients don't seem to be as excited about curative therapy; they usually like to wait and see; see mostly young people (who are unable to enter the job market or school) asking for it; childhood success is directly related to parental involvement; successful sickle cell patient is an independent patient, so efforts need to be on pediatrics.
  - If we approve the drugs, we should approve them for patients who understand the process and want to have a cure.
  - Sickle cell variations-gene cell therapies did not include anyone with SC or SL+; Haplo identical stem cell transplant included everyone and still had a 96% cure rate; excited about gene therapy but stem cell therapies are still the workhorse in terms of curative therapy (doesn't have exclusions, reduce risk of stroke by 99% and increasingly available) and should be on our options to offer patients
  - Exclusion criteria in clinical trials not congruent with clinical practice; some children may not meet the criteria for these studies; will be challenging to come up with guidelines that are fair and equitable; excluded patients had significant end organ damage or couldn't receive red blood cell transfusions-safety concerns for gene therapies but not stem cell transplants (new immune system, no worry of previous antibody history)
- Lyfgenia
  - Black box warning with previous formulation but no instances of hematological malignancies after formulation change; was noted patients had thalassemia trait; now screening people before getting treatment.
  - Stroke patients-consider non-myeloablative stem cell transplant first; if they don't want that, then could extrapolate that gene cell therapy would help reduce the strokes
  - Data from studies for children under 12 still being collected and probably available in 24 months
- Bimzelx
  - Affect on arthritis has not been studied; phototherapy is still a recommended therapy; biologics still being looked at in other conditions-Rheumatoid Arthritis and Psoriatic Arthritis

DCH Decisions

DCH Decisions from the April 2024 DUR Board meeting were provided in the DCH Decision section of the DUR Board binder.

Upcoming Meetings

The following upcoming meetings were announced:

- Drug Utilization Review Board
  2 Martin Luther King Jr. Drive, SE
  East Tower
  Atlanta, Georgia 30334

  Wednesday, October16, 2024: 10:00am –2:00pm

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 have the Executive Session pursuant to the Open Meetings 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, Magellan Rx Management, NorthStar HealthCare Consulting, OptumRx, and pharmacy students (UGA, MUSC, PCOM). A motion was made by Osgood (Drew) A. Miller, R.Ph. and seconded Brent L. Rollins, R.Ph., Ph.D. to approve the closed session. There was a unanimous vote approving the closed session. The Chair, M. Celeste Fowler, Pharm.D., HCMBA, adjourned the open session at approximately 12:34pm, at which time members took a break then reconvened for the executive (closed) session.

Executive Session

The Executive Session was held from 12:56pm to 1:36pm.

Reconvening of Open Session

The DUR Board reconvened for the open session at 1:38pm.

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) or Physician Administered Drug List (PADL) as noted in Attachment A. All motions and votes are noted in Attachment B.

Future Agenda Items

The were no future agenda items noted.

Conclusion

At the conclusion of the open session and no other business for discussion, Chair Fowler adjourned the meeting at 1:43pm.

THESE MINUTES ARE HEREBY APPROVED AND ADOPTED, THIS THE _____ DAY OF _____, 2024.

_____

M. Celeste Fowler, Pharm.D., HCMBA, Chair

Drug Utilization Review Board
Motions - Votes - New Drugs
July 17, 2024

New Drug	Drug	PDL Status	Motion - Recommendations	Additional Comments	
Sickle Cell Agents	**Casgevy**	**N/A**	**Pending DCH negotiations**		
Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1 Collins, Douglas, M.D.			√		
2 Condra III, Alton, R.Ph.			√		
3 Doad, Gurinder J.S., M.D., Ph.D.-**Vice-Chair**			√		
4 Fowler, M. Celeste, Pharm.D., HCMBA-**Chair**					
5 Gordon, Glenda Wrenn, M.D., MSHP, FAPA			√		
6 ~~Goyco, Otto, M.D.~~					
7 Jones, Torey, Pharm.D.			√		
8 Lesnick, Burton, M.D., FAAP			√		
9 Lorys, Robyn, Pharm.D.			√		
10 May, J. Russell (Rusty), Pharm.D.			√		
11 Miller,Osgood (Drew) A., R.Ph.			√		
12 ~~Perri, Matthew, R.Ph., Pharm.D., Ph.D.~~					
13 Rollins, Brent L., R.Ph., Ph.D.			√		
14 ~~Toth, Danny, R.Ph.~~					
15 Walton, Suzanne, Pharm.D., BCPS, BCOP			√		
		TOTAL	11	0	0

New Drug	Drug	PDL Status	Motion - Recommendations	Additional Comments	
Sickle Cell Agents	**Lyfgenia**	N/A	**Pending DCH negotiations**		
Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1 Collins, Douglas, M.D.			√		
2 Condra III, Alton, R.Ph.			√		
3 Doad, Gurinder J.S., M.D., Ph.D.-**Vice-Chair**			√		
4 Fowler, M. Celeste, Pharm.D., HCMBA-**Chair**					
5 Gordon, Glenda Wrenn, M.D., MSHP, FAPA			√		
6 ~~Goyco, Otto, M.D.~~					
7 Jones, Torey, Pharm.D.			√		
8 Lesnick, Burton, M.D., FAAP			√		
9 Lorys, Robyn, Pharm.D.			√		
10 May, J. Russell (Rusty), Pharm.D.			√		
11 Miller,Osgood (Drew) A., R.Ph.			√		
12 ~~Perri, Matthew, R.Ph., Pharm.D., Ph.D.~~					
13 Rollins, Brent L., R.Ph., Ph.D.			√		
14 ~~Toth, Danny, R.Ph.~~					
15 Walton, Suzanne, Pharm.D., BCPS, BCOP			√		
		TOTAL	11	0	0

New Drug	Drug	PDL Status	Motion - Recommendations	Additional Comments

Drug Utilization Review Board
Motions - Votes - New Drugs
July 17, 2024

	Biologic Immunomodulators	Bimzelx	N/A	NP/PA		
	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Collins, Douglas, M.D.			√		
2	Condra III, Alton, R.Ph.			√		
3	Doad, Gurinder J.S., M.D., Ph.D.-**Vice-Chair**			√		
4	Fowler, M. Celeste, Pharm.D., HCMBA-**Chair**					
5	Gordon, Glenda Wrenn, M.D., MSHP, FAPA			√		
6	~~Goyco, Otto, M.D.~~					
7	Jones, Torey, Pharm.D.			√		
8	Lesnick, Burton, M.D., FAAP			√		
9	Lorys, Robyn, Pharm.D.			√		
10	May, J. Russell (Rusty), Pharm.D.		√	√		
11	Miller,Osgood (Drew) A., R.Ph.	√		√		
12	~~Perri, Matthew, R.Ph., Pharm.D., Ph.D.~~					
13	Rollins, Brent L., R.Ph., Ph.D.			√		
14	~~Toth, Danny, R.Ph.~~					
15	Walton, Suzanne, Pharm.D., BCPS, BCOP			√		
			TOTAL	11	0	0

	New Drug	Drug	PDL Status	Motion - Recommendations	Additional Comments	
	Biologic Immunomodulators	Velsipity	N/A	NP/PA		
	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Collins, Douglas, M.D.			√		
2	Condra III, Alton, R.Ph.			√		
3	Doad, Gurinder J.S., M.D., Ph.D.-**Vice-Chair**			√		
4	Fowler, M. Celeste, Pharm.D., HCMBA-**Chair**					
5	Gordon, Glenda Wrenn, M.D., MSHP, FAPA			√		
6	~~Goyco, Otto, M.D.~~					
7	Jones, Torey, Pharm.D.			√		
8	Lesnick, Burton, M.D., FAAP		√	√		
9	Lorys, Robyn, Pharm.D.			√		
10	May, J. Russell (Rusty), Pharm.D.			√		
11	Miller,Osgood (Drew) A., R.Ph.			√		
12	~~Perri, Matthew, R.Ph., Pharm.D., Ph.D.~~					
13	Rollins, Brent L., R.Ph., Ph.D.	√		√		
14	~~Toth, Danny, R.Ph.~~					
15	Walton, Suzanne, Pharm.D., BCPS, BCOP			√		
			TOTAL	11	0	0

	New Drug	Drug	PDL Status	Motion - Recommendations	Additional Comments	
	Biologic Immunomodulators	Omvoh (syringe/pen)	N/A	NP/PA		
		Omvoh (vial)	N/A	NP/PA-PADL		
	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)

Drug Utilization Review Board
Motions - Votes - New Drugs
July 17, 2024

1	Collins, Douglas, M.D.			√		
2	Condra III, Alton, R.Ph.			√		
3	Doad, Gurinder J.S., M.D., Ph.D.**-Vice-Chair**			√		
4	Fowler, M. Celeste, Pharm.D., HCMBA**-Chair**					
5	Gordon, Glenda Wrenn, M.D., MSHP, FAPA			√		
6	~~Goyco, Otto, M.D.~~					
7	Jones, Torey, Pharm.D.			√		
8	Lesnick, Burton, M.D., FAAP			√		
9	Lorys, Robyn, Pharm.D.	√		√		
10	May, J. Russell (Rusty), Pharm.D.			√		
11	Miller,Osgood (Drew) A., R.Ph.			√		
12	~~Perri, Matthew, R.Ph., Pharm.D., Ph.D.~~					
13	Rollins, Brent L., R.Ph., Ph.D.			√		
14	~~Toth, Danny, R.Ph.~~					
15	Walton, Suzanne, Pharm.D., BCPS, BCOP		√	√		
			TOTAL	**11**	**0**	**0**

GEORGIA DEPARTMENT OF COMMUNITY HEALTH

PRIME THERAPEUTICS | MagellanRx MANAGEMENT

Listed below are Preferred Drug List changes for the State of Georgia Fee-For-Service Medicaid and PeachCare for Kids Programs

Effective October 1, 2024 (see chart below)*

DCH rebate vendor, Magellan Medicaid Administration (MMA), has reviewed specific drugs at the July 2024 DURB meeting and corresponding supplemental rebate offers. The Preferred Drug List (PDL)/Providers' Administered Drug List (PADL) decisions/changes for categories reviewed are outlined below. For a full listing of our PDL, go to www.dch.georgia.gov/pharmacy and select the "Preferred Drug Lists" option; for the PADL, go to https://www.mmis.georgia.gov/portal/ and select "Provider Information", "Fee Schedule", then "Providers' Administered Drug List."

PREFERRED AGENTS	NON-PREFERRED AGENTS
BIOLOGIC IMMUNOMODULATORS	
	BIMZELX (INJECTION) – PA OMVOH (INJECTION)* – PA VELSIPITY (ORAL) – PA
SICKLE CELL ANEMIA TREATMENTS	
CASGEVY (INJECTION)* – PENDING ADDITIONAL FINANCIAL CONSIDERATION LYFGENIA (INJECTION)* – PENDING ADDITIONAL FINANCIAL CONSIDERATION	

*PADL drugs may be subject to a different effective date.

GEORGIA DEPARTMENT OF COMMUNITY HEALTH

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: New 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.

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 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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2025

Upcoming Meetings

Drug Utilization Review Board Meeting

2 Martin Luther King Jr. Drive, S.E.
Atlanta, Georgia 30334
Department of Community Health Board Room - Room 470-A
East Tower, Balcony Level

2025 Meeting Dates To Be Determined

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Drug Utilization Review Board

Board Member	Credentials	Specialty/Area of Expertise
M. Celeste Fowler, Chair	Pharm.D., HCMBA	340B Pharmacy
Gurinder J.S. Doad, Vice-Chair	M.D., Ph.D.	Family Practice
Douglas C. Collins	M.D.	Hematology/Oncology
Alton Condra III	R.Ph.	HIV/AIDS Pharmacy - Infectious Disease Program
Otto C. Goyco	M.D., FACP	Internal Medicine
Torey A. Jones	Pharm.D., MBA	340B Pharmacy
Burton L. Lesnick	M.D., FAAP	Pediatrics/Pediatric Pulmonology
Robyn Lorys	Pharm.D.	Academia - Professor
J. Russell May	Pharm.D.	Academia - Professor
Drew A. Miller	R.Ph.	Retail Pharmacy
Matthew Perri III	Ph.D., R.Ph.	Academia - Professor
Brent L. Rollins	R.Ph., Ph.D.	Academia - Professor
Danny A. Toth	R.Ph.	Pharmacy Benefit Plans
Suzanne M. Walton	Pharm.D., BCPS, BCOP	Hematology/Oncology
Glenda Wrenn	M.D.	Psychiatry, Academia - Professor