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

September 19, 2013

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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
September 19, 2013
9:30 a.m. to 1:30 p.m.

CALL TO ORDER	*Laurel Ashworth, PharmD, Chair*
COMMENTS FROM THE DEPARTMENT	*Linda Wiant, PharmD, Director*
MINUTES FROM PREVIOUS MEETING	*Chair*
CONSUMER COMMENTS SESSION	*Chair*
ADJOURNMENT OF OPEN SESSION	*Chair*
EXECUTIVE SESSION	
BREAK	
RECONVENING OF OPEN SESSION	*Chair*
CLINICAL REVIEW AND DURB VOTES	*Emily Baker, PharmD, BCPS, MBA, MHA* *Tara R. Cockerham, PharmD*

- **Manufacturers' Forum**

- **New Drug Reviews**
  - ●Eliquis™
  - ●Gattex™
  - ●Juxtapid™
  - ●Kynamro™
  - ●Ravicti™
  - ●Vascepa™

- **Therapeutic Class Reviews**
  - ●Buprenorphine-Naloxone Agents
  - ●Influenza Agents

- **Utilization Trends Review**

- **Drug Information Review**
  - ●Drug Update Newsletter
  - ●Horizon Watch Report
  - ●Patent Expiration Report
  - ●Clinical Compass Newsletter

FUTURE AGENDA ITEMS	*Chair*
ADJOURNMENT	*Chair*

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Department of Community Health
Drug Utilization Review Board (DURB)
MINUTES
Thursday, June 6, 2013

MEMBERS PRESENT

Laurel E. Ashworth, Pharm.D., Chair
Joseph R. Bona, M.D., MBA, Vice-Chair
Karen L. Carter, M.D.
Melissa D. Carter, J.D.
Ann R. Damon, Pharm.D.
Deborah W. Fincher, M.S., R.Ph.
Thomas B. Gore, M.D.
John Greeson, M.D., MBA
Edwina L. Jones, Pharm.D.
Robyn Lorys, Pharm.D.
J. Russell May, Pharm.D.
Osgood (Drew) A. Miller, R.Ph.
Donald A. Paul, M.D.
Matthew Perri, III, R.Ph., Ph.D.
Mary Virginia "Ginny" Yates, Pharm.D.

MEMBERS ABSENT

Paul D. Boyce, M.D.
Carl Ellis, R.Ph.
Rondell C. Jaggers, Pharm.D.
Sandra L. White, M.D., MBA, FACR

Staff

Linda Wiant, Pharm.D., 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
Rose Marie Duncan, MBA, Program Associate, Pharmacy Services
Jacob Mouchet, Pharm. D. Candidate

NorthStar HealthCare Consulting

Emily Baker, Pharm.D., BCPS, MHA, MBA, President
Tara R. Cockerham, Pharm.D., Clinical Programs Director

Catamaran

Talmahjia “Tami” Sweat, Pharm.D., Clinical Systems Product Manager
Tabitha Brown, Provider Relations Specialist

Goold Health Services

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

Call to Order

The Drug Utilization Review Board (DUR Board) held its second meeting for the calendar year on June 6, 2013. The Chair, Laurel E. Ashworth, Pharm.D., called the meeting to order at 9:59am.

Comments from the Department

Linda Wiant, Pharm.D., Pharmacy Director, Pharmacy Services, commented on the following items:

- Agenda changes - A new meeting format moves up the Consumer Comment and Executive Sessions earlier on the agenda. The Executive Session accommodates the financial discussions. Members are no longer asked to move to another room, as the Executive Session is held in the same room as the open session. Immediately following the Executive Session, the Board reconvenes the open session for clinical reviews, motions, discussions, and votes. The intent is to facilitate discussions in open meetings.

Minutes from the Previous Meeting

Dr. Ashworth asked for comments regarding the minutes from the March 19, 2013 meeting. There were no corrections. A motion was made (J. Russell May, Pharm.D.), seconded (Joseph R. Bona, M.D., MBA, Vice-Chair), and carried to approve the minutes as written.

Consumer Comments Session

There were no consumer comments.

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 USCS1396R-8B3D. The individuals recorded in attendance were from the Department of Community Health, Goold Health Services, NorthStar HealthCare Consulting, and Catamaran. Jacob Mouchet (DCH pharmacy intern), and Winta Haley (Mercer University student) attended the closed session with the Board members. A motion was made by Osgood (Drew) A. Miller, R.Ph., and seconded by John Greeson, M.D., MBA, to adjourn the open session and approve the closed session. There was a unanimous vote approving the closed session. The Chairman, Dr. Laurel Ashworth, adjourned the open session at approximately 10:07am, at which time members reconvened for the Executive (closed) Session.

Executive Session

The Executive Session was held from 10:09am to 11:29am.

Reconvening of Open Session

The DUR Board reconvened for the open session at 11:36am.

Manufacturers' Forum

Tara Cockerham, Pharm.D., reviewed information regarding the Manufacturers' Forum that was provided in the Manufacturer Information section in the DUR Board binder. A total of ten (10) manufacturers participated and provided information regarding the following drugs to be discussed at the June 6, 2013 DUR Board meeting:

Manufacturers	Drugs
Otsuka	Abilify Maintena
Pfizer	Bosulif, Toviaz, Xeljanz
Forest	Linzess, Turdorza Pressair
Genzyme/Sanofi	Aubagio
Astellas	Myrbetriq
Boehringer Ingelheim	Combivent Respimat, Spiriva HandiHaler
Allergen	Restasis
Arbor	BiDil
Digestive Care	Pertzye
Janssen	Invega Sustenna

There were no questions or comments. The next forum will be held on Thursday, August 1, 2013 from 9am-5pm at the NorthStar Healthcare Consulting office: 1121 Alderman Drive, Suite 112, Alpharetta, GA 30005.

Agenda

A motion was made by Dr. Laurel Ashworth and seconded by Dr. Joseph R. Bona to change the order in which items were discussed in the agenda to: New Drug Reviews, Class Reviews and Follow-Up Review of HIV agents. The motion carried.

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
Multiple Sclerosis Agent	*Aubagio*	Tara Cockerham, Pharm.D.
Antineoplastic	*Bosulif*	Tara Cockerham, Pharm.D.
Irritable Bowel Syndrome – Constipation	*Linzess*	Tara Cockerham, Pharm.D.
Antispasmodics	*Myrbetriq*	Tara Cockerham, Pharm.D.
Antineoplastic	*Stivarga*	Tara Cockerham, Pharm.D.
Antineoplastic	*Synribo*	Tara Cockerham, Pharm.D.
Chronic Obstructive Pulmonary Disorder	*Tudorza*	Tara Cockerham, Pharm.D.
Biologic Immunomodulators	*Xeljanz*	Tara Cockerham, Pharm.D.

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

- Aubagio – no head to head comparisons with the other oral agent in this class, 33% reduction in relapse rate, black box warning and cost
- Bosulif – intent to treat analysis, number of patients that could not tolerate dose
- Linzess – no subgroup analysis in males, no black box warning, concerns of accidental ingestion, safety concerns
- Myrbetriq – first beta-3 agonist approved; dose-dependent hypertension; similar efficacy with other products; place in therapy after other agents and cost
- Stivarga – limited study (1 month)
- Tudorza – may offer an advantage but is costly
- Xeljanz – adverse events, active comparative dosing

The Board voted and made recommendations for all new drug reviews noted in the Board's Recommendations to the Department.

Class Reviews – New Clinical Information Review

Clinical updates for class review categories were listed in the Class Reviews Clinical Updates section of the DUR Board binder and presented by Emily Baker, Pharm.D. The following therapeutic categories had updates:

Drug Class/Name
Anaphylaxis Therapy
Angiotensin Converting Enzyme Inhibitors and Combinations
Antidepressants – Selective Serotonin Reuptake Inhibitors
Antifungals – Oral
Antispasmodics
Atypical Antipsychotics – Long-Acting Injectables
Beta Adrenergic – Short-Acting Nebulizers
Betalactam/Clavulanate Combinations
Calcium Channel Blockers
Chronic Obstructive Pulmonary Disorder – Inhaled Agents
Contraceptives - Oral
Diabetic - Oral
Drug for Gout
Fluoroquinolones - Oral
Gastrointestinal – Antiulcer Antiinfectives
Gastrointestinal – Digestive Enzymes
Glucocorticosteroids - Oral
Hemostatics
Herpes Agents - Oral
Immunosuppressants
Leukotriene Modifiers
Ophthalmics - Miscellaneous
Sedative Hypnotics

Statins
Topical - Antipsoriatics
Topical – Antivirals
Topical Local Anesthetics

Comments and/or questions were received from the Board regarding the following:

- COPD-Inhaled agents – Combivent formulation, days supply
- Atypical Antipsychotics-Long-Acting injectables – compliance
- Contraceptives-Emergency – dosing of 0.75mg vs. 1.5mg levonorgestrel
- Gastrointestinal-Digestive Enzymes – seek expert consultation for further review
- Sedative Hypnotics - look at financial and clinical outcomes of zolpidem compared to other sedative hypnotics

Follow-Up Class Review

Clinical information for the following therapeutic class was presented for discussion by Dr. Tara Cockerham. The complete detailed therapeutic class review was provided in the Follow-Up Review section of the DUR Board binder.

Clinical Review	Description	Presenter
Human Immunodeficiency Virus (HIV) Antiretroviral Drugs	*Evaluate utilization of and adherence to HIV antiretroviral medications to determine if physicians are prescribing appropriately and patients are adherent to therapy, and to review prior authorization statistics*	Tara Cockerham, Pharm.D.

Comments and questions were received from the Board regarding the following:

- Differences in PA denials and first level approvals and reasons for second level denials

Utilization Trend Review

Utilization trends for Georgia Medicaid Fee-for-Service were provided in detail in the Utilization Trends section of the DUR Board binder.

Drug Information

Information from the following was provided in detail in the Drug Information section of the DUR Board binder used for this meeting:

- Drug Update Newsletter
- Horizon Watch Report
- Patent Expiration Report
- Clinical Compass Newsletter

Future Agenda Items

The following future agenda items were noted:

- Prescribers of neomycin containing ophthalmic products

- Sub-group of oncology specialists to review this class of medication
- Study outcome of Long-Acting Atypical Antipsychotic injectables (committee: Joseph R. Bona, M.D., MBA, Vice-Chair, Edwina L. Jones, Pharm.D. and Robyn Lorys, Pharm.D.)
- Anticonvulsants (by indication)
- Immunomodulators

Upcoming Meetings

The following dates for upcoming meetings were published in the DUR Board binder:

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

  Thursday, September 19, 2013
  Tuesday, December 10, 2013

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

  Thursday, August 1, 2013
  Thursday, November 7, 2013

Disclosure Forms

Disclosure forms were received and reviewed by the Department for completeness for all Board members attending the meeting.

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 Drug Reviews

Multiple Sclerosis Agent

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

Antineoplastic

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

Irritable Bowel Syndrome – Constipation

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

Antispasmodic

The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Myrbetriq™ (Oral) Tablet Extended-Release***.

Antineoplastic

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

Antineoplastic

The DUR Board recommended ***Preferred*** status with ***Prior Authorization*** for ***Synribo™ (Subcutaneous) Vial***.

Chronic Obstructive Pulmonary Disorder Inhaler

The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Tudorza™ (Inhalation)***.

Biologic Immunomodulator

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

Class Reviews

Anaphylaxis Therapy

The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Auvi-Q® (Injection) Auto Injector***.

Angiotensin Converting Enzyme Inhibitors and Combinations

The DUR Board recommended ***Preferred*** status for ***Amlodipine-Benazepril (Oral) Capsule*** and ***Non-Preferred*** status with ***Prior Authorization*** for ***Lotrel® (Oral) Capsule***.

Antidepressants – Selective Serotonin Reuptake Inhibitors

The DUR Board recommended ***Preferred*** status for ***Escitalopram Oxalate (Oral) Solution*** and ***Non-Preferred*** status with ***Prior Authorization*** for ***Lexapro® (Oral) Solution***.

Antifungals – Oral

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

Antispasmodics

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

Atypical Antipsychotics – Long-Acting Injectables

The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Abilify® Maintena® (Intramuscular) Vial*** and that the prior authorization criteria should be at parity to other atypical antipsychotic long-acting injectables.

Betalactam-Clavulanate Combinations

The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Amoxicillin Trihydrate-Potassium Clavulanate (Oral) Tablet 250mg-125mg*** and ***Augmentin® (Oral) Suspension for Reconstitution 250mg-62.5mg/5mL***.

Calcium Channel Blockers

The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Isradipine (Oral) Capsule, Nicardipine Hydrochloride (Oral) Capsule*** and ***Verapamil Extended-Release PM (Oral) Capsule 24 Hour***.

Chronic Obstructive Pulmonary Disorder Inhalers

The DUR Board recommended ***Preferred*** status for ***Combivent® Respimat® (Inhalation).***

Contraceptives – Emergency

The DUR Board recommended ***Preferred*** status for ***Next Choice® One Dose (Oral) Tablet***, and ***Non-Preferred*** status with ***Prior Authorization*** for ***Ella® (Oral) Tablet, Levonorgestrel (Oral) Tablet*** and ***Next Choice® (Oral) Tablet***.

Diabetic – Oral

The DUR Board recommended ***Preferred*** status for ***Starlix® (Oral) Tablet*** and ***Non-Preferred*** status with ***Prior Authorization*** for ***Chlorpropamide (Oral) Tablet, Fortamet® (Oral) Tablet Extended-Release, Tolazamide (Oral) Tablet*** and ***Tolbutamide (Oral) Tablet***.

Gastrointestinal – Antiulcer Antiinfectives

The DUR Board recommended ***Preferred*** status with ***Prior Authorization*** for ***Prevpac® (Oral) Combination Package*** and ***Pylera® (Oral) Capsule***.

Gastrointestinal – Digestive Enzymes

The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Pancreaze® (Oral) Capsule Delayed-Release with grandfathering and a request for expert consultation in the future***.

Herpes Agents – Oral

The DUR Board recommended ***Preferred*** status for ***Valacyclovir (Oral) Tablet*** and ***Non-Preferred*** status for ***Valtrex® (Oral) Tablet***.

Ophthalmic – Miscellaneous

The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Neomycin-Polymyxin B-Hydrocortisone (Ophthalmic) Drops Suspension***.

Prenatal Vitamins

The DUR Board recommended ***Preferred*** status for ***Citranatal® DHA Products*** and ***Non-Preferred*** status with ***Prior Authorization*** for ***DHA Products That Cost More Than $26 Per Claim***.

Topical – Antipsoriatics

The DUR Board recommended ***Preferred*** status for ***Calcipotriene (Topical) Solution*** and ***Non-Preferred*** status with ***Prior Authorization*** for ***Dovonex® (Topical) Solution***.

Topical – Antivirals

The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Denavir® (Topical) Cream***.

Topical – Genital Warts

The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Veregen® (Topical) Ointment***.

Urinary Antiinfectives

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

Conclusion

At the conclusion of the reconvened open session and no other business for discussion, Chair Ashworth adjourned the meeting at 2:23pm.

THESE MINUTES ARE HEREBY APPROVED AND ADOPTED, THIS THE _____ DAY OF _____, 2013.

_____

Laurel Ashworth, Pharm.D., Chair

Drug Utilization Review Board

Motions - Votes

New Drugs

June 6, 2013

MS AGENTS (New Drug Review)

Motion:

Drug	PDL Status
Aubagio (Oral) Tablet	**NP/PA**

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Ashworth, Laurel E. Pharm.D. - Chair			√		
2	Bona, Joseph R. M.D. - Co-Chair			√		
3	Carter, Karen L., M.D.			√		
4	Carter, Melissa			√		
5	Damon, Ann R., Pharm.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Gore, Thomas B., M.D.			√		
8	Greeson, John D., M.D., MBA			√		
9	Jones, Edwina L., Pharm.D., MBA			√		
10	Lorys, Robyn Pharm.D.		√	√		
11	May, J. Russell, Pharm.D.	√		√		
12	Miller, Osgood (Drew) A. R.Ph.			√		
13	Paul, Donald A., M.D.			√		
14	Perri, III, Matthew, R,Ph., Ph.D.			√		
15	Yates, Mary Virginia "Ginny", Pharm.D.			√		
			TOTAL	15	0	0

	Board Members - Absent
1	Boyce, Paul D., M.D.
2	Ellis, Carl, R.Ph.
3	Jaggers, Rondell C., Pharm.D.
4	White, Sandra L., M.D., MBA, FACR

15

Drug Utilization Review Board

Motions - Votes

New Drugs

June 6, 2013

ANTINEOPLASTICS (New Drug Review)

Motion:

Drug	PDL Status
Bosulif™ (Oral) Tablet	**P/PA**

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Ashworth, Laurel E. Pharm.D. - Chair			√		
2	Bona, Joseph R. M.D. - Co-Chair			√		
3	Carter, Karen L., M.D.			√		
4	Carter, Melissa			√		
5	Damon, Ann R., Pharm.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Gore, Thomas B., M.D.			√		
8	Greeson, John D., M.D., MBA			√		
9	Jones, Edwina L., Pharm.D., MBA			√		
10	Lorys, Robyn Pharm.D.	√		√		
11	May, J. Russell, Pharm.D.			√		
12	Miller, Osgood (Drew) A. R.Ph.		√	√		
13	Paul, Donald A., M.D.			√		
14	Perri, III, Matthew, R,Ph., Ph.D.			√		
15	Yates, Mary Virginia "Ginny", Pharm.D.			√		
			TOTAL	15	0	0

	Board Members - Absent
1	Boyce, Paul D., M.D.
2	Ellis, Carl, R.Ph.
3	Jaggers, Rondell C., Pharm.D.
4	White, Sandra L., M.D., MBA, FACR

Drug Utilization Review Board

Motions - Votes

New Drugs

June 6, 2013

IRRITABLE BOWEL SYNDROME (IBS)- CONSTIPATION (New Drug Review)

Motion:

Drug	PDL Status
Linzess™ (Oral) Capsule	**NP/PA**

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Ashworth, Laurel E. Pharm.D. - Chair			√		
2	Bona, Joseph R. M.D. - Co-Chair		√	√		
3	Carter, Karen L., M.D.			√		
4	Carter, Melissa			√		
5	Damon, Ann R., Pharm.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Gore, Thomas B., M.D.			√		
8	Greeson, John D., M.D., MBA			√		
9	Jones, Edwina L., Pharm.D., MBA			√		
10	Lorys, Robyn Pharm.D.			√		
11	May, J. Russell, Pharm.D.			√		
12	Miller, Osgood (Drew) A. R.Ph.			√		
13	Paul, Donald A., M.D.	√		√		
14	Perri, III, Matthew, R,Ph., Ph.D.				√	
15	Yates, Mary Virginia "Ginny", Pharm.D.			√		
			TOTAL	**14**	**1**	**0**

	Board Members - Absent
1	Boyce, Paul D., M.D.
2	Ellis, Carl, R.Ph.
3	Jaggers, Rondell C., Pharm.D.
4	White, Sandra L., M.D., MBA, FACR

Drug Utilization Review Board

Motions - Votes

New Drugs

June 6, 2013

ANTISPASMODICS (New Drug Review)

Motion:

Drug	PDL Status
Myrbetriq (Oral) Tablet Extended-Release	**NP/PA**

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Ashworth, Laurel E. Pharm.D. - Chair			√		
2	Bona, Joseph R. M.D. - Co-Chair			√		
3	Carter, Karen L., M.D.			√		
4	Carter, Melissa			√		
5	Damon, Ann R., Pharm.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Gore, Thomas B., M.D.		√	√		
8	Greeson, John D., M.D., MBA			√		
9	Jones, Edwina L., Pharm.D., MBA			√		
10	Lorys, Robyn Pharm.D.			√		
11	May, J. Russell, Pharm.D.	√		√		
12	Miller, Osgood (Drew) A. R.Ph.			√		
13	Paul, Donald A., M.D.			√		
14	Perri, III, Matthew, R,Ph., Ph.D.			√		
15	Yates, Mary Virginia "Ginny", Pharm.D.			√		
			TOTAL	15	0	0

	Board Members - Absent
1	Boyce, Paul D., M.D.
2	Ellis, Carl, R.Ph.
3	Jaggers, Rondell C., Pharm.D.
4	White, Sandra L., M.D., MBA, FACR

Drug Utilization Review Board

Motions - Votes

New Drugs

June 6, 2013

ANTINEOPLASTIC (New Drug Review)

Motion:

Drug	PDL Status
Stivarga ™ ***(Oral) Tablet***	**P/PA**

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Ashworth, Laurel E. Pharm.D. - Chair				√	
2	Bona, Joseph R. M.D. - Co-Chair			√		
3	Carter, Karen L., M.D.			√		
4	Carter, Melissa			√		
5	Damon, Ann R., Pharm.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Gore, Thomas B., M.D.				√	
8	Greeson, John D., M.D., MBA		√	√		
9	Jones, Edwina L., Pharm.D., MBA			√		
10	Lorys, Robyn Pharm.D.				√	
11	May, J. Russell, Pharm.D.			√		
12	Miller, Osgood (Drew) A. R.Ph.	√		√		
13	Paul, Donald A., M.D.					√
14	Perri, III, Matthew, R,Ph., Ph.D.				√	
15	Yates, Mary Virginia "Ginny", Pharm.D.			√		
			TOTAL	10	4	1

	Board Members - Absent
1	Boyce, Paul D., M.D.
2	Ellis, Carl, R.Ph.
3	Jaggers, Rondell C., Pharm.D.
4	White, Sandra L., M.D., MBA, FACR

Drug Utilization Review Board

Motions - Votes

New Drugs

June 6, 2013

ANTINEOPLASTICS (New Drug Review)

Motion:

	Drug	PDL Status
	Synribo ™ (Subcutaneous) Vial	**P/PA**

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Ashworth, Laurel E. Pharm.D. - Chair			√		
2	Bona, Joseph R. M.D. - Co-Chair			√		
3	Carter, Karen L., M.D.			√		
4	Carter, Melissa			√		
5	Damon, Ann R., Pharm.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.		√	√		
7	Gore, Thomas B., M.D.			√		
8	Greeson, John D., M.D., MBA			√		
9	Jones, Edwina L., Pharm.D., MBA	√		√		
10	Lorys, Robyn Pharm.D.			√		
11	May, J. Russell, Pharm.D.			√		
12	Miller, Osgood (Drew) A. R.Ph.			√		
13	Paul, Donald A., M.D.					√
14	Perri, III, Matthew, R,Ph., Ph.D.			√		
15	Yates, Mary Virginia "Ginny", Pharm.D.			√		
			TOTAL	**14**	**0**	**1**

	Board Members - Absent
1	Boyce, Paul D., M.D.
2	Ellis, Carl, R.Ph.
3	Jaggers, Rondell C., Pharm.D.
4	White, Sandra L., M.D., MBA, FACR

20

Drug Utilization Review Board

Attachment A

Motions - Votes

New Drugs

June 6, 2013

COPD INHALERS (New Drug Review)

Motion:

Drug	PDL Status
Tudorza™ (Inhalation	**NP/PA**

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Ashworth, Laurel E. Pharm.D. - Chair					√
2	Bona, Joseph R. M.D. - Co-Chair			√		
3	Carter, Karen L., M.D.			√		
4	Carter, Melissa			√		
5	Damon, Ann R., Pharm.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Gore, Thomas B., M.D.	√		√		
8	Greeson, John D., M.D., MBA			√		
9	Jones, Edwina L., Pharm.D., MBA		√	√		
10	Lorys, Robyn Pharm.D.			√		
11	May, J. Russell, Pharm.D.			√		
12	Miller, Osgood (Drew) A. R.Ph.			√		
13	Paul, Donald A., M.D.					√
14	Perri, III, Matthew, R,Ph., Ph.D.			√		
15	Yates, Mary Virginia "Ginny", Pharm.D.			√		
			TOTAL	13	0	2

	Board Members - Absent
1	Boyce, Paul D., M.D.
2	Ellis, Carl, R.Ph.
3	Jaggers, Rondell C., Pharm.D.
4	White, Sandra L., M.D., MBA, FACR

Drug Utilization Review Board

Motions - Votes

New Drugs

June 6, 2013

BIOLOGIC IMMUNOMODULATORS (New Drug Review)

Motion:

Drug	PDL Status
Xeljanz™ (Oral) Table	**NP/PA**

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Ashworth, Laurel E. Pharm.D. - Chair			√		
2	Bona, Joseph R. M.D. - Co-Chair			√		
3	Carter, Karen L., M.D.			√		
4	Carter, Melissa			√		
5	Damon, Ann R., Pharm.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Gore, Thomas B., M.D.			√		
8	Greeson, John D., M.D., MBA			√		
9	Jones, Edwina L., Pharm.D., MBA			√		
10	Lorys, Robyn Pharm.D.		√	√		
11	May, J. Russell, Pharm.D.			√		
12	Miller, Osgood (Drew) A. R.Ph.	√		√		
13	Paul, Donald A., M.D.					√
14	Perri, III, Matthew, R,Ph., Ph.D.			√		
15	Yates, Mary Virginia "Ginny", Pharm.D.			√		
			TOTAL	14	0	1

	Board Members - Absent
1	Boyce, Paul D., M.D.
2	Ellis, Carl, R.Ph.
3	Jaggers, Rondell C., Pharm.D.
4	White, Sandra L., M.D., MBA, FACR

22

Drug Utilization Review Board

Attachment A

Motions - Votes

Class Reviews

June 6, 2013

ANAPHYLAXIS THERAPY

	Motion:	*Auvi-Q® (Injection) Auto Injector*	PDL Status NP/PA			
	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Ashworth, Laurel E. Pharm.D. - Chair			√		
2	Bona, Joseph R. M.D. - Co-Chair			√		
3	Carter, Karen L., M.D.			√		
4	Carter, Melissa			√		
5	Damon, Ann R., Pharm.D.		√	√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Gore, Thomas B., M.D.			√		
8	Greeson, John D., M.D., MBA			√		
9	Jones, Edwina L., Pharm.D., MBA	√		√		
10	Lorys, Robyn Pharm.D.			√		
11	May, J. Russell, Pharm.D.			√		
12	Miller, Osgood (Drew) A. R.Ph.			√		
13	Paul, Donald A., M.D.			√		
14	Perri, III, Matthew, R,Ph., Ph.D.			√		
15	Yates, Mary Virginia "Ginny", Pharm.D.			√		
			TOTAL	15	0	0

	Board Members - Absent
1	Boyce, Paul D., M.D.
2	Ellis, Carl, R.Ph.
3	Jaggers, Rondell C., Pharm.D.
4	White, Sandra L., M.D., MBA, FACR

Drug Utilization Review Board

Motions - Votes

Class Reviews

June 6, 2013

ANGIOTENSIN CONVERTING ENZYME INHIBITORS AND COMBINATIONS

Motion:

Drug	PDL Status
Amlodipine-Benazepril (Oral) Capsule	P
Lotrel® (Oral) Capsule	NP/PA

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Ashworth, Laurel E. Pharm.D. - Chair			√		
2	Bona, Joseph R. M.D. - Co-Chair			√		
3	Carter, Karen L., M.D.			√		
4	Carter, Melissa			√		
5	Damon, Ann R., Pharm.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Gore, Thomas B., M.D.			√		
8	Greeson, John D., M.D., MBA			√		
9	Jones, Edwina L., Pharm.D., MBA			√		
10	Lorys, Robyn Pharm.D.			√		
11	May, J. Russell, Pharm.D.		√	√		
12	Miller, Osgood (Drew) A. R.Ph.	√		√		
13	Paul, Donald A., M.D.			√		
14	Perri, III, Matthew, R,Ph., Ph.D.			√		
15	Yates, Mary Virginia "Ginny", Pharm.D.			√		
			TOTAL	15	0	0

	Board Members - Absent
1	Boyce, Paul D., M.D.
2	Ellis, Carl, R.Ph.
3	Jaggers, Rondell C., Pharm.D.
4	White, Sandra L., M.D., MBA, FACR

Drug Utilization Review Board

Motions - Votes

Class Reviews

June 6, 2013

ANTIDEPRESSANTS, Selective Serotonin Reuptake Inhibitors

Motion:

Drug	PDL Status
Escitalopram Oxalate (Oral) Solution	P
Lexapro® (Oral) Solution	NP/PA

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Ashworth, Laurel E. Pharm.D. - Chair		√	√		
2	Bona, Joseph R. M.D. - Co-Chair			√		
3	Carter, Karen L., M.D.			√		
4	Carter, Melissa			√		
5	Damon, Ann R., Pharm.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Gore, Thomas B., M.D.			√		
8	Greeson, John D., M.D., MBA			√		
9	Jones, Edwina L., Pharm.D., MBA			√		
10	Lorys, Robyn Pharm.D.	√		√		
11	May, J. Russell, Pharm.D.			√		
12	Miller, Osgood (Drew) A. R.Ph.			√		
13	Paul, Donald A., M.D.			√		
14	Perri, III, Matthew, R,Ph., Ph.D.			√		
15	Yates, Mary Virginia "Ginny", Pharm.D.			√		
			TOTAL	15	0	0

	Board Members - Absent
1	Boyce, Paul D., M.D.
2	Ellis, Carl, R.Ph.
3	Jaggers, Rondell C., Pharm.D.
4	White, Sandra L., M.D., MBA, FACR

25

Drug Utilization Review Board

Attachment A

Motions - Votes

Class Reviews

June 6, 2013

ANTIFUNGALS, ORAL

Motion:

Drug	PDL Status
Griseofulvin (Oral) Microsize Tablet	NP/PA

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Ashworth, Laurel E. Pharm.D. - Chair			√		
2	Bona, Joseph R. M.D. - Co-Chair			√		
3	Carter, Karen L., M.D.			√		
4	Carter, Melissa			√		
5	Damon, Ann R., Pharm.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Gore, Thomas B., M.D.		√	√		
8	Greeson, John D., M.D., MBA			√		
9	Jones, Edwina L., Pharm.D., MBA	√		√		
10	Lorys, Robyn Pharm.D.			√		
11	May, J. Russell, Pharm.D.			√		
12	Miller, Osgood (Drew) A. R.Ph.			√		
13	Paul, Donald A., M.D.					√
14	Perri, III, Matthew, R,Ph., Ph.D.			√		
15	Yates, Mary Virginia "Ginny", Pharm.D.			√		
			TOTAL	14	0	1

	Board Members - Absent
1	Boyce, Paul D., M.D.
2	Ellis, Carl, R.Ph.
3	Jaggers, Rondell C., Pharm.D.
4	White, Sandra L., M.D., MBA, FACR

Drug Utilization Review Board

Motions - Votes

Class Reviews

June 6, 2013

ANTISPASMODICS

Motion:

Drug	PDL Status
Trospium Chloride (Oral) Tablet	NP/PA

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Ashworth, Laurel E. Pharm.D. - Chair			√		
2	Bona, Joseph R. M.D. - Co-Chair			√		
3	Carter, Karen L., M.D.			√		
4	Carter, Melissa			√		
5	Damon, Ann R., Pharm.D.	√		√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Gore, Thomas B., M.D.			√		
8	Greeson, John D., M.D., MBA			√		
9	Jones, Edwina L., Pharm.D., MBA			√		
10	Lorys, Robyn Pharm.D.			√		
11	May, J. Russell, Pharm.D.			√		
12	Miller, Osgood (Drew) A. R.Ph.			√		
13	Paul, Donald A., M.D.			√		
14	Perri, III, Matthew, R,Ph., Ph.D.			√		
15	Yates, Mary Virginia "Ginny", Pharm.D.		√	√		
			TOTAL	15	0	0

	Board Members - Absent
1	Boyce, Paul D., M.D.
2	Ellis, Carl, R.Ph.
3	Jaggers, Rondell C., Pharm.D.
4	White, Sandra L., M.D., MBA, FACR

Drug Utilization Review Board

Motions - Votes

Class Reviews

June 6, 2013

ANTIPSYCHOTICS, ATYPICAL - Long-Acting Injectables

Motion:

Drug	PDL Status	
Abilify® Maintena® (Intramuscular) Vial	**NP/PA**	The prior authorization criteria should be at parity to other atypical antipsychotic long-acting injectables

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Ashworth, Laurel E. Pharm.D. - Chair		√	√		
2	Bona, Joseph R. M.D. - Co-Chair			√		
3	Carter, Karen L., M.D.			√		
4	Carter, Melissa			√		
5	Damon, Ann R., Pharm.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Gore, Thomas B., M.D.			√		
8	Greeson, John D., M.D., MBA			√		
9	Jones, Edwina L., Pharm.D., MBA	√		√		
10	Lorys, Robyn Pharm.D.			√		
11	May, J. Russell, Pharm.D.			√		
12	Miller, Osgood (Drew) A. R.Ph.			√		
13	Paul, Donald A., M.D.			√		
14	Perri, III, Matthew, R,Ph., Ph.D.			√		
15	Yates, Mary Virginia "Ginny", Pharm.D.			√		
			TOTAL	15	0	0

	Board Members - Absent
1	Boyce, Paul D., M.D.
2	Ellis, Carl, R.Ph.
3	Jaggers, Rondell C., Pharm.D.
4	White, Sandra L., M.D., MBA, FACR

Drug Utilization Review Board

Motions - Votes

Class Reviews

June 6, 2013

BETA ADRENERGICS - SHORT-ACTING NEB SOLUTION

Motion: No changes to the current PDL status of the drugs in this class.

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Ashworth, Laurel E. Pharm.D. - Chair			√		
2	Bona, Joseph R. M.D. - Co-Chair			√		
3	Carter, Karen L., M.D.			√		
4	Carter, Melissa			√		
5	Damon, Ann R., Pharm.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Gore, Thomas B., M.D.			√		
8	Greeson, John D., M.D., MBA			√		
9	Jones, Edwina L., Pharm.D., MBA			√		
10	Lorys, Robyn Pharm.D.			√		
11	May, J. Russell, Pharm.D.	√		√		
12	Miller, Osgood (Drew) A. R.Ph.		√	√		
13	Paul, Donald A., M.D.			√		
14	Perri, III, Matthew, R,Ph., Ph.D.			√		
15	Yates, Mary Virginia "Ginny", Pharm.D.			√		
			TOTAL	15	0	0

	Board Members - Absent
1	Boyce, Paul D., M.D.
2	Ellis, Carl, R.Ph.
3	Jaggers, Rondell C., Pharm.D.
4	White, Sandra L., M.D., MBA, FACR

Drug Utilization Review Board

Motions - Votes

Class Reviews

June 6, 2013

Betalactam/Clavulanate Combinations

Motion:

Drug	PDL Status
Amoxicillin Trihydrate-Potassium Clavulanate (Oral) Tablet 250mg-125mg	**NP/PA**
Augmentin® (Oral) Suspension for Reconstitution 250mg-62.5mg/5ml	**NP/PA**

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Ashworth, Laurel E. Pharm.D. - Chair			√		
2	Bona, Joseph R. M.D. - Co-Chair			√		
3	Carter, Karen L., M.D.			√		
4	Carter, Melissa			√		
5	Damon, Ann R., Pharm.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Gore, Thomas B., M.D.			√		
8	Greeson, John D., M.D., MBA		√	√		
9	Jones, Edwina L., Pharm.D., MBA	√		√		
10	Lorys, Robyn Pharm.D.			√		
11	May, J. Russell, Pharm.D.			√		
12	Miller, Osgood (Drew) A. R.Ph.			√		
13	Paul, Donald A., M.D.			√		
14	Perri, III, Matthew, R,Ph., Ph.D.			√		
15	Yates, Mary Virginia "Ginny", Pharm.D.			√		
			TOTAL	15	0	0

	Board Members - Absent
1	Boyce, Paul D., M.D.
2	Ellis, Carl, R.Ph.
3	Jaggers, Rondell C., Pharm.D.
4	White, Sandra L., M.D., MBA, FACR

Drug Utilization Review Board

Motions - Votes

Class Reviews

June 6, 2013

CALCIUM CHANNEL BLOCKERS

Motion:

Drug	PDL Status
Isradipine (Oral) Capsule	NP/PA
Nicardipine Hydrochloride (Oral) Capsule	NP/PA
Verapamil Extended-Release PM (Oral) Capsule 24	NP/PA

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Ashworth, Laurel E. Pharm.D. - Chair			√		
2	Bona, Joseph R. M.D. - Co-Chair			√		
3	Carter, Karen L., M.D.			√		
4	Carter, Melissa			√		
5	Damon, Ann R., Pharm.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Gore, Thomas B., M.D.			√		
8	Greeson, John D., M.D., MBA			√		
9	Jones, Edwina L., Pharm.D., MBA	√		√		
10	Lorys, Robyn Pharm.D.			√		
11	May, J. Russell, Pharm.D.			√		
12	Miller, Osgood (Drew) A. R.Ph.		√	√		
13	Paul, Donald A., M.D.					√
14	Perri, III, Matthew, R,Ph., Ph.D.			√		
15	Yates, Mary Virginia "Ginny", Pharm.D.			√		
			TOTAL	14	0	1

	Board Members - Absent
1	Boyce, Paul D., M.D.
2	Ellis, Carl, R.Ph.
3	Jaggers, Rondell C., Pharm.D.
4	White, Sandra L., M.D., MBA, FACR

Drug Utilization Review Board

Attachment A

Motions - Votes

Class Reviews

June 6, 2013

CHRONIC OBSTRUCTIVE PULMONARY DISORDER INHALERS

Motion:

Drug	PDL Status
Combivent Respimat (Inhalation)	P

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Ashworth, Laurel E. Pharm.D. - Chair			√		
2	Bona, Joseph R. M.D. - Co-Chair	√		√		
3	Carter, Karen L., M.D.			√		
4	Carter, Melissa			√		
5	Damon, Ann R., Pharm.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Gore, Thomas B., M.D.			√		
8	Greeson, John D., M.D., MBA			√		
9	Jones, Edwina L., Pharm.D., MBA			√		
10	Lorys, Robyn Pharm.D.				√	
11	May, J. Russell, Pharm.D.			√		
12	Miller, Osgood (Drew) A. R.Ph.		√	√		
13	Paul, Donald A., M.D.					√
14	Perri, III, Matthew, R,Ph., Ph.D.			√		
15	Yates, Mary Virginia "Ginny", Pharm.D.			√		
			TOTAL	13	1	1

	Board Members - Absent
1	Boyce, Paul D., M.D.
2	Ellis, Carl, R.Ph.
3	Jaggers, Rondell C., Pharm.D.
4	White, Sandra L., M.D., MBA, FACR

Drug Utilization Review Board

Motions - Votes

Class Reviews

June 6, 2013

CONTRACEPTIVES - BIPHASIC - ORAL

Motion: No changes to the current PDL status of the drugs in this class.

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Ashworth, Laurel E. Pharm.D. - Chair			√		
2	Bona, Joseph R. M.D. - Co-Chair			√		
3	Carter, Karen L., M.D.			√		
4	Carter, Melissa			√		
5	Damon, Ann R., Pharm.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Gore, Thomas B., M.D.			√		
8	Greeson, John D., M.D., MBA			√		
9	Jones, Edwina L., Pharm.D., MBA			√		
10	Lorys, Robyn Pharm.D.			√		
11	May, J. Russell, Pharm.D.	√		√		
12	Miller, Osgood (Drew) A. R.Ph.		√	√		
13	Paul, Donald A., M.D.			√		
14	Perri, III, Matthew, R,Ph., Ph.D.			√		
15	Yates, Mary Virginia "Ginny", Pharm.D.			√		
			TOTAL	15	0	0

	Board Members - Absent
1	Boyce, Paul D., M.D.
2	Ellis, Carl, R.Ph.
3	Jaggers, Rondell C., Pharm.D.
4	White, Sandra L., M.D., MBA, FACR

Drug Utilization Review Board

Motions - Votes

Class Reviews

June 6, 2013

CONTRACEPTIVES - EMERGENCY

Motion:

Drug	PDL Status
Next Choice® One Dose (Oral) Tablet	P
Ella® (Oral) Tablet	NP/PA
Levonorgestrel (Oral) Tablet	NP/PA
Next Choice® (Oral) Tablet	NP/PA

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Ashworth, Laurel E. Pharm.D. - Chair	√		√		
2	Bona, Joseph R. M.D. - Co-Chair			√		
3	Carter, Karen L., M.D.			√		
4	Carter, Melissa			√		
5	Damon, Ann R., Pharm.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Gore, Thomas B., M.D.			√		
8	Greeson, John D., M.D., MBA			√		
9	Jones, Edwina L., Pharm.D., MBA			√		
10	Lorys, Robyn Pharm.D.		√	√		
11	May, J. Russell, Pharm.D.			√		
12	Miller, Osgood (Drew) A. R.Ph.			√		
13	Paul, Donald A., M.D.			√		
14	Perri, III, Matthew, R,Ph., Ph.D.			√		
15	Yates, Mary Virginia "Ginny", Pharm.D.			√		
			TOTAL	15	0	0

	Board Members - Absent
1	Boyce, Paul D., M.D.
2	Ellis, Carl, R.Ph.
3	Jaggers, Rondell C., Pharm.D.
4	White, Sandra L., M.D., MBA, FACR

Drug Utilization Review Board

Motions - Votes

Class Reviews

June 6, 2013

CONTRACEPTIVES - PROGESTINS

Motion: No changes to the current PDL status of the drugs in this class.

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Ashworth, Laurel E. Pharm.D. - Chair			√		
2	Bona, Joseph R. M.D. - Co-Chair			√		
3	Carter, Karen L., M.D.			√		
4	Carter, Melissa			√		
5	Damon, Ann R., Pharm.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Gore, Thomas B., M.D.			√		
8	Greeson, John D., M.D., MBA			√		
9	Jones, Edwina L., Pharm.D., MBA			√		
10	Lorys, Robyn Pharm.D.			√		
11	May, J. Russell, Pharm.D.	√		√		
12	Miller, Osgood (Drew) A. R.Ph.		√	√		
13	Paul, Donald A., M.D.			√		
14	Perri, III, Matthew, R,Ph., Ph.D.			√		
15	Yates, Mary Virginia "Ginny", Pharm.D.			√		
			TOTAL	15	0	0

	Board Members - Absent
1	Boyce, Paul D., M.D.
2	Ellis, Carl, R.Ph.
3	Jaggers, Rondell C., Pharm.D.
4	White, Sandra L., M.D., MBA, FACR

Drug Utilization Review Board

Motions - Votes

Class Reviews

June 6, 2013

CONTRACEPTIVES - TRIPHASIC

Motion: No changes to the current PDL status of the drugs in this class.

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Ashworth, Laurel E. Pharm.D. - Chair			√		
2	Bona, Joseph R. M.D. - Co-Chair			√		
3	Carter, Karen L., M.D.			√		
4	Carter, Melissa			√		
5	Damon, Ann R., Pharm.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Gore, Thomas B., M.D.			√		
8	Greeson, John D., M.D., MBA			√		
9	Jones, Edwina L., Pharm.D., MBA			√		
10	Lorys, Robyn Pharm.D.			√		
11	May, J. Russell, Pharm.D.	√		√		
12	Miller, Osgood (Drew) A. R.Ph.		√	√		
13	Paul, Donald A., M.D.			√		
14	Perri, III, Matthew, R,Ph., Ph.D.			√		
15	Yates, Mary Virginia "Ginny", Pharm.D.			√		
			TOTAL	15	0	0

	Board Members - Absent
1	Boyce, Paul D., M.D.
2	Ellis, Carl, R.Ph.
3	Jaggers, Rondell C., Pharm.D.
4	White, Sandra L., M.D., MBA, FACR

Drug Utilization Review Board

Motions - Votes

Class Reviews

June 6, 2013

COUGH AND COLD PRODUCTS

Motion: No changes to the current PDL status of the drugs in this class.

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Ashworth, Laurel E. Pharm.D. - Chair			√		
2	Bona, Joseph R. M.D. - Co-Chair			√		
3	Carter, Karen L., M.D.			√		
4	Carter, Melissa			√		
5	Damon, Ann R., Pharm.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Gore, Thomas B., M.D.			√		
8	Greeson, John D., M.D., MBA			√		
9	Jones, Edwina L., Pharm.D., MBA			√		
10	Lorys, Robyn Pharm.D.			√		
11	May, J. Russell, Pharm.D.		√	√		
12	Miller, Osgood (Drew) A. R.Ph.			√		
13	Paul, Donald A., M.D.			√		
14	Perri, III, Matthew, R,Ph., Ph.D.	√		√		
15	Yates, Mary Virginia "Ginny", Pharm.D.			√		
			TOTAL	15	0	0

	Board Members - Absent
1	Boyce, Paul D., M.D.
2	Ellis, Carl, R.Ph.
3	Jaggers, Rondell C., Pharm.D.
4	White, Sandra L., M.D., MBA, FACR

Drug Utilization Review Board

Motions - Votes

Class Reviews

June 6, 2013

DIABETIC - ORAL

Motion:

Drug	PDL Status
Starlix® (Oral) Tablet	**P**
Chlorpropamide (Oral) Tablet	**NP/PA**
Fortamet® (Oral) Tablet Extended-Release	**NP/PA**
Tolazamide (Oral) Tablet	**NP/PA**
Tolbutamide (Oral) Tablet	**NP/PA**

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Ashworth, Laurel E. Pharm.D. - Chair			√		
2	Bona, Joseph R. M.D. - Co-Chair			√		
3	Carter, Karen L., M.D.			√		
4	Carter, Melissa			√		
5	Damon, Ann R., Pharm.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Gore, Thomas B., M.D.			√		
8	Greeson, John D., M.D., MBA		√	√		
9	Jones, Edwina L., Pharm.D., MBA			√		
10	Lorys, Robyn Pharm.D.	√		√		
11	May, J. Russell, Pharm.D.			√		
12	Miller, Osgood (Drew) A. R.Ph.			√		
13	Paul, Donald A., M.D.			√		
14	Perri, III, Matthew, R,Ph., Ph.D.			√		
15	Yates, Mary Virginia "Ginny", Pharm.D.			√		
			TOTAL	15	0	0

	Board Members - Absent
1	Boyce, Paul D., M.D.
2	Ellis, Carl, R.Ph.
3	Jaggers, Rondell C., Pharm.D.
4	White, Sandra L., M.D., MBA, FACR

Drug Utilization Review Board

Motions - Votes

Class Reviews

June 6, 2013

DRUGS FOR GOUT

Motion: No changes to the current PDL status of the drugs in this class.

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Ashworth, Laurel E. Pharm.D. - Chair			√		
2	Bona, Joseph R. M.D. - Co-Chair			√		
3	Carter, Karen L., M.D.			√		
4	Carter, Melissa			√		
5	Damon, Ann R., Pharm.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Gore, Thomas B., M.D.			√		
8	Greeson, John D., M.D., MBA		√	√		
9	Jones, Edwina L., Pharm.D., MBA			√		
10	Lorys, Robyn Pharm.D.			√		
11	May, J. Russell, Pharm.D.			√		
12	Miller, Osgood (Drew) A. R.Ph.	√		√		
13	Paul, Donald A., M.D.			√		
14	Perri, III, Matthew, R,Ph., Ph.D.			√		
15	Yates, Mary Virginia "Ginny", Pharm.D.			√		
			TOTAL	15	0	0

	Board Members - Absent
1	Boyce, Paul D., M.D.
2	Ellis, Carl, R.Ph.
3	Jaggers, Rondell C., Pharm.D.
4	White, Sandra L., M.D., MBA, FACR

Drug Utilization Review Board

Motions - Votes

Class Reviews

June 6, 2013

FLUOROQUINOLONES, ORAL

Motion: No changes to the current PDL status of the drugs in this class.

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Ashworth, Laurel E. Pharm.D. - Chair			√		
2	Bona, Joseph R. M.D. - Co-Chair			√		
3	Carter, Karen L., M.D.			√		
4	Carter, Melissa			√		
5	Damon, Ann R., Pharm.D.		√	√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Gore, Thomas B., M.D.			√		
8	Greeson, John D., M.D., MBA			√		
9	Jones, Edwina L., Pharm.D., MBA			√		
10	Lorys, Robyn Pharm.D.			√		
11	May, J. Russell, Pharm.D.			√		
12	Miller, Osgood (Drew) A. R.Ph.	√		√		
13	Paul, Donald A., M.D.					√
14	Perri, III, Matthew, R,Ph., Ph.D.			√		
15	Yates, Mary Virginia "Ginny", Pharm.D.			√		
			TOTAL	14	0	1

	Board Members - Absent
1	Boyce, Paul D., M.D.
2	Ellis, Carl, R.Ph.
3	Jaggers, Rondell C., Pharm.D.
4	White, Sandra L., M.D., MBA, FACR

Drug Utilization Review Board

Attachment A

Motions - Votes

Class Reviews

June 6, 2013

GASTROINTESTINAL - ANTIULCER ANTIINFECTIVE

Motion:

Drug	PDL Status
Prevpac (Oral) Combination Package	**P/PA**
Pylera® (Oral) Capsule	**P/PA**

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Ashworth, Laurel E. Pharm.D. - Chair			√		
2	Bona, Joseph R. M.D. - Co-Chair			√		
3	Carter, Karen L., M.D.			√		
4	Carter, Melissa			√		
5	Damon, Ann R., Pharm.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Gore, Thomas B., M.D.			√		
8	Greeson, John D., M.D., MBA			√		
9	Jones, Edwina L., Pharm.D., MBA			√		
10	Lorys, Robyn Pharm.D.			√		
11	May, J. Russell, Pharm.D.			√		
12	Miller, Osgood (Drew) A. R.Ph.		√	√		
13	Paul, Donald A., M.D.	√		√		
14	Perri, III, Matthew, R,Ph., Ph.D.			√		
15	Yates, Mary Virginia "Ginny", Pharm.D.			√		
			TOTAL	15	0	0

	Board Members - Absent
1	Boyce, Paul D., M.D.
2	Ellis, Carl, R.Ph.
3	Jaggers, Rondell C., Pharm.D.
4	White, Sandra L., M.D., MBA, FACR

Drug Utilization Review Board

Attachment A

Motions - Votes

Class Reviews

June 6, 2013

GASTROINTESTINAL - DIGESTIVE ENZYMES

Motion: Grandfathering of members and a request for expert consultation in the future.

	Drug	PDL Status
	Pancreaze® (Oral) Capsule Delayed-Release	**NP/PA**

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Ashworth, Laurel E. Pharm.D. - Chair			√		
2	Bona, Joseph R. M.D. - Co-Chair			√		
3	Carter, Karen L., M.D.			√		
4	Carter, Melissa			√		
5	Damon, Ann R., Pharm.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Gore, Thomas B., M.D.			√		
8	Greeson, John D., M.D., MBA			√		
9	Jones, Edwina L., Pharm.D., MBA			√		
10	Lorys, Robyn Pharm.D.			√		
11	May, J. Russell, Pharm.D.	√		√		
12	Miller, Osgood (Drew) A. R.Ph.			√		
13	Paul, Donald A., M.D.			√		
14	Perri, III, Matthew, R,Ph., Ph.D.			√		
15	Yates, Mary Virginia "Ginny", Pharm.D.		√	√		
			TOTAL	15	0	0

	Board Members - Absent
1	Boyce, Paul D., M.D.
2	Ellis, Carl, R.Ph.
3	Jaggers, Rondell C., Pharm.D.
4	White, Sandra L., M.D., MBA, FACR

Drug Utilization Review Board

Motions - Votes

Class Reviews

June 6, 2013

GLUCOCORTICOIDS, ORAL

Motion: No changes to the current PDL status of the drugs in this class.

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Ashworth, Laurel E. Pharm.D. - Chair			√		
2	Bona, Joseph R. M.D. - Co-Chair			√		
3	Carter, Karen L., M.D.			√		
4	Carter, Melissa			√		
5	Damon, Ann R., Pharm.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Gore, Thomas B., M.D.			√		
8	Greeson, John D., M.D., MBA		√	√		
9	Jones, Edwina L., Pharm.D., MBA			√		
10	Lorys, Robyn Pharm.D.			√		
11	May, J. Russell, Pharm.D.			√		
12	Miller, Osgood (Drew) A. R.Ph.	√		√		
13	Paul, Donald A., M.D.			√		
14	Perri, III, Matthew, R,Ph., Ph.D.			√		
15	Yates, Mary Virginia "Ginny", Pharm.D.			√		
			TOTAL	15	0	0

	Board Members - Absent
1	Boyce, Paul D., M.D.
2	Ellis, Carl, R.Ph.
3	Jaggers, Rondell C., Pharm.D.
4	White, Sandra L., M.D., MBA, FACR

Drug Utilization Review Board

Motions - Votes

Class Reviews

June 6, 2013

HEMOSTATICS

Motion: No changes to the current PDL status of the drugs in this class.

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Ashworth, Laurel E. Pharm.D. - Chair		√	√		
2	Bona, Joseph R. M.D. - Co-Chair			√		
3	Carter, Karen L., M.D.			√		
4	Carter, Melissa			√		
5	Damon, Ann R., Pharm.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.	√		√		
7	Gore, Thomas B., M.D.			√		
8	Greeson, John D., M.D., MBA			√		
9	Jones, Edwina L., Pharm.D., MBA			√		
10	Lorys, Robyn Pharm.D.			√		
11	May, J. Russell, Pharm.D.			√		
12	Miller, Osgood (Drew) A. R.Ph.			√		
13	Paul, Donald A., M.D.			√		
14	Perri, III, Matthew, R,Ph., Ph.D.			√		
15	Yates, Mary Virginia "Ginny", Pharm.D.			√		
			TOTAL	15	0	0

	Board Members - Absent
1	Boyce, Paul D., M.D.
2	Ellis, Carl, R.Ph.
3	Jaggers, Rondell C., Pharm.D.
4	White, Sandra L., M.D., MBA, FACR

Drug Utilization Review Board

Motions - Votes

Class Reviews

June 6, 2013

HERPES AGENTS - ORAL

Motion:

Drug	PDL Status
Valacyclovir (Oral)	P
Valtrex® (Oral) Tablet	NP

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Ashworth, Laurel E. Pharm.D. - Chair			√		
2	Bona, Joseph R. M.D. - Co-Chair			√		
3	Carter, Karen L., M.D.			√		
4	Carter, Melissa			√		
5	Damon, Ann R., Pharm.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Gore, Thomas B., M.D.			√		
8	Greeson, John D., M.D., MBA			√		
9	Jones, Edwina L., Pharm.D., MBA		√	√		
10	Lorys, Robyn Pharm.D.	√		√		
11	May, J. Russell, Pharm.D.			√		
12	Miller, Osgood (Drew) A. R.Ph.			√		
13	Paul, Donald A., M.D.			√		
14	Perri, III, Matthew, R,Ph., Ph.D.			√		
15	Yates, Mary Virginia "Ginny", Pharm.D.			√		
			TOTAL	15	0	0

	Board Members - Absent
1	Boyce, Paul D., M.D.
2	Ellis, Carl, R.Ph.
3	Jaggers, Rondell C., Pharm.D.
4	White, Sandra L., M.D., MBA, FACR

Drug Utilization Review Board

Attachment A

Motions - Votes

Class Reviews

June 6, 2013

IMMUNOSUPPRESSANTS

Motion: No changes to the current PDL status of the drugs in this class.

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Ashworth, Laurel E. Pharm.D. - Chair	√		√		
2	Bona, Joseph R. M.D. - Co-Chair			√		
3	Carter, Karen L., M.D.			√		
4	Carter, Melissa			√		
5	Damon, Ann R., Pharm.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Gore, Thomas B., M.D.			√		
8	Greeson, John D., M.D., MBA			√		
9	Jones, Edwina L., Pharm.D., MBA		√	√		
10	Lorys, Robyn Pharm.D.			√		
11	May, J. Russell, Pharm.D.			√		
12	Miller, Osgood (Drew) A. R.Ph.			√		
13	Paul, Donald A., M.D.			√		
14	Perri, III, Matthew, R,Ph., Ph.D.			√		
15	Yates, Mary Virginia "Ginny", Pharm.D.			√		
			TOTAL	15	0	0

	Board Members - Absent
1	Boyce, Paul D., M.D.
2	Ellis, Carl, R.Ph.
3	Jaggers, Rondell C., Pharm.D.
4	White, Sandra L., M.D., MBA, FACR

Drug Utilization Review Board

Motions - Votes

Class Reviews

June 6, 2013

LEUKOTRIENE MODIFIERS

Motion: No changes to the current PDL status of the drugs in this class.

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Ashworth, Laurel E. Pharm.D. - Chair			√		
2	Bona, Joseph R. M.D. - Co-Chair			√		
3	Carter, Karen L., M.D.			√		
4	Carter, Melissa			√		
5	Damon, Ann R., Pharm.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Gore, Thomas B., M.D.			√		
8	Greeson, John D., M.D., MBA			√		
9	Jones, Edwina L., Pharm.D., MBA			√		
10	Lorys, Robyn Pharm.D.			√		
11	May, J. Russell, Pharm.D.			√		
12	Miller, Osgood (Drew) A. R.Ph.	√		√		
13	Paul, Donald A., M.D.					√
14	Perri, III, Matthew, R,Ph., Ph.D.		√	√		
15	Yates, Mary Virginia "Ginny", Pharm.D.			√		
			TOTAL	14	0	1

	Board Members - Absent
1	Boyce, Paul D., M.D.
2	Ellis, Carl, R.Ph.
3	Jaggers, Rondell C., Pharm.D.
4	White, Sandra L., M.D., MBA, FACR

Drug Utilization Review Board

Attachment A

Motions - Votes

Class Reviews

June 6, 2013

OPHTHALMIC MISC

Motion:

Drug	PDL Status
Neomycin-Polymyxin B-Hydrocortisone (Ophthalmic) Drops Suspension	NP/PA

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Ashworth, Laurel E. Pharm.D. - Chair			√		
2	Bona, Joseph R. M.D. - Co-Chair			√		
3	Carter, Karen L., M.D.			√		
4	Carter, Melissa			√		
5	Damon, Ann R., Pharm.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Gore, Thomas B., M.D.			√		
8	Greeson, John D., M.D., MBA		√	√		
9	Jones, Edwina L., Pharm.D., MBA			√		
10	Lorys, Robyn Pharm.D.			√		
11	May, J. Russell, Pharm.D.			√		
12	Miller, Osgood (Drew) A. R.Ph.			√		
13	Paul, Donald A., M.D.	√		√		
14	Perri, III, Matthew, R,Ph., Ph.D.			√		
15	Yates, Mary Virginia "Ginny", Pharm.D.			√		
			TOTAL	15	0	0

	Board Members - Absent
1	Boyce, Paul D., M.D.
2	Ellis, Carl, R.Ph.
3	Jaggers, Rondell C., Pharm.D.
4	White, Sandra L., M.D., MBA, FACR

Drug Utilization Review Board

Motions - Votes

Class Reviews

June 6, 2013

PRENATAL VITAMINS

Motion:

Drug	PDL Status
Citranatal® DHA Product	P
DHA Product - Cost >$26.00 per Claim	NP

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Ashworth, Laurel E. Pharm.D. - Chair		√	√		
2	Bona, Joseph R. M.D. - Co-Chair			√		
3	Carter, Karen L., M.D.			√		
4	Carter, Melissa			√		
5	Damon, Ann R., Pharm.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Gore, Thomas B., M.D.			√		
8	Greeson, John D., M.D., MBA			√		
9	Jones, Edwina L., Pharm.D., MBA	√		√		
10	Lorys, Robyn Pharm.D.			√		
11	May, J. Russell, Pharm.D.			√		
12	Miller, Osgood (Drew) A. R.Ph.			√		
13	Paul, Donald A., M.D.			√		
14	Perri, III, Matthew, R,Ph., Ph.D.			√		
15	Yates, Mary Virginia "Ginny", Pharm.D.			√		
				15	0	0

	Board Members - Absent
1	Boyce, Paul D., M.D.
2	Ellis, Carl, R.Ph.
3	Jaggers, Rondell C., Pharm.D.
4	White, Sandra L., M.D., MBA, FACR

Drug Utilization Review Board

Attachment A

Motions - Votes

Class Reviews

June 6, 2013

SEDATIVE HYPNOTICS

Motion: No changes to the current PDL status of the drugs in this class. Also, a study comparing zolpidem to other sedative hypnotics.

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Ashworth, Laurel E. Pharm.D. - Chair			√		
2	Bona, Joseph R. M.D. - Co-Chair			√		
3	Carter, Karen L., M.D.			√		
4	Carter, Melissa			√		
5	Damon, Ann R., Pharm.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Gore, Thomas B., M.D.			√		
8	Greeson, John D., M.D., MBA			√		
9	Jones, Edwina L., Pharm.D., MBA		√	√		
10	Lorys, Robyn Pharm.D.	√		√		
11	May, J. Russell, Pharm.D.			√		
12	Miller, Osgood (Drew) A. R.Ph.			√		
13	Paul, Donald A., M.D.			√		
14	Perri, III, Matthew, R,Ph., Ph.D.			√		
15	Yates, Mary Virginia "Ginny", Pharm.D.			√		
			TOTAL	15	0	0

	Board Members - Absent
1	Boyce, Paul D., M.D.
2	Ellis, Carl, R.Ph.
3	Jaggers, Rondell C., Pharm.D.
4	White, Sandra L., M.D., MBA, FACR

Drug Utilization Review Board

Motions - Votes

Class Reviews

June 6, 2013

STATINS

Motion: No changes to the current PDL status of the drugs in this class.

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Ashworth, Laurel E. Pharm.D. - Chair			√		
2	Bona, Joseph R. M.D. - Co-Chair			√		
3	Carter, Karen L., M.D.			√		
4	Carter, Melissa			√		
5	Damon, Ann R., Pharm.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.	√		√		
7	Gore, Thomas B., M.D.			√		
8	Greeson, John D., M.D., MBA			√		
9	Jones, Edwina L., Pharm.D., MBA			√		
10	Lorys, Robyn Pharm.D.			√		
11	May, J. Russell, Pharm.D.			√		
12	Miller, Osgood (Drew) A. R.Ph.			√		
13	Paul, Donald A., M.D.					√
14	Perri, III, Matthew, R,Ph., Ph.D.		√	√		
15	Yates, Mary Virginia "Ginny", Pharm.D.			√		
			TOTAL	14	0	1

	Board Members - Absent
1	Boyce, Paul D., M.D.
2	Ellis, Carl, R.Ph.
3	Jaggers, Rondell C., Pharm.D.
4	White, Sandra L., M.D., MBA, FACR

Drug Utilization Review Board

Motions - Votes

Class Reviews

June 6, 2013

TOPICAL ANTIPSORIATICS

Motion:

Drug	PDL Status
Calcipotriene (Topical) Solution	P
Dovonex® (Topical) Solution	NP/PA

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Ashworth, Laurel E. Pharm.D. - Chair		√	√		
2	Bona, Joseph R. M.D. - Co-Chair			√		
3	Carter, Karen L., M.D.			√		
4	Carter, Melissa			√		
5	Damon, Ann R., Pharm.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Gore, Thomas B., M.D.			√		
8	Greeson, John D., M.D., MBA			√		
9	Jones, Edwina L., Pharm.D., MBA			√		
10	Lorys, Robyn Pharm.D.			√		
11	May, J. Russell, Pharm.D.			√		
12	Miller, Osgood (Drew) A. R.Ph.	√		√		
13	Paul, Donald A., M.D.			√		
14	Perri, III, Matthew, R,Ph., Ph.D.			√		
15	Yates, Mary Virginia "Ginny", Pharm.D.			√		
			TOTAL	15	0	0

	Board Members - Absent
1	Boyce, Paul D., M.D.
2	Ellis, Carl, R.Ph.
3	Jaggers, Rondell C., Pharm.D.
4	White, Sandra L., M.D., MBA, FACR

Drug Utilization Review Board

Attachment A

Motions - Votes

Class Reviews

June 6, 2013

TOPICAL ANTIVIRALS

Motion:

	Drug	PDL Status
	Denavir® (Topical) Cream	NP/PA

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Ashworth, Laurel E. Pharm.D. - Chair			√		
2	Bona, Joseph R. M.D. - Co-Chair			√		
3	Carter, Karen L., M.D.			√		
4	Carter, Melissa			√		
5	Damon, Ann R., Pharm.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Gore, Thomas B., M.D.			√		
8	Greeson, John D., M.D., MBA		√	√		
9	Jones, Edwina L., Pharm.D., MBA			√		
10	Lorys, Robyn Pharm.D.	√		√		
11	May, J. Russell, Pharm.D.			√		
12	Miller, Osgood (Drew) A. R.Ph.			√		
13	Paul, Donald A., M.D.			√		
14	Perri, III, Matthew, R,Ph., Ph.D.			√		
15	Yates, Mary Virginia "Ginny", Pharm.D.			√		
			TOTAL	15	0	0

	Board Members - Absent
1	Boyce, Paul D., M.D.
2	Ellis, Carl, R.Ph.
3	Jaggers, Rondell C., Pharm.D.
4	White, Sandra L., M.D., MBA, FACR

Drug Utilization Review Board

Motions - Votes

Class Reviews

June 6, 2013

TOPICAL ENZYMES

Motion: No changes to the current PDL status of the drug in this class.

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Ashworth, Laurel E. Pharm.D. - Chair			√		
2	Bona, Joseph R. M.D. - Co-Chair			√		
3	Carter, Karen L., M.D.			√		
4	Carter, Melissa			√		
5	Damon, Ann R., Pharm.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Gore, Thomas B., M.D.			√		
8	Greeson, John D., M.D., MBA			√		
9	Jones, Edwina L., Pharm.D., MBA			√		
10	Lorys, Robyn Pharm.D.		√	√		
11	May, J. Russell, Pharm.D.	√		√		
12	Miller, Osgood (Drew) A. R.Ph.			√		
13	Paul, Donald A., M.D.			√		
14	Perri, III, Matthew, R,Ph., Ph.D.			√		
15	Yates, Mary Virginia "Ginny", Pharm.D.			√		
			TOTAL	15	0	0

	Board Members - Absent
1	Boyce, Paul D., M.D.
2	Ellis, Carl, R.Ph.
3	Jaggers, Rondell C., Pharm.D.
4	White, Sandra L., M.D., MBA, FACR

Drug Utilization Review Board

Attachment A

Motions - Votes

Class Reviews

June 6, 2013

TOPICAL GENITAL WARTS

Motion:

Drug	PDL Status
Veregen® (Topical) Ointment	NP/PA

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Ashworth, Laurel E. Pharm.D. - Chair	√		√		
2	Bona, Joseph R. M.D. - Co-Chair			√		
3	Carter, Karen L., M.D.			√		
4	Carter, Melissa			√		
5	Damon, Ann R., Pharm.D.		√	√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Gore, Thomas B., M.D.			√		
8	Greeson, John D., M.D., MBA			√		
9	Jones, Edwina L., Pharm.D., MBA			√		
10	Lorys, Robyn Pharm.D.			√		
11	May, J. Russell, Pharm.D.			√		
12	Miller, Osgood (Drew) A. R.Ph.			√		
13	Paul, Donald A., M.D.			√		
14	Perri, III, Matthew, R,Ph., Ph.D.			√		
15	Yates, Mary Virginia "Ginny", Pharm.D.			√		
			TOTAL	15	0	0

	Board Members - Absent
1	Boyce, Paul D., M.D.
2	Ellis, Carl, R.Ph.
3	Jaggers, Rondell C., Pharm.D.
4	White, Sandra L., M.D., MBA, FACR

Drug Utilization Review Board

Motions - Votes

Class Reviews

June 6, 2013

TOPICAL LOCAL ANESTHETICS

Motion: No changes to the current PDL status of the drugs in this class.

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Ashworth, Laurel E. Pharm.D. - Chair			√		
2	Bona, Joseph R. M.D. - Co-Chair			√		
3	Carter, Karen L., M.D.			√		
4	Carter, Melissa			√		
5	Damon, Ann R., Pharm.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.	√		√		
7	Gore, Thomas B., M.D.			√		
8	Greeson, John D., M.D., MBA			√		
9	Jones, Edwina L., Pharm.D., MBA			√		
10	Lorys, Robyn Pharm.D.			√		
11	May, J. Russell, Pharm.D.			√		
12	Miller, Osgood (Drew) A. R.Ph.			√		
13	Paul, Donald A., M.D.			√		
14	Perri, III, Matthew, R,Ph., Ph.D.		√	√		
15	Yates, Mary Virginia "Ginny", Pharm.D.			√		
			TOTAL	15	0	0

	Board Members - Absent
1	Boyce, Paul D., M.D.
2	Ellis, Carl, R.Ph.
3	Jaggers, Rondell C., Pharm.D.
4	White, Sandra L., M.D., MBA, FACR

Drug Utilization Review Board

Motions - Votes

Class Reviews

June 6, 2013

URINARY ANTI-INFECTIVES

Motion:

	Drug	PDL Status
	Urelle® (Oral) Tablet	NP/PA

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Ashworth, Laurel E. Pharm.D. - Chair			√		
2	Bona, Joseph R. M.D. - Co-Chair			√		
3	Carter, Karen L., M.D.			√		
4	Carter, Melissa			√		
5	Damon, Ann R., Pharm.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Gore, Thomas B., M.D.			√		
8	Greeson, John D., M.D., MBA			√		
9	Jones, Edwina L., Pharm.D., MBA			√		
10	Lorys, Robyn Pharm.D.			√		
11	May, J. Russell, Pharm.D.	√		√		
12	Miller, Osgood (Drew) A. R.Ph.			√		
13	Paul, Donald A., M.D.			√		
14	Perri, III, Matthew, R,Ph., Ph.D.			√		
15	Yates, Mary Virginia "Ginny", Pharm.D.		√	√		
			TOTAL	15	0	0

	Board Members - Absent
1	Boyce, Paul D., M.D.
2	Ellis, Carl, R.Ph.
3	Jaggers, Rondell C., Pharm.D.
4	White, Sandra L., M.D., MBA, FACR

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Manufacturers' Forum
Manufacturer Presentations

Dates: August 1, 2013

Location: NorthStar HealthCare Consulting
1121 Alderman Drive
Suite 112
Alpharetta, Georgia 30005

Attendees
Department of Community Health
Linda Wiant, PharmD, Director, Pharmacy Services
Trent Leonard, PharmD Candidate

NorthStar HealthCare Consulting
Tara R. Cockerham, PharmD, Clinical Programs Director
Emily Baker, PharmD, BCPS, MBA, MHA, President
Nekia Austin, PharmD, JD, Director, Program Compliance
Sook Kim, PharmD Candidate

Catamaran Health Solutions
Talmahjia "Tami" Sweat, PharmD, Clinical Systems Product Manager

Drug Summary Documents
Please note that relevant, electronic materials that were provided by manufacturers were forwarded to the Drug Utilization Review Board (DURB). For the drugs presented at the Forum, the information is highlighted below. The manufacturers presenting at the Forum referred the audience and the readers of the materials to the prescribing information for additional information on the drug, especially in regards to safety.

Drug Presentations

I. GlaxoSmithKline
Gabrial Zimmer Lott, PharmD, Sr. Regional Medical Scientist
Vivian Lee Ryan, Executive Account Manager

Relenza® (zanamivir powder for oral inhalation)
Relenza is indicated for treatment of uncomplicated acute illness due to influenza A and B virus in adults and pediatric patients aged 7 years and older who have been symptomatic for no more than 2 days. *Relenza* is indicated for prophylaxis of influenza in adults and pediatric patients aged 5 years and older.

About Relenza
- *Relenza* is an inhibitor of influenza virus neuraminidase, an enzyme common to both influenza A and B and essential for release of viral progeny from infected respiratory epithelial cells. Inhibition of the activity of this enzyme prevents release of newly formed virus from infected cells and reduces the spread of virus within the respiratory tract.
- In controlled clinical trials, there were no variants of influenza A or B virus noted to be resistant to *Relenza*. Viruses with reduced susceptibility have been recovered *in vitro* and a variant virus emerged following investigational treatment with zanamivir in an immunocompromised child infected with influenza B virus.

Important Limitations on the Use of Relenza
- *Relenza* is not recommended for treatment or prophylaxis of influenza in individuals with underlying airways disease (such as asthma or COPD) due to risk of serious bronchospasm.
- *Relenza* has not been proven effective for treatment of influenza in individuals with underlying airways disease.
- *Relenza* has not been proven effective for prophylaxis of influenza in the nursing home setting.
- *Relenza* is not a substitute for early influenza vaccination on an annual basis as recommended by the Centers for Disease Control's Immunization Practices Advisory Committee.

- Influenza viruses change over time. Emergence of resistance mutations could decrease drug effectiveness. Other factors (for example, changes in viral virulence) might also diminish clinical benefit of antiviral drugs. Prescribers should consider available information on influenza drug susceptibility patterns and treatment effects when deciding whether to use *Relenza*.
- There is no evidence for efficacy of zanamivir in any illness caused by agents other than influenza virus A and B.
- Patients should be advised that the use of *Relenza* for treatment of influenza has not been shown to reduce the risk of transmission of influenza to others.

Studies on Treatment of Influenza

- **Adult Patients**: A Phase II and a Phase III study conducted in North America (total of over 600 influenza-positive patients) suggested up to 1 day of shortening of median time to improvement in symptoms in patients receiving zanamivir compared with placebo, although statistical significance was not reached in either of these studies. In a study conducted in the Southern Hemisphere (321 influenza-positive patients), a 1.5-day difference in median time to symptom improvement was observed.
- **Pediatric Patients**: Results from a study in 471 pediatric patients aged 5 to 12 years who received *Relenza* 10 mg twice daily for the treatment of influenza A and B showed a 1 day improvement in the median time to alleviation of clinically significant symptoms of influenza compared to placebo.

Studies on Prophylaxis of Influenza

- **Household Setting**: Two studies assessed post-exposure prophylaxis in household contacts of an index case. In the first study (index cases treated), the proportion of households with at least 1 new case of symptomatic laboratory-confirmed influenza was reduced from 19.0% (32 of 168 households) for the placebo group to 4.1% (7 of 169 households) for the group receiving *Relenza*. In the second study (index cases were not treated), the incidence of symptomatic laboratory-confirmed influenza was reduced from 19.0% (46 of 242 households) for the placebo group to 4.1% (10 of 245 households) for the group receiving *Relenza*. In this study, the incidence of symptomatic laboratory-confirmed influenza was reduced from 1.4% (23 of 1,685) for the placebo group to 0.2% (4 of 1,678) for the group receiving *Relenza*.
- **Community Setting**: Two seasonal prophylaxis studies assessed *Relenza* versus placebo during community outbreaks. In the first study, the incidence of symptomatic laboratory-confirmed influenza was reduced from 6.1% (34 of 554) for the placebo group to 2.0% (11 of 553) for the group receiving *Relenza*. In the second study, the incidence of symptomatic laboratory-confirmed influenza was reduced from 1.4% (23 of 1,685) for the placebo group to 0.2% (4 of 1,678) for the group receiving *Relenza*.

Contraindications

- Do not use *Relenza* in patients with a history of allergic reaction to any ingredient of *Relenza* including milk proteins.

Warnings and Precautions

- **Bronchospasm**: *Relenza* is not recommended for treatment or prophylaxis of influenza in individuals with underlying airways disease (such as asthma or chronic obstructive pulmonary disease). Serious cases of bronchospasm, including fatalities, have been reported during treatment with *Relenza* in patients with and without underlying airways disease. Many of these cases were reported during postmarketing and causality was difficult to assess.
- **Allergic Reactions**: Allergic-like reactions, including oropharyngeal edema, serious skin rashes, and anaphylaxis have been reported in postmarketing experience with *Relenza*. *Relenza* should be stopped and appropriate treatment instituted if an allergic reaction occurs or is suspected.
- **Neuropsychiatric Events**: Influenza can be associated with a variety of neurologic and behavioral symptoms which can include events such as seizures, hallucinations, delirium, and abnormal behavior, in some cases resulting in fatal outcomes. Because these events were reported voluntarily during clinical practice, estimates of frequency cannot be made, but they appear to be uncommon based on usage data for *Relenza*.
- **Limitations of Populations Studies**: Safety and efficacy of *Relenza* have not been demonstrated in patients with high-risk underlying medical conditions.
- **Bacterial Infections**: Serious bacterial infections may begin with influenza-like symptoms or may coexist with or occur as complications during the course of influenza. *Relenza* has not been shown to prevent such complications.
- **Importance of Proper Route of Administration**: *Relenza* Inhalation Powder must not be made into an extemporaneous solution for administration by nebulization or mechanical ventilation. There have been reports of hospitalized patients with influenza who received a solution made with *Relenza* Inhalation Powder administered by nebulization or mechanical ventilation, including a fatal case where it was reported that the lactose in this

formulation obstructed the proper functioning of the equipment. *Relenza* Inhalation Powder must only be administered using the device provided.
- **Importance of Proper Use of Diskhaler**: Effective and safe use of *Relenza* requires proper use of the *Diskhaler* to inhale the drug.

Safety
- In treatment studies, individual adverse events occurred at rates of 5% or less in adults, adolescents and pediatric patients. Adverse events which occurred at rates >2% included: ear, nose and throat infections, diarrhea, nausea, nasal signs and symptoms, and sinusitis.
- In prophylaxis studies, individual adverse events occurred at rates 24% or less in adults, adolescents and pediatric patients. Adverse events which occurred at rates >2% included: headaches, throat and tonsil discomfort and pain, cough, viral respiratory infections, nasal signs and symptoms, temperature regulation disturbances, muscle pain, malaise and fatigue, musculoskeletal pain, and feeding problems.

Questions and Answers
Q: Are there any studies that show impact of prior authorization on outcomes of zanamivir?
A: No, none that the presenter is aware of.

Q: Are there any head-to-head trials with zanamivir?
A: There are inferiority and superiority studies but none have shown one neuraminidase inhibitor is better than the other.

Q: Is a different formulation being studied?
A: No, other formulations were not successful; there is an intravenous (IV) formulation available to hospitalized patients for compassionate use.

Q: How many days does zanamivir shorten influenza symptoms by?
A: 1 to 1.5 days.

II. Aegerion

Rabecka Martin, PhD, Senior Medical Science Liaison
Nancy Wilson, RPh, CIP, National Account Manager

Juxtapid™ (lomitapide)
Lomitapide is a first in class oral, selective inhibitors of microsomal triglyceride transfer protein (MTP) as an adjunct to a low-fat diet and other lipid-lowering treatments, including LDL apheresis where available, to reduce low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), apolipoprotein B (apo B), and non-high-density lipoprotein cholesterol (non-HDL-C) in patients with homozygous familial hypercholesterolemia (HoFH).

Limitations of Use
- The safety and effectiveness of JUXTAPID have not been established in patients with hypercholesterolemia who do not have HoFH.
- The effect of JUXTAPID on cardiovascular morbidity and mortality has not been determined.

Warning
- JUXTAPID (lomitapide) is associated with a risk of hepatotoxicity.
- It should also be noted that safety and effectiveness of JUXTAPID (lomitapide) has not been established in pediatric patients.

Pivotal Phase 3 Clinical Study
- A multi-site, multi-national, Phase 3 study was conducted which utilized a single-arm, open-label, dose-escalation design to evaluate the efficacy and long-term safety of lomitapide in the treatment of adults with HoFH.

- Twenty-nine patients were enrolled and had a clinical diagnosis of HoFH by at least one of the following three criteria: genetic confirmation, skin fibroblast LDL receptor activity <20% of normal, and/or untreated total cholesterol (TC) >500 mg/dL plus triglycerides <300 mg/dL, with both parents having untreated TC >250 mg/dL. In this trial, the mean age was 30.7 years (range, 18 to 55 years), 16 (55%) patients were men, 25 (86%) patients were Caucasian, 2 (7%) were Asian, 1 (3%) was African American, and 1 (3%)was multi-racial. Eligible patients entered a minimum 6 week run-in phase during which they were to be on a stable dose of their current regimen of LLTs, including apheresis, initiate a low-fat diet supplying < 20% energy as fat and take dietary supplements that provided approximately 400 international units vitamin E, 210 mg alpha-linolenic acid (ALA), 200 mg linoleic acid, 110 mg eicosapentaenoic acid (EPA), and 80 mg docosahexaenoic acid (DHA) per day. Following the run-in phase, patients entered a 26 week efficacy phase during which they were started on low-dose lomitapide, 5 mg/day, for 2 weeks, followed by escalations at 4 week intervals on an individual basis to their maximum tolerated dose with a target of 60 mg/day (i.e., 10, 20, 40, and 60 mg/day). Background LLT was stabilized from the run-in phase through the efficacy phase to Week 26. All patients received dietary counseling and were instructed to consume a diet containing <20% of energy from total dietary fat. During the safety phase (Week 26-78), patients continued to administer lomitapide at their individually determined maximum tolerated dose as defined in the efficacy phase. Adjustments to LLT were permitted during the safety phase. During the entire trial, the lomitapide dose could be decreased if dose modification criteria were met. Patients who completed the study were eligible to enter an optional open-label Phase 3 extension study designed to evaluate long-term safety and efficacy. Those who did not elect to enroll in the extension study entered a 6-week follow up period after the last dose of lomitapide during which they remained on their stable concomitant LLT regimen and attended a final study visit at Week 84.
- The primary efficacy endpoint was percent change in LDL-C from baseline to the end of the efficacy phase, Week 26, for the intent to treat (ITT) population. The key secondary efficacy parameters were TC, apo B, and triglycerides. Additional secondary parameters included non-HDL-C, VLDL-C, HDL-C, and Lp(a). In addition to safety laboratory analyses, nuclear magnetic resonance spectroscopy (NMRS)/MRI of the liver was obtained to evaluate hepatic fat content throughout the study. Of the 29 patients enrolled in the study, 23 (79%) completed the efficacy phase (Weeks 0-26) as well as the entire 78 weeks of treatment. Treatment with lomitapide at an individualized maximum tolerated dose, concurrently with other LLTs and a low-fat diet for 26 weeks (mean caloric intake from fat was in the range of 24-27% during the Efficacy Phase) significantly reduced LDL-C. In the ITT population (N=29, with missing data from non-completers being imputed via last observation carried forward, LOCF), mean LDL-C decreased from 336 mg/dL at baseline to 190 mg/dL at the end of the efficacy phase (Week 26/LOCF), representing a statistically significant and clinically meaningful mean change from baseline of -40% ($p<0.001$).
- The change in LDL-C in the completer population was -50% from baseline to Week 26. The mean dose taken by patients at the end of the efficacy phase was 38.4 mg in the ITT population (LOCF) and 44.6 mg in the completer population. A dose response was evident, with progressive reduction in LDL-C during the dose escalation in the efficacy phase. Mean dose taken by patients in the study was 40.2 mg for the safety phase. Reductions in LDL-C were maintained during the safety phase with mean change from baseline to Week 56 of -44.0% ($p <0.001$) and to Week 78 of -38.4% ($p <0.001$, Figure 2). At the end of the efficacy phase, 8 patients (35%) had an LDL-C <100 mg/dL with one of these patients having an LDL-C <70 mg/dL. During the 1 year safety phase lipids were measured ~ every 10 weeks. During this time, 8 patients had at least one LDL-C value <100 mg/dL and 3 patients had at least one value <70 mg/dL. At the beginning of the safety phase, 13 of the 23 patients (57%) were receiving apheresis. During the safety phase, when concomitant lipid-lowering therapies could be modified, 6 of these patients (46%) had a permanent change to their apheresis regimen; patients permanently stopped apheresis; and 3 patients permanently increased the interval in between apheresis treatments.
- Significant reductions were also seen in the secondary lipid and lipoprotein parameters at Week 26, with reductions largely maintained throughout the remainder of the study. Mean percent changes from baseline to Week 26/LOCF were -36% for TC, -39% for apo B, -45% for triglycerides (median), -40% for non-HDL-C, and -29% for VLDL-C.). Mean percent changes from baseline to Week 78 were as follows: TC, -35%; apo B, -43%; triglycerides (median), -42%; non-HDL- C, -39%; and VLDL-C, –31%. Mean percent change in HDL-C from baseline to Week 26/LOCF was -7% and was not statistically significant; levels trended towards baseline by week 78 (mean percent change was -5% compared to baseline). The median percent change in Lp(a) from baseline to Week 26/LOCF was -13%. The median percent changes in Lp(a) for the completer population were -26%, -21%, and -4%% at Weeks 26, 56, and 78, respectively.

Phase 3 Safety Data

- Adverse events reported by ≥8 (28%) patients in the trial included: diarrhea, nausea, vomiting, dyspepsia, and abdominal pain. Other common adverse events, reported by 5 to 7 (17-24%) patients, included weight loss, abdominal discomfort, abdominal distension, constipation, flatulence, increased ALT, chest pain, influenza, nasopharyngitis, and fatigue. Six of the 29 HoFH patients enrolled in the study withdrew (all during the efficacy phase). Five (17%) of the patients who withdrew did so due to treatment emergent adverse events and 4 of these

were gastrointestinal-related. Adverse events that contributed to treatment discontinuations included 2 patients (7%) with diarrhea, 1 patient (3%) with abdominal pain, nausea, gastroenteritis, weight loss, headache, and 1 patient (3%) with difficulty controlling INR on warfarin.

- The most common adverse events were gastrointestinal events and were reported by 27 (93%) of 29 patients during the efficacy phase. A lower incidence of gastrointestinal events was reported during the safety phase (74%), during which time patients were maintained on their maximally tolerated dose of lomitapide. The majority of gastrointestinal AEs were classified as mild to moderate in intensity. Gastrointestinal adverse events of severe intensity were reported by 6 (21%) of 29 patients, with the most common being diarrhea (4 patients, 14%); vomiting (3 patients, 10%); and abdominal pain, distension, and/or discomfort (2 patients, 7%).
- Elevated serum liver transaminases were observed during lomitapide treatment. Shifts of ≥3 x ULN in ALT and/or AST were observed in 10 patients (33%); shifts of ≥5 x ULN (defined as two laboratory values separated by at least 7 days) were observed in 4 patients (14%), while 1 patient had a transient elevation ≥10 x ULN. In all 4 patients with confirmed shifts of ≥5 x ULN in ALT and/or AST, ALT/AST elevations fell below this level within 1 to 4 weeks by reducing the dose or interrupting treatment. There were no concomitant changes in bilirubin or alkaline phosphatase in these patients, and no patients discontinued lomitapide due to abnormal LFTs. Among the 19 patients who completed the 78-week trial and subsequently enrolled in the HoFH extension study, one discontinued because of increased transaminases that persisted despite several dose reductions, and one temporarily discontinued because of markedly elevated transaminases (ALT 24x ULN, AST 13x ULN) that had several possible causes, including a drug-drug interaction between lomitapide and the strong CYP3A4 inhibitor, clarithromycin. Increases in mean hepatic fat were observed. Mean percent hepatic fat increased from 1.0% at baseline, to 9% at Week 26, and then stabilized at Weeks 56 and 78, at 7.3% and 8.2% respectively.

Questions and Answers

Q: Does lomitapide have a limited distribution?
A: Yes, lomitapide is only available through a REMS program and one specialty pharmacy, Centrix.

Q: Which health plans can enroll in the Juxtapid cost assistance program?
A: Commercial, Medicaid and Medicare plans with an agreement.

III. Hyperion

John Fiorito, PharmD, Medical Science Liaison
Brian J. Groch, Senior Director, Payer and Trade Accounts
Deborah Howard Mance, CPC, Associate Director, Payer and Trade Accounts

Ravicti® (glycerol phenylbutyrate)

RAVICTI (glycerol phenylbutyrate) oral liquid is indicated for the treatment of urea cycle disorders.

Background

- Urea cycle disorders are rare (~1,100 diagnosed patients in the US) inborn errors of metabolism resulting in an inability to excrete nitrogen from the body, resulting in hyperammonemia. Untreated hyperammonemia can cause neurocognitive impairment, developmental delays, lethargy, seizures, stroke, irreversible brain damage, coma and death. Early and consistent treatment, including dietary management and potential use of alternative pathway agents is important.
- RAVICTI was FDA approved on February 1, 2013 as a nitrogen-binding agent for chronic management of adult and pediatric patients greater than or equal to 2 years of age with urea cycle disorders that cannot be managed by dietary protein restriction and/or amino acid supplementation alone. RAVICTI must be used with dietary protein restriction and, in some cases, dietary supplements. RAVICTI is not indicated for the treatment of acute hyperammonemia in patients with UCD, the safety and efficacy of RAVICTI has not been established in N-acetylglutamate synthase (NAGS) deficiency, and the use of RAVICTI in patients <2 months of age is contraindicated because it is unknown if children of this age have mature enough pancreatic enzyme function to absorb phenylbutyrate.
- RAVICTI was developed as an alternative to BUPHENYL (sodium phenylbutyrate) for the chronic management of UCD patients. BUPHENYL contains high amounts of sodium, often requiring consumption of a large number of pills (up to 40/day) with an unpleasant taste and smell. In contrast, RAVICTI is sodium free and a nearly odorless and tasteless liquid. A little over one teaspoon of RAVICTI three times a day is equal to 40 BUPHENYL pills (20 grams).

Clinical Efficacy

- RAVICTI has been studied in five clinical trials involving ~ 100 total UCD patients including 49 pediatric patients aged 2 months to 17 years, representing approximately 20% of all patients currently treated with BUPHENYL.
- In four controlled, short-term, switch-over studies in pediatric and adult patients that had been stable on BUPHENYL therapy and underwent 24 hour ammonia measurement after 7 or 14 days on BUPHENYL or RAVICTI, RAVICTI consistently demonstrated non-inferiority of ammonia control compared to BUPHENYL across studies and subpopulations. As compared with BUPHENYL, total urinary output of PAGN during RAVICTI dosing in the pivotal study was nearly identical overall, but more evenly distributed over 24 hours (output from 0-12 and 12-24 hours = 8.2 and 5.4 grams on NaPBA ($p<0.0001$) vs 7.1 and 6.4 grams on RAVICTI ($p=0.2182$).
- Although not allowed in the FDA labeling in a pooled analysis of these trials ammonia control with RAVICTI was demonstrated to be significantly lower ($p<0.05$) to that of BUPHENYL.
- At the end of three of the short-term trials patients were given the choice to remain on RAVICTI in long-term extension trials; >90% of patients chose to remain on RAVICTI. In the long-term, open label extension trials RAVICTI treated pediatric and adult UCD patients experienced average monthly ammonia levels below the upper limit of normal. During a one year treatment with RAVICTI 16 patients had a total of 23 hyperammonemic crises. Although not allowed in the FDA labeling, in the year prior to enrolling in the studies while being treated with BUPHENYL, 25 patients experienced a total of 45 hyperammonemic crises.

Clinical Safety

- Neuropsychological tests in long-term studies showed no change in adult UCD patients. Among the tests performed in pediatric patients 6-17 years of age (n=26), no change was noted in tests for IQ or behavior, but improvement was observed in executive cognitive function as mentioned in the Behavior Rating Inventory of Executive Function (BRIEF) assessment . As with the data pertaining to hyperammonemic crises, these data were not allowed in the FDA labeling for RAVICTI therapy.
- Common AE (>10%) reported in the long term studies with RAVICTI, regardless of causality, included nausea, vomiting, diarrhea, dizziness, headache, fatigue, abdominal pain and rash.

Summary

- In sum, RAVICTI is an important newly approved treatment for the chronic management of urea cycle disorder patients.

Questions and Answers

Q: What are considered the advantages of Ravicti over Buphenyl?
A: Superior ammonia control; decreased administration burden; improved smell, taste and administration which can increase compliance and thus improve ammonia control and cognitive function; can use in patients with congestive heart failure or renal impairment.

Q: When is the generic version of the tablet formulation of Buphenyl expected?
A: Not expected soon.

Q: How are other Medicaid plans covering?
A: Maryland and Indiana have preferred on PDL; New York does not have on PDL.

Q: What is the approximate AWP cost per year per patient?
A: Approximately $250,000 per year per patient.

IV. Bristol-Myers Squibb and Pfizer

Manan Shah, PharmD, PhD, Director, Health Services & Outcomes Research
David Reed, MD, FACP, Senior Director, Regional Medical & Research Specialist
Tom Heard, RPh, CGP, Associate Director, Medical Outcomes Specialist

Eliquis® (apixaban)

ELIQUIS is indicated to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation (NVAF).

Clinical Studies

- Two double-blind, multinational studies evaluated ELIQUIS for risk reduction of stroke and systemic embolism in patients with NVAF. Patients had to have one or more of the following additional risk factors for stroke: prior stroke or transient ischemic attack (TIA), prior systemic embolism (ARISTOTLE only), age ≥75 years, arterial

hypertension requiring treatment, diabetes mellitus, heart failure ≥ New York Heart Association Class 2, left ventricular ejection fraction ≤ 40% (≤ 35% for AVERROES), documented peripheral artery disease (AVERROES only).

ARISTOTLE: ELIQUIS vs. Warfarin

- A total of 18,201 patients were randomized to ELIQUIS 5 mg twice daily (or 2.5 mg twice daily) or warfarin (target INR range 2.0-3.0) and followed for a median of 89 weeks.
- ELIQUIS was superior to warfarin with a 21% relative risk reduction (RRR) for the primary endpoint of reducing the risk of stroke and systemic embolism (1.27%/yr vs. 1.60%/yr, HR 0.79 [0.66, 0.95], *P*=0.01). Superiority to warfarin was primarily attributable to a reduction in hemorrhagic stroke and ischemic strokes with hemorrhagic conversion compared to warfarin. Purely ischemic strokes occurred with similar rates on both drugs.
- ELIQUIS resulted in a significantly lower rate of all-cause death (*P*=0.046) versus warfarin, primarily because of a reduction in cardiovascular death, particularly stroke deaths. Non-vascular death rates were similar.
- ELIQUIS was superior to warfarin for the primary safety endpoint of major bleeding with a 31% RRR (2.13%/yr vs. 3.09%/yr, HR 0.69 [0.60, 0.80], *P*<0.0001).
    - Major gastrointestinal (GI) bleeds were lower with ELIQUIS compared to warfarin (0.83%/yr vs. 0.93%/yr, HR=0.89 [0.70, 1.14]).
    - Intracranial hemorrhage (ICH) events were lower with ELIQUIS compared to warfarin (0.33%/yr vs. 0.82%/yr, HR=0.41 [0.30, 0.57]).
    - Major intraocular bleeds were numerically higher with ELIQUIS compared to warfarin (0.21%/yr vs. 0.14%/yr, HR=1.42 [0.83, 2.45]).
    - Fatal bleeds were lower with ELIQUIS compared to warfarin (0.06%/yr vs. 0.24%/yr, HR=0.27 [0.13, 0.53]).
- ELIQUIS demonstrated fewer clinically relevant non major bleeding (CRNM) vs. warfarin (2.08%/yr vs. 3.00%/yr, HR= 0.70 [0.60, 0.80], *P*<0.0001]).
- The most common reason for treatment discontinuation was for bleeding-related adverse reactions; this occurred in 1.7% and 2.5% of patients treated with ELIQUIS and warfarin.
- The results for the primary efficacy endpoint were generally consistent across most major subgroups including weight, CHADS2 score, prior warfarin use, level of renal impairment, geographic region, ELIQUIS dose, type of AF, and aspirin use at randomization.
- The results for major bleeding were generally consistent across most major subgroups including age, weight, CHADS2 score, prior warfarin use, geographic region, ELIQUIS dose, type of AF, and aspirin use at randomization. Subjects treated with apixaban with diabetes bled more (3.0%/year) than did subjects without diabetes (1.9%/year).

AVERROES: ELIQUIS vs. Aspirin

- Patients thought not to be candidates for warfarin therapy were randomized to treatment with ELIQUIS 5 mg twice daily (or 2.5 mg twice daily) or aspirin 81 to 324 mg once daily. AVERROES was stopped early on the basis of a prespecified interim analysis showing reduction in stroke and systemic embolism for apixaban compared to aspirin that was associated with a modest increased in major bleeding.
- ELIQUIS was statistically superior to aspirin with a 55% relative risk reduction for the primary endpoint of stroke and systemic embolism (1.62%/yr vs. 3.63%/yr, HR 0.45 [0.32, 0.62], *P*<0.0001).
- ELIQUIS was associated with an increase in major bleeding compared to aspirin that was not statistically significant (1.41%/year vs. 0.92%/year, HR 1.54 [0.96, 2.45], *P*=0.07).
- The most common reason for treatment discontinuation was for bleeding-related adverse reactions; this occurred in 1.5% and 1.3% on ELIQUIS and aspirin.

Pharmacoeconomics

- Based on a medical cost avoidance analysis, which used the event rates derived from ARISTOTLE trial, ELIQUIS was estimated to deliver medical cost avoidance ($485 in a patient year vs. warfarin, in 2010 dollars) both by reducing the incidence of stroke and having a lower risk for bleeding as compared with warfarin.

Warnings and Precautions

- **BLACK BOX WARNING - Increased Risk of Stroke with Discontinuation of ELIQUIS:** Discontinuing ELIQUIS in the absence of adequate alternative anticoagulation increases the risk of thrombotic events. An increased rate of stroke was observed during the transition from ELIQUIS to warfarin in clinical trials in patients with nonvalvular atrial fibrillation. If ELIQUIS must be discontinued for a reason other than pathological bleeding, consider coverage with another anticoagulant.
- **Bleeding Risk:** ELIQUIS increases the risk of bleeding and can cause serious, potentially fatal bleeding. Concomitant use of drugs affecting hemostasis increases the risk of bleeding including aspirin and other anti-platelet agents, other anticoagulants, heparin, thrombolytic agents, SSRIs, SNRIs, and NSAIDs. Patients should

be made aware of signs or symptoms of blood loss and instructed to immediately report to an emergency room. Discontinue ELIQUIS in patients with active pathological hemorrhage.
- **Prosthetic Heart Valves:** The safety and efficacy of ELIQUIS has not been studied in patients with prosthetic heart valves and is not recommended in these patients.

Questions and Answers
Q: What are considered the advantages of Eliquis over other anticoagulants?
A: Only anticoagulant to demonstrate superiority over warfarin to reduce the risk of stroke and systemic embolism as well as major bleeding and all-cause mortality in patients with nonvalvular atrial fibrillation.

Q: How are other Medicaid plans covering?
A: Florida added as preferred with prior authorization for indication only; Texas and Nevada added as preferred without prior authorization; hospitals are adding to formularies.

Q: Are other indications being sought?
A: A supplemental new drug application has been submitted for prevention of venous thromboembolism following hip or knee replacement surgery.

V. Amarin

David Wrenn, PhD, Senior Medical Science Liaison
Kelli Frank, National Account Manager

Vascepa® (icosapent ethyl)
VASCEPA®, an ethyl ester of the omega-3 fatty acid eicosapentaenoic acid (EPA) is indicated as an adjunct to diet to reduce triglyceride levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia. The effect of VASCEPA® on cardiovascular mortality and morbidity or the risk for pancreatitis in patients with severe hypertriglyceridemia has not been determined.

Triglycerides are a type of fat in the bloodstream and severe hypertriglyceridemia increases the risk of acute pancreatitis. It is estimated that approximately four million adults in the United States have triglyceride levels above 500mg/dL.

VASCEPA® is the first EPA only omega-3 fatty acid with an FDA approval for very high triglycerides, which is defined as a triglyceride level of greater than or equal to 500 mg/dL. It is the only agent in the Omega-3 fatty acid class that effectively lowers triglycerides without increasing LDL cholesterol in this patient population.

FDA approval was based on a prospective, randomized, placebo-controlled 12-week trial called MARINE4. In this study, adult patients with very high triglycerides were randomized to receive either 4 grams of VASCEPA® daily or matched placebo. Twenty five percent of patients were on concomitant statin therapy and 28% were diabetic. Compared to placebo, VASCEPA® significantly reduced triglycerides by 33%, the primary endpoint and importantly, did not increase median LDL cholesterol. Other agents in this treatment class such as prescription Omega-3s and fibrates, report an average or median LDL cholesterol rise of approximately 45%.

VASCEPA® was also effective in patients with higher baseline triglyceride levels of greater than 750mg/dL, significantly reducing median placebo-adjusted triglycerides by 45%. Other beneficial lipid effects included a 16% reduction in total cholesterol, 18% decrease in non-HDL cholesterol and a 29% reduction in VLDL cholesterol, all relative to placebo. VASCEPA® also significantly reduced median placebo-adjusted hsCRP by 36% and Lp-PLA2 by 14%. There was no significant change in HDL cholesterol in this patient population.

In addition, lipoprotein particle numbers were significantly decreased as evidenced by a 9% placebo-adjusted reduction in apoB. The National Lipid Association Expert Panel states that ApoB or particle number is a better indicator of cardiovascular risk than LDL cholesterol or LDL size7.

VASCEPA® has a tolerability and safety profile similar to placebo the most common reported adverse reaction was arthralgia, reported at an incidence of 2.3% versus 1% in placebo.

The FDA has accepted Amarin's filing of a supplemental New Drug Application for VASCEPA® seeking approval for use as an adjunct to diet in the treatment of adult patients with high triglycerides (≥200 mg/dL and < 500 mg/dL) with mixed dyslipidemia. This sNDA submission is based on the published ANCHOR trial, and Amarin has been assigned a

PDUFA date of December 20th, 2013. In addition, the effects of VASCEPA® on major coronary events is being investigated in REDUCE-IT, an outcomes study of approximately 8,000 patients with elevated triglycerides over a 4 to 6 year period.

Questions and Answers
Q: Approximately how many patients have triglyceride levels ≥500 mg/dL?
A: Approximately 1% of hypertriglyceridemia patients.

Q: What are considered the advantages of Vascepa over Lovaza?
A: Similar efficacy in lowering triglycerides, does not raise LDL and decreases markers.

Q: Are there head-to-head trials vs. Lovaza?
A: Not yet.

Q: Have any outcomes studies been conducted?
A: There is a phase III, 5-year trial ongoing that is evaluating major cardiovascular events as the primary endpoint and is secondarily assessing particle size and number as well as patients with diabetes.

VI. Eisai

Stefanie Cribb, PharmD, Sr Medical Science Liaison
Kirk Burns, Regional Account Manager
Anthony N. Duca, National Account Manager

Belviq® (lorcaserin)
CMS stated their commitment to finding appropriate ways of preventing obesity, beginning with reimbursement of screening and counseling, and has acknowledged that good treatment options are needed to prevent this epidemic from reaching catastrophic proportions.

Indication
BELVIQ is Indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults who are overweight (BMI≥27 kg/m_2) with at least one weight-related comorbid condition (e.g., hypertension, dyslipidemia, type 2 diabetes) or who are obese (BMI≥30 kg/m_2).

Limitations of Use
The safety and efficacy of co-administration of BELVIQ with other products intended for weight loss, including prescription drugs (e.g., phentermine), over-the-counter drugs, and herbal preparations, have not been established. The effect of BELVIQ on cardiovascular morbidity and mortality has not been established.

Clinical Efficacy
- BELVIQ, along with a reduced caloric intake and increased physical activity, was associated with clinically meaningful and sustained weight loss in adults with obesity (BMI≥30 kg/m_2) or adults who are overweight (BMI≥27 kg/m_2) with a weight related comorbidity. The safety and efficacy of co-administration of BELVIQ with other products intended for weight loss have not been established. The effect of BELVIQ on cardiovascular morbidity and mortality has not been established.
- BELVIQ was approved on the basis of 3 pivotal randomized, double-blind, placebo-controlled trials. Two trials were pooled and included over 7,000 patients who were overweight with at least one weight-related comorbid condition such as hypertension or dyslipidemia or patients who were obese. A third study included over 604 obese or overweight patients with inadequately controlled type 2 diabetes. In each trial, BELVIQ, along with a reduced caloric intake and increased physical activity, was associated with clinically meaningful weight loss over 52 weeks. Clinical trials demonstrated that BELVIQ met all three co-primary endpoints which included ≥ 5% weight loss, ≥ 10% weight loss, and mean weight change vs. diet and exercise alone. BELVIQ was also associated with changes in cardiometabolic parameters, including total cholesterol, HDL, systolic and diastolic blood pressure, and fasting insulin in the patients without diabetes, and improvements in A1c and fasting plasma glucose in overweight patients with type 2 diabetes.

Clinical Safety
- BELVIQ is contraindicated during pregnancy, because weight loss offers no potential benefit to a pregnant woman and may result in fetal harm. Please see additional important safety information, including warnings and precautions below.

- The most common adverse reactions in patients without diabetes were headache, dizziness, fatigue, nausea, dry mouth, and constipation. The most common adverse reactions for overweight patients with diabetes were hypoglycemia, headache, back pain, cough, and fatigue. In clinical trials of at least one year in duration, 8.6% of patients treated with BELVIQ prematurely discontinued due to adverse reactions, compared with 6.7% of placebo patients. The most common adverse reactions leading to discontinuation were headache, depression and dizziness.

Contraindications

- BELVIQ should not be taken during pregnancy or by women who are planning to become pregnant.

Warnings and Precautions

- BELVIQ is a serotonergic drug. The development of potentially life-threatening serotonin syndrome or Neuroleptic Malignant Syndrome (NMS)-like reactions have been reported during use of serotonergic drugs, including, but not limited to, selective serotonin-norepinephrine reuptake inhibitors, and selective serotonin reuptake inhibitors, tricyclic antidepressants, bupropion, triptans, dietary supplements such as St. John's Wort and tryptophan, drugs that impair metabolism of serotonin (including monoamine oxidase inhibitors), dextromethorphan, lithium, tramadol, antipsychotics or other dopamine antagonists, particularly when used in combination. Patients should be monitored for the emergence of serotonin syndrome symptoms or NMS-like reactions, including agitation, hallucinations, coma, tachycardia, labile blood pressure, hyperthermia, hyperreflexia, incoordination, nausea, vomiting, diarrhea, and muscle rigidity. Treatment with BELVIQ and any concomitant serotonergic or antidopaminergic agents should be discontinued immediately if the above events occur and supportive symptomatic treatment should be initiated.
- Patients should not take BELVIQ in combination with drugs that have been associated with valvular heart disease (e.g., cabergoline). In clinical trials, 2.4% of patients taking BELVIQ and 2.0% of patients taking placebo developed valvular regurgitation: none of these patients were symptomatic. BELVIQ should be used with caution in patients with congestive heart failure (CHF). Patients who develop signs and symptoms of valvular heart disease, including dyspnea, dependent edema, CHF, or a new cardiac murmur, should be evaluated and discontinuation of BELVIQ should be considered.
- Impairment in attention, memory, somnolence, confusion, and fatigue, have been reported in patients taking BELVIQ. Patients should not drive a car or operate heavy machinery until they know how BELVIQ affects them.
- The recommended dose of 10 mg twice daily should not be exceeded, as higher doses may cause euphoria, hallucination, and dissociation. Monitor patients for the development or worsening of depression, suicidal thoughts or behaviors, and/ or any changes in mood. Discontinue BELVIQ in patients who develop suicidal thoughts or behaviors.
- Weight loss may increase the risk of hypoglycemia in patients with type 2 diabetes mellitus who are being treated with antidiabetic medications, so measurement of blood sugar levels before and during treatment with BELVIQ is recommended. Decreases in doses of antidiabetic medications or changes in medication regimen should be considered.
- Men who experience priapism should immediately discontinue BELVIQ and seek emergency medical attention. BELVIQ should be used with caution with erectile dysfunction medications. BELVIQ should be used with caution in men who have conditions that might predispose them to priapism (e.g.., sickle cell anemia, multiple myeloma, or leukemia), or in men with anatomical deformation of the penis (e.g., angulation, cavernosal fibrosis, or Peyronie's disease).
- Because BELVIQ may cause a slow heartbeat, it should be used with caution in patients with a history of bradycardia or heart block greater than first degree.
- Consider monitoring for CBC changes, prolactin excess and pulmonary hypertension.

Questions and Answers

Q: Are any Medicaid plans covering weight loss products?
A: Approximately 20 states cover Xenical and approximately 10 states are covering Belviq, including Virginia, Rhode Island, Michigan and New Mexico.

Q: Is an indication in pediatrics being sought?
A: The potential for studying in pediatrics is being looking at.

Q: Does CMS still consider covering weight loss medication as optional?
A: Yes but there is a federal bipartisan bill to gain Medicare Part D coverage for weight loss. The American Medical Association recently added an ICD-9 diagnostic code to obesity.

Q: What % of weight loss does the FDA require for approval?
A: The FDA requires a medication to show at least a $\geq$5% in weight loss for approval.

Q: What were the most common reasons for trial discontinuation?
A: Headache, depression and dizziness.

Q: Does Belviq affect 5-HT2B receptors that have been associated with cardiac issues of some other weight loss products?
A: Belviq is the first weight loss product selective for 5-HT2C.

VII. Sunovion

Lizbhet Delgado, PharmD, Senior Area Medical Specialist
Danny Van Deventer, Account Director

Latuda® (lurasidone)

Lurasidone is indicated for the treatment of schizophrenia (efficacy established in five 6-week controlled studies) and in the treatment of depressive episodes associated with bipolar disorder (bipolar depression), both as monotherapy and as adjunctive therapy with lithium or valproate (efficacy established in one 6-week controlled monotherapy and one adjunctive therapy study) in adults.

Two 6-week, double-blind, placebo-controlled, fixed-flexible dose, multicenter studies assessed the safety and effectiveness of lurasidone treatment, either as monotherapy or adjunctive to ongoing stable therapeutic levels of lithium or valproate, as compared to placebo in adult depressed bipolar I patients.

- Both studies enrolled patients with Bipolar I disorder experiencing a major depressive episode.
- Lurasidone monotherapy (D1050236) significantly improved depressive symptoms as determined by Montgomery-Asberg Rating Scale (MADRS) score reductions from baseline to end of Week 6 (primary outcome) whether dosed at 20-60 mg/day (-15.4; p<0.001) or at 80-120 mg/day group (-15.4; p<0.001) vs. placebo (-10.7); all comparisons by Mixed Model Repeated Measures (MMRM) analysis.
- Lurasidone 20-120 mg/day adjunctive to Li/VPA (D1050235) also significantly improved depressive symptoms, reflected by a mean (SE) MADRS score reduction at end of week 6 of -17.1 (0.87) vs. placebo + lithium or valproate -13.5 (0.91); p<0.01)].
- Both lurasidone mono- and adjunctive therapy also provided significantly greater improvements vs. placebo on all secondary efficacy endpoints, including the Hamilton Anxiety Scale, Sheehan Disability Scale score and Quality of Life Enjoyment and Satisfaction Questionnaire – Short Form score.
- **Monotherapy trial (D1050236): Adverse events (≥5% Incidence and at least twice the rate of placebo)**

	Akathisia	Parkinsonism*
Lurasidone 20-60 mg/day	8%	5%
Lurasidone 80-120 mg/day	11%	8%
Placebo	2%	2%

- The rates of discontinuation due to adverse events in the monotherapy study were 7% for lurasidone 20-60 mg/day and 6% for lurasidone 80-120 mg/day, respectively, vs. 6% for placebo.
- **Adjunctive trial (D1050235): Adverse events (≥5% Incidence and at least twice the rate of placebo)**

	Somnolence**	Akathisia
Lurasidone 20-120 mg/day	11%	11%
Placebo	5%	5%

- The rates of discontinuation due to adverse events in the adjunctive study were 6% for lurasidone and 8% for placebo.

Note: Figures rounded to the nearest integer
*Parkinsonism includes adverse event terms: bradykinesia, cogwheel rigidity, drooling, extrapyramidal disorder, glabellar reflex abnormal, hypokinesia, muscle rigidity, parkinsonism, psychomotor retardation, and tremor.
**Somnolence includes adverse event terms: hypersomnia, hypersomnolence, sedation, and somnolence.

Indications and Usage

- LATUDA is indicated for the treatment of major depressive episodes associated with bipolar I disorder (bipolar depression) as monotherapy and as adjunctive therapy with either lithium or valproate.
- LATUDA is indicated for the treatment of patients with schizophrenia.
- The efficacy of LATUDA as monotherapy and adjunctive therapy with lithium or valproate for the treatment of bipolar depression, were each established in a 6-week controlled study of adult patients with bipolar depression.
- The efficacy of LATUDA in schizophrenia was established in five 6-week controlled studies of adult patients with schizophrenia.

- The effectiveness of LATUDA for longer-term use, that is, for more than 6 weeks, has not been established in controlled studies. Therefore, the physician who elects to use LATUDA for extended periods should periodically re-evaluate the long-term usefulness of the drug for the individual patient. The efficacy of LATUDA in the treatment of mania associated with bipolar disorder has not been established.

BOXED WARNINGS

- **INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS; AND SUICIDAL THOUGHTS AND BEHAVIORS**
    - **Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death.**
    - **LATUDA is not approved for use in patients with dementia-related psychosis.**
    - **Increased risk of suicidal thinking and behavior in children, adolescents, and young adults taking antidepressants.**
    - **Monitor for worsening and emergence of suicidal thoughts and behaviors.**

Questions and Answers

Q: Is Latuda being marketed as first-line therapy in bipolar depression?
A: Yes.

VIII. Orexo

Stuart Gitlow, MD, MPH, MBA, Medical Director and Associate Professor
Brenda McLaughlin, Medicaid Consultant

Zubsolv® (buprenorphine and naloxone sublingual tablets, CIII)

ZUBSOLV® Sublingual Tablets (buprenorphine and naloxone) (CIII) are indicated for the maintenance treatment of opioid dependence. ZUBSOLV is a new choice for patients with opioid dependence that offers an advanced formulation. ZUBSOLV has the same active components (buprenorphine/naloxone) as previously approved Suboxone® sublingual tablets, but offers demonstrated advantages to meet the needs of patients: bioavailability, dissolve time, taste, dosing, and tablet size.

ZUBSOLV (buprenorphine and naloxone) is available in two dosage strengths—a lower dosage strength of 1.4 mg buprenorphine with 0.36 mg naloxone, and a higher dosage of 5.7 mg buprenorphine with 1.4 mg naloxone. Advanced dry formulation techniques were used to achieve small, fast-dissolving tablets with good dose uniformity. For optimal masking of the bitter taste of the active ingredients, a volatile flavor was combined with a long-acting sweetener in the ZUBSOLV formulation.

Buprenorphine exposure from ZUBSOLV met standard bioequivalence criteria to Suboxone® tablet (90% confidence interval [CI] of ZUBSOLV: Suboxone® tablet and area under the curve [AUC] and maximum concentration [Cmax] geometric mean ratios were within 80.00% and 125.00%).

ZUBSOLV displayed a median dissolve time of 5 minutes compared with 12.5 minutes for Suboxone® tablet.

ZUBSOLV was preferred over Suboxone® tablet by 41 of 53 subjects (77.4%); $P < 0.0001$ (post-hoc chi-square test)

Conclusions

- ZUBSOLV demonstrated equivalent systemic buprenorphine exposure to Suboxone® tablet and a naloxone exposure not higher than Suboxone® tablet.
- ZUBSOLV dissolve time was significantly decreased compared with Suboxone® tablet, and similar to that of Suboxone® film.
- Taste was a major discriminating factor between treatments, with significantly better taste ratings for ZUBSOLV than for Suboxone® tablet and Suboxone® film, and a higher subject preference for ZUBSOLV.
- Subjects preferred the mouthfeel of the ZUBSOLV sublingual tablet over Suboxone® film.
- ZUBSOLV received better overall acceptability ratings than both the Suboxone® tablet and the Suboxone® film and a higher overall preference over both formulations.

Questions and Answers
Q: Are any other studies being conducted?
A: There is an induction study ongoing and a switch study that will start soon.

IX. Reckitt Benckiser

Paul Bragoli, MS, CADAC, Director, Disease State Management
Juan Trippe, RPh, MBA, Disease State Manager
Sam Moffit, National Account Manager

Suboxone® Film (buprenorphine-naloxone)
Suboxone has established a strong baseline of efficacy starting the pivotal studies that supported the approval of the tablets in 2003. Treatment has continued to evolve with the 2010 approval of Suboxone Film. This presentation will emphasize some of the key differences between Suboxone Film and tablet, including Pediatric Exposure, Abuse, Persistence and Abuse and Diversion.

Pediatric Exposure- The Researched Abuse, Diversion and Addiction-Related Surveillance (RADARS®) System Poison Center program collects data about opioid medication exposures, including patient age, reason for exposure, specific formulation, and medical outcome. In the first quarter of 2012, 49 poison centers covering 90% of the US population provided data to the RADARS System. The program analyzed unintentional exposures to buprenorphine/naloxone tablets and oral film among children aged 0-5 years from October 2009 to March 2012. TO account for drug availability, rates were standardized using unique recipients of dispensed drugs (URDD). From January to March 2012, the risk of unintentional pediatric exposures was 8.5 times greater for Suboxone tablet than for Suboxone Film. For the entire period of the study, there was a 7.8 times lower rate of pediatric exposure for Suboxone Film vs. Suboxone tablet.
(Unintentional Exposures to Buprenorphine/Naloxone Sublingual Tablets and Film Among Children Less than Six Years Old- Data presented at ISPOR, Lavonas et al, November 2012).

Abuse and Diversion- The Researched Abuse, Diversion and Addiction-Related Surveillance (RADARS®) System collects product specific data about diversion and abuse of prescription opioids. This specific data was obtained from the RADARS® Drug Diversion, Opioid Treatment (OTP) and Survey of Key Informants' Patients (SKIP) Programs. Data was analyzed from October 2010 through June 2012 for 3 formulations: buprenorphine tablets, buprenorphine/naloxone tablets and buprenorphine sublingual film. To account for variation in prescribing over the 21-month study period, event rates were once again calculated based on unique recipients of dispensed drug (URDD). Diversion and abuse rates of buprenorphine sublingual tablets, with or without naloxone, consistently exceed the rates for buprenorphine/naloxone combination film.
(Buprenorphine/Naloxone Sublingual Film Diversion and Abuse Rates are Less than Rates for Tablet Formulations- Data presented at ASAM 2013, Lavonas et al)

Persistence in Treatment- The buprenorphine/naloxone combination has been available in a film formulation for the treatment of opioid dependence since 2010. A clinical trial showed that patients preferred the film to tablet formulation. Insurance claims were analyzed to compare patient persistence with the two formulations. A retrospective cohort analysis was performed using medical insurance claims extracted from the Invision Datamart database from January 2006 to December 2011. The film and tablet groups included 1095 and 1048 patients respectively, and outcomes included discontinuation, controlled discontinuation, switch, daily dose and monthly total healthcare charges. Patients receiving film and tablet formulations of buprenorphine/naloxone after September 2010 have similar characteristics overall. Compared to patients taking the tablet formulation, patients initiating therapy with the film formulation are less likely to discontinue treatment early. In addition, health care charges during treatment (maintenance phase) are lower among patients taking the film formulation.
(Patient persistence with buprenorphine/naloxone film and tablet formulations in the treatment of opioid dependence in the US: results from a privately insured retrospective database, data presented at ISPOR, Clay et al, November 2012).

Questions and Answers
Q: Are any additional formulations being sought?
A: None have been identified yet but looking at ways to address decreasing abuse/diversion, length of treatment and dosing regimen as well as to improve compliance.

Q: In the Clay et al study, was there a statistical difference in baseline characteristics between the tablet and film groups?
A: A higher proportion of patients were diagnosed with mental disorder in the tablet group compared to the film group.

Q: Is a pain indication being sought?
A: No.

Q: Has the tablet formulation of Suboxone been discontinued in Europe as it has been in the US?
A: The company is working on, but the film formulation is not available in all markets of Europe yet.

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 Catamaran, announces the Manufacturers' Forum occurring on Thursday, November 7, 2013.

Date: **Thursday, November 7, 2013 from 9am to 5pm EST**

Location: **Manufacturers' Forum - Georgia Department of Community Health**
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/durb-meeting-information** (or at **http://dch.georgia/gov** under Providers – Provider Type – Pharmacy – Drug Utilization Review Board – Meeting Information) approximately 30 days prior to the Forum. Manufacturers with drugs under 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 please include the drug(s) being requested to present.

Guidelines for Participation:
- To ensure equitable treatment of all manufacturers, individual manufacturer participation shall be limited to one 30-minute time segment per Forum. **The presentation should be limited to approximately 20 minutes with 10 minutes for questions and answers.**
- Manufacturer presentations may be audio-recorded for review after the Forum and the associated information shall be presented by NHC in summary fashion at regularly scheduled DURB meetings.
- 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 as posted on the DCH website, and to other drugs within the class. **New drug entities are not reviewed by the DURB until on the market for at least 6 months.**
- 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 of the presentation should be provided one week prior to the presentation via email to GAMedicaid@nhc-llc.com.**

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 **GAOffers@ghsinc.com**.
- Manufacturers with comments or inquiries related to Georgia Medicaid FFS **claims processing and drug benefit plan design** should submit these to the address or phone number below:

Catamaran, Inc.
Georgia Department of Community Health
Windward Fairways I, 3025 Windward Plaza Suite 200
Alpharetta, Georgia 30005
Phone: 1-800-282-3232 Fax: 630-268-0008

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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 Catamaran by its vendor NorthStar HealthCare Consulting (NHC). Manufacturer input on recommendations is welcomed and appreciated using these opportunities. **Please note that new drug entities are 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 up for review will be posted to the DCH website at **http://dch.georgia.gov** (under Providers – Pharmacy – Drug Utilization Review Board – 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/Catamaran clinical management strategies (e.g. review of drug benefit plan designs, new drugs coming to market, new drug indications, etc.) as deemed necessary by NHC/Catamaran.

Please see the Manufacturers' Forum Announcement at **http://dch.georgia.gov** under Providers – Pharmacy – Drug Utilization Review Board – 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 for review directly with GDCH within 10 business days following DURB meetings. **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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2013

Upcoming Meetings

Drug Utilization Review Board Meeting

2 Peachtree Street, N.W.

5th Floor Board Room

Atlanta, Georgia 30303

Tuesday, December 10, 2013: 9:30am – 1:30pm

Manufacturers' Forum

NorthStar HealthCare Consulting

1121 Alderman Drive

Suite 112

Alpharetta, Georgia 30005

Thursday, November 7, 2013: 9:00am – 5:00pm