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

December 11, 2012

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DRUG UTILIZATION REVIEW BOARD MEETING
AGENDA

2 Peachtree Street - 5th Floor DCH Board Room
Atlanta, Georgia 30303

December 11, 2012 – 10:00 a.m. to 2:00 p.m.

CALL TO ORDER	*Laurel Ashworth, PharmD, Chair*
COMMENTS FROM THE DEPARTMENT	*Jerry Dubberly, PharmD, MBA, Chief* *Linda Wiant, PharmD, Director*
MINUTES FROM PREVIOUS MEETING	*Chair*
PDL MANAGEMENT	*Emily Baker, PharmD, BCPS, MBA, MHA* *Tara R. Cockerham, PharmD*

- **Manufacturers' Forum**
- **New Drug Reviews**
  - Elelyso™
  - Korlym™
  - Potiga™
- **Class Review**
  - Antiretrovirals for Human Immunodeficiency Virus
- **Clinical Utilization Review**
  - Angeliq®

FUTURE AGENDA ITEMS	*Chair*
CONSUMER COMMENTS SESSION	
ADJOURNMENT OF OPEN SESSION	*Chair*
EXECUTIVE SESSION	
RECONVENING OF OPEN SESSION	*Chair*

- Board's Voting for Recommendations to DCH

ADJOURNMENT OF MEETING	*Chair*

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Department of Community Health
Drug Utilization Review Board (DURB)
MINUTES
Thursday, September 20, 2012

MEMBERS PRESENT

Gary M. Williams, M.D., Chairman
Laurel E. Ashworth, Pharm.D., Vice-Chairperson
Joseph R. Bona, M.D., MBA
Paul D. Boyce, M.D.
Karen L. Carter, M.D.
Melissa D. Carter, J.D.
John Greeson, M.D., MBA
Rondell C. Jaggers, Pharm.D.
Edwina L. Jones, Pharm.D.
Robyn Lorys, Pharm.D.
J. Russell May, Pharm.D.
Osgood (Drew) A. Miller, R.Ph.
Michael S. O'Connor, Pharm.D.
Sandra L. White, M.D., MBA, FACR
Mary Virginia "Ginny" Yates, Pharm.D.

MEMBERS ABSENT

Truddie Darden, M.D.
Carl Ellis, R.Ph.
Arvind Gupta, M.D.
Donald A. Paul, M.D.
Matthew Perri, III, R.Ph., Ph.D.

Staff

Jerry Dubberly, Pharm.D., MBA, Chief, Medical Assistance Plans
Linda Wiant, Pharm.D., Pharmacy Director, Pharmacy Services
Turkesia Robertson-Jones, Pharm.D., Pharmacy Operations Manager, Pharmacy Services
Gilletta Gray, R.Ph., Pharmacy Clinical Manager, Pharmacy Services
Rose Marie Duncan, MBA, Program Associate, Pharmacy Services
Sara Khajehei, Pharm.D. Candidate

NorthStar HealthCare Consulting

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

Catamaran

Susan McCreight, Account Manager
Mark Hall, Sr. Manager
Talmahjia “Tami” Sweat, Pharm.D., Clinical Systems Product Manager
Kelly Coleman, Provider Relations Specialist

Goold Health Services

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

University of Georgia Pharmacy School
Meredith Miles, Pharm.D. Candidate
Brian Griffin, Pharm.D. Candidate

Mercer University Pharmacy Resident
Yolanda Whitty, Pharm.D.

Call to Order
The Drug Utilization Review Board (DURB/DUR Board/Board) held its third meeting for the calendar year on September 20, 2012. The Chairman, Gary M. Williams, M.D., called the meeting to order at 10:04am. Two DUR Board members who will be leaving the Board, Truddie Darden, M.D. and Michael O'Connor, Pharm.D., were thanked for their participation and expertise brought to the Board. The structure of the DURB will be changing to include representation from Centene (Peach State), Amerigroup, and WellCare, private contractors who provide Medicaid services to the citizens of Georgia. The Chief Officer of Pharmacy and Medical Director of each organization will participate on the Board and is represented by the following: Amerigroup – Edwina Jones, Pharm.D., and Donald Paul, M.D.; WellCare – Ginny Yates, Pharm.D. and Sandra White, M.D., MBA, FACR; Centene/Peach State – John Greeson, M.D., and Robyn Lorys, Pharm.D. Dr. Williams reminded attendees of the new meeting format. The open session will be closed to discuss confidential materials and voting will occur in the reconvened open session. All Board members are requested to attend the reconvened open session to ensure a quorum. Abridged minutes of the executive session will be taken and made available to interested parties as part of the complete minutes of the DURB sessions. Financial information and other confidential information will not be included.

Comments from the Chief
Jerry Dubberly, Pharm.D., MBA, Chief Medical Assistance Plans, commented on the following:

1) Budget reductions – DCH is looking at a 3% budget reduction in the current Fiscal Year '13 and 5% reduction in Fiscal Year '14. Several strategies are being reviewed to obtain the necessary savings and meet the fiscal obligations.
2) Medicaid Redesign – There will be a common Preferred Drug List (PDL) for selected therapeutic categories across Fee-For-Service (FFS) and the Care Management Organizations (CMO). This is an administrative simplification process being promoted and implemented to improve continuity of care. Additionally, this will be an opportunity to pursue supplemental rebates in the near future in areas where there is commonality on the PDL. This collaborative effort will initially begin looking at just Preferred and Non-Preferred agents without additional restrictions. Representation from each of the CMOs has been added to the DUR Board. They will participate in discussions and vote on recommendations. The DURB remains advisory in nature.
3) Board Members – Dr. Dubberly expressed thanks to the Board members leaving and welcomed new members. The Board was also commended on the great work that has been done.

The Chairman, Gary Williams, M.D., responded with comments regarding the restructuring of the DUR Board.

Minutes from the Previous Meeting

Board members reviewed the minutes from the September 20, 2012 meeting. There were no corrections. A motion was made and seconded. The motion carried unanimously to approve the minutes as written.

Manufacturers' Forum

Emily Baker, Pharm.D., BCPS , reviewed information regarding the Manufacturers' Forum that was provided in the Manufacturer Information section in the DUR Board binder. A total of six (6) manufacturers participated and provided information regarding the following drugs discussed at the September 2012 DURB meeting:

Manufacturers	Drugs
Vertex	Kalydeco
Merck	Zioptan
Genentech	Erivedge
Novartis	Arcapta
Pfizer	Inlyta
Aptalis	Rectiv

A question was asked regarding the publication date for the study on Kalydeco in patients 6-11 years old. Tara R. Cockerham, PharmD responded that the manufacturer could not provide the anticipated publication date due to legal reasons per the manufacturer. The next forum is Thursday, November 1, 2012 from 9am-5pm at the NorthStar Healthcare Consulting office: 1121 Alderman Drive, Suite 112, Alpharetta, GA 30005.

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 new drug evaluation monographs are in the New Drugs for Review section of the September 2012 DUR Board binder.

Therapeutic Class	Drugs	Presenter
Long-Acting Beta-Agonist Inhaler	*Arcapta*	Emily Baker, Pharm.D., BCPS
Antineoplastic	*Erivedge*	Emily Baker, Pharm.D., BCPS
Antineoplastic	*Inlyta*	Emily Baker, Pharm.D., BCPS
Respiratory Agent – Miscellaneous	*Kalydeco*	Emily Baker, Pharm.D., BCPS
Anticonvulsant	*Onfi*	Emily Baker, Pharm.D., BCPS
Topical Antineoplastic	*Picato*	Emily Baker, Pharm.D., BCPS
Topical Anorectal	*Rectiv*	Emily Baker, Pharm.D., BCPS
Ophthalmic Prostaglandin	*Zioptan*	Emily Baker, Pharm.D., BCPS

There was one question raised regarding the effect of Rectiv on hemorrhoids. Dr. Cockerham responded that the effect of Rectiv on hemorrhoids was not provided in the study article or prescribing information for Rectiv.

Clinical Utilization Reviews

Clinical information for the following Clinical Utilization Review topics was presented for discussion. The complete detailed clinical reviews were provided in the Clinical Utilization Review section of the September 2012 DUR Board binder.

Clinical Topic	Description	Presenter
Long-Acting Beta-Agonist Containing Products in Asthma	*Clinical review of the safety requirements by the Food and Drug Administration for long-acting beta-agonist containing products in asthma*	Tara Cockerham, Pharm.D.
Oral Progesterone	*Clinical review of the indications and utilization of oral progesterone*	Tara Cockerham, Pharm.D.
Simvastatin 80mg Containing Products in Dyslipidemia	*Clinical review of the safety requirements by the Food and Drug Administration for simvastatin containing products in dyslipidemia*	Tara Cockerham, Pharm.D.

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

- Long-Acting Beta-Agonists - Risk Evaluation and Mitigation Strategy (REMS) program and follow-up of additional education letters
- Oral Progesterone – off label use, black box warning and costs
- Simvastatin 80mg – rationale for grandfathering patients

Follow-up Class Reviews – Clinical Updates

Clinical updates to the below therapeutic drug classes were provided by Dr. Cockerham and are listed in the Follow-Up Class Reviews section of the DURB binder. The following therapeutic categories had updates:

Drug Class/Name
Antihyperkinesis Agents
Long-Acting Beta Agonist Inhalers
Statins

There were no comments or questions from the Board.

DCH Decisions

DCH decisions from the June 21, 2012 DURB meeting were provided in the DCH Decisions section of the DUR Board binder.

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

Acknowledgement of Pharmacy Students

- Linda Wiant, Pharm.D., Pharmacy Director, Pharmacy Services, welcomed Sara Khajehei, a Mercer pharmacy student.
- J. Russell May, Pharm.D. welcomed UGA pharmacy students, Meredith Miles and Brian Griffin.
- Laurel E. Ashworth, Pharm.D., Vice-Chairperson, welcomed a Mercer University pharmacy resident, Yolanda Whitty, Pharm.D.

Future Agenda Items

The following future agenda items were noted:

- Duplication of therapy in expensive classes

Linda Wiant, Pharm.D., Pharmacy Director, Pharmacy Services, gave a status update on narcotics. The Department implemented a narcotic limitation on more than 6 claims per month in September. A Retrospective Drug Utilization Review (Retro-Dur) intervention on the concomitant use of Suboxone and Opioids or Benzodiazepines was conducted in May.

Consumer Comments Session

Dr. Williams gave an overview of the guidelines for the Consumer Comments Session. There were no consumer comments.

Upcoming Meetings

The following upcoming meetings were published in the DURB binder:

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

  Tuesday, December 11, 2012

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

Thursday, November 1, 2012

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

Dr. Williams requested Laurel E. Ashworth, Pharm.D., Vice-Chairperson, to chair the executive session and following portions of the meeting in his absence.

Adjournment of Open Session
The DUR Board voted to close the open meeting pursuant to the Open Meeting Act of Georgia Section 50-14-1 – 50-14-6 and pursuant to Federal Law Section 1396R-8B3D. The individuals recorded in attendance from the Department of Community Health, Goold Health Services, NorthStar HealthCare Consulting, and Catamaran attended the closed session with the Board members. A motion was made by Robyn Lorys, Pharm.D., and seconded by Osgood (Drew) A. Miller, R.Ph., to adjourn the open session and approve the closed session. There was a unanimous vote passing the motion. The Chairman, Dr. Gary Williams, adjourned the open session at approximately 11:27 am**,** at which time members took a break then reconvened for the executive (closed) session.

Executive Session
The executive session was held from 11:45am to 1:37pm.

Board's Recommendations to the Department
After all clinical and financial evaluations and discussions, the DUR Board reconvened in the open session and 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

Long-Acting Beta-Agonist

The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Arcapta™***.

Antineoplastics

The DUR Board recommended ***Preferred*** status with ***Prior Authorization*** for ***Erivedge™*** and ***Inlyta™***.

Respiratory Agent

The DUR Board recommended ***Preferred*** status with ***Prior Authorization*** for ***Kalydeco™***.

Anticonvulsant

The DUR Board recommended ***Preferred*** status with ***Prior Authorization*** for diagnosis, trial of clonazepam and trial of one other agent for Lennox-Gastaut Syndrome for ***Onfi™***.

Topical Antineoplastics

The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Picato™***. The DUR Board also recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Zyclara®***.

Topical Anorectal

The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Rectiv™***.

Ophthalmic Prostaglandin

The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Zioptan™***.

Class Reviews

Antihyperkinesis Agents

The DUR Board recommended ***No Changes*** from the current PDL status.

Long-Acting Beta-Agonist Inhalers

The DUR Board recommended ***No Changes*** from the current PDL status.

Statins

The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Crestor®*** and ***No Changes*** from the current PDL status for all other agents.

Conclusion

At the conclusion of the executive session, the open session reconvened at 2:03pm and audience participants were invited back in to hear the Board's recommendations submitted to the Department. Dr. Laurel Ashworth presided over the voting and presented the recommendations from the Board to the Department.

With no other business for discussion, Vice-Chair Ashworth adjourned the meeting at 2:14pm.

THESE MINUTES ARE HEREBY APPROVED AND ADOPTED, THIS THE _____ DAY OF _____, 2012.

_____

Laurel Ashworth, Pharm.D., Vice-Chairperson

Drug Utilization Review Board

Motions - Votes

New Drugs

September 20, 2012

New Drug	Drug	PDL Status	Motion/Recommendation
Long-Acting Beta-Agonist Inhaler	Arcapta™	NP/PA	NP/PA
	Foradil Cap Aerolize	P	P
	Servent Dis Aer	P	P

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Ashworth, Laurel E. Pharm.D. - Vice Chair	N/A					
2	Bona, Joseph R. M.D.			√			
3	Carter, Karen L., M.D.			√			
4	Carter, Melissa D., J.D.	√		√			
5	Greeson, John D., M.D., MBA			√			
6	Jaggers, Rondell C., Pharm.D.		√	√			
7	Jones, Edwina, Pharm.D., MBA			√			
8	Lorys, Robyn Pharm.D.			√			
9	May, J. Russell, Pharm.D.			√			
10	Miller, Osgood (Drew) A. R.Ph.			√			
11	O'Connor, Michael S., Pharm.D.			√			
12	White, Sandra L., M.D., MBA, FACR			√			
13	Yates, Mary Virginia "Ginny", Pharm.D.			√			
			TOTAL	12	0	0	0

New Drug	Drug	PDL Status	Motion/Recommendation
Antineoplastic	Erivedge™	P/PA	P/PA

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Ashworth, Laurel E. Pharm.D. - Vice Chair	N/A					
2	Bona, Joseph R. M.D.		√	√			
3	Carter, Karen L., M.D.			√			
4	Carter, Melissa D., J.D.			√			
5	Greeson, John D., M.D., MBA			√			
6	Jaggers, Rondell C., Pharm.D.			√			
7	Jones, Edwina, Pharm.D., MBA			√			
8	Lorys, Robyn Pharm.D.	√		√			
9	May, J. Russell, Pharm.D.			√			
10	Miller, Osgood (Drew) A. R.Ph.			√			
11	O'Connor, Michael S., Pharm.D.			√			
12	White, Sandra L., M.D., MBA, FACR			√			
13	Yates, Mary Virginia "Ginny", Pharm.D.			√			
			TOTAL	12	0	0	0

Drug Utilization Review Board

Motions - Votes

New Drugs

September 20, 2012

New Drug	Drug	PDL Status	Motion/Recommendation			
Antineoplastic	Inlyta™	P/PA	P/PA			
Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1 Ashworth, Laurel E. Pharm.D. - Vice Chair	N/A					
2 Bona, Joseph R. M.D.	√		√			
3 Carter, Karen L., M.D.			√			
4 Carter, Melissa D., J.D.			√			
5 Greeson, John D., M.D., MBA		√	√			
6 Jaggers, Rondell C., Pharm.D.			√			
7 Jones, Edwina, Pharm.D., MBA			√			
8 Lorys, Robyn Pharm.D.			√			
9 May, J. Russell, Pharm.D.			√			
10 Miller, Osgood (Drew) A. R.Ph.			√			
11 O'Connor, Michael S., Pharm.D.			√			
12 White, Sandra L., M.D., MBA, FACR			√			
13 Yates, Mary Virginia "Ginny", Pharm.D.			√			
		TOTAL	12	0	0	0

New Drug	Drug	PDL Status	Motion/Recommendation			
Respiratory Agent - Miscellaneous	Kalydeco™	P/PA	P/PA			
Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1 Ashworth, Laurel E. Pharm.D. - Vice Chair	N/A					
2 Bona, Joseph R. M.D.			√			
3 Carter, Karen L., M.D.		√	√			
4 Carter, Melissa D., J.D.			√			
5 Greeson, John D., M.D., MBA			√			
6 Jaggers, Rondell C., Pharm.D.			√			
7 Jones, Edwina, Pharm.D., MBA			√			
8 Lorys, Robyn Pharm.D.			√			
9 May, J. Russell, Pharm.D.			√			
10 Miller, Osgood (Drew) A. R.Ph.			√			
11 O'Connor, Michael S., Pharm.D.			√			
12 White, Sandra L., M.D., MBA, FACR	√		√			
13 Yates, Mary Virginia "Ginny", Pharm.D.			√			
		TOTAL	12	0	0	0

Drug Utilization Review Board

Motions - Votes

New Drugs

September 20, 2012

New Drug	Drug	PDL Status	Motion/Recommendation
Anticonvulsant	Onfi™	P/PA	P/PA

Prior approval requires the confirmation of the diagnosis of Lennox Gastaut Syndrome (LGS) and the failure of Clonazepam and one other agent for LGS.

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Ashworth, Laurel E. Pharm.D. - Vice Chair	N/A					
2	Bona, Joseph R. M.D.	√		√			
3	Carter, Karen L., M.D.			√			
4	Carter, Melissa D., J.D.			√			
5	Greeson, John D., M.D., MBA			√			
6	Jaggers, Rondell C., Pharm.D.			√			
7	Jones, Edwina, Pharm.D., MBA			√			
8	Lorys, Robyn Pharm.D.			√			
9	May, J. Russell, Pharm.D.			√			
10	Miller, Osgood (Drew) A. R.Ph.		√	√			
11	O'Connor, Michael S., Pharm.D.			√			
12	White, Sandra L., M.D., MBA, FACR			√			
13	Yates, Mary Virginia "Ginny", Pharm.D.			√			
			TOTAL	12	0	0	0

New Drug	Drug	PDL Status	Motion/Recommendation	Additional Information
Topical Antineoplastic	Picato™	NP/PA	NP/PA	The Board also recommended a PDL staus change for Zyclara, which is not a new drug.
	Zyclara™	P/PA	NP/PA	

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Ashworth, Laurel E. Pharm.D. - Vice Chair	N/A					
2	Bona, Joseph R. M.D.			√			
3	Carter, Karen L., M.D.			√			
4	Carter, Melissa D., J.D.			√			
5	Greeson, John D., M.D., MBA			√			
6	Jaggers, Rondell C., Pharm.D.			√			
7	Jones, Edwina, Pharm.D., MBA	√		√			
8	Lorys, Robyn Pharm.D.			√			
9	May, J. Russell, Pharm.D.			√			
10	Miller, Osgood (Drew) A. R.Ph.			√			
11	O'Connor, Michael S., Pharm.D.		√	√			
12	White, Sandra L., M.D., MBA, FACR			√			
13	Yates, Mary Virginia "Ginny", Pharm.D.			√			
			TOTAL	12	0	0	0

Drug Utilization Review Board

Motions - Votes

New Drugs

September 20, 2012

New Drug	Drug	PDL Status	Motion/Recommendation			
Topical Anorectal	Rectiv™	NP/PA	NP/PA			
Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1 Ashworth, Laurel E. Pharm.D. - Vice Chair	N/A					
2 Bona, Joseph R. M.D.			√			
3 Carter, Karen L., M.D.	√		√			
4 Carter, Melissa D., J.D.			√			
5 Greeson, John D., M.D., MBA			√			
6 Jaggers, Rondell C., Pharm.D.			√			
7 Jones, Edwina, Pharm.D., MBA			√			
8 Lorys, Robyn Pharm.D.		√	√			
9 May, J. Russell, Pharm.D.			√			
10 Miller, Osgood (Drew) A. R.Ph.			√			
11 O'Connor, Michael S., Pharm.D.			√			
12 White, Sandra L., M.D., MBA, FACR			√			
13 Yates, Mary Virginia "Ginny", Pharm.D.			√			
TOTAL			12	0	0	0

New Drug	Drug	PDL Status	Motion/Recommendation			
Ophthalmic Prostaglandin	Zioptan™	NP/PA	NP/PA			
Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1 Ashworth, Laurel E. Pharm.D. - Vice Chair	N/A					
2 Bona, Joseph R. M.D.			√			
3 Carter, Karen L., M.D.			√			
4 Carter, Melissa D., J.D.			√			
5 Greeson, John D., M.D., MBA			√			
6 Jaggers, Rondell C., Pharm.D.			√			
7 Jones, Edwina, Pharm.D., MBA		√	√			
8 Lorys, Robyn Pharm.D.			√			
9 May, J. Russell, Pharm.D.	√		√			
10 Miller, Osgood (Drew) A. R.Ph.			√			
11 O'Connor, Michael S., Pharm.D.			√			
12 White, Sandra L., M.D., MBA, FACR			√			
13 Yates, Mary Virginia "Ginny", Pharm.D.			√			
TOTAL			12	0	0	0

Attachment A

Drug Utilization Review Board

Motions Votes

Follow-Up Class Review

September 20, 2012

Antihyperkinesis Agents

Drug Name	PDL Status	Recommendations	Drug Name	PDL Status	Recommendations
Adderall Tab	NP/PA	**NP/PA**	Kapvay Tab	NP/PA	**NP/PA**
Adderall XR Cap	NP/PA	**NP/PA**	Metadate CD Cap	P/PA - Age	**P/PA - Age**
Amphetamine Cap ER	NP/PA	**NP/PA**	Methylin Chw	P/PA - Age	**P/PA - Age**
Amphetamine Tab	P/PA - Age	**P/PA - Age**	Methylin Sol	P/PA - Age	**P/PA - Age**
Concerta Tab	NP/PA	**NP/PA**	Methylin Tab	P/PA - Age	**P/PA - Age**
Daytrana Dis	NP/PA	**NP/PA**	Methylin ER Tab	P/PA - Age	**P/PA - Age**
Desoxyn Tab	NP/PA	**NP/PA**	Methylinphenid Tab	P/PA - Age	**P/PA - Age**
Dexmethylph Tab	NP/PA	**NP/PA**	Nuvigil tab	NP/PA	**NP/PA**
Dextroamphet Cap	P/PA - Age	**P/PA - Age**	Procentra Sol	NP/PA	**NP/PA**
Dextroamphet Tab	P/PA - Age	**P/PA - Age**	Provigil Tab	NP/PA	**NP/PA**
Focalin Tab	P/PA - Age	**P/PA - Age**	Ritalin LA Cap	NP/PA	**NP/PA**
Focalin XR Cap	P/PA - Age	**P/PA - Age**	Strattera Cap	NP/PA	**NP/PA**
Intuniv Tab	NP/PA	**NP/PA**	Vyvanse Cap	P/PA - Age	**P/PA - Age**

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Ashworth, Laurel E. Pharm.D. - Vice Chair	N/A					
2	Bona, Joseph R. M.D.	√		√			
3	Carter, Karen L., M.D.		√	√			
4	Carter, Melissa D., J.D.			√			
5	Greeson, John D., M.D., MBA			√			
6	Jaggers, Rondell C., Pharm.D.			√			
7	Jones, Edwina, Pharm.D., MBA			√			
8	Lorys, Robyn Pharm.D.			√			
9	May, J. Russell, Pharm.D.			√			
10	Miller, Osgood (Drew) A. R.Ph.			√			
11	O'Connor, Michael S., Pharm.D.			√			
12	White, Sandra L., M.D., MBA, FACR			√			
13	Yates, Mary Virginia "Ginny", Pharm.D.			√			
			TOTAL	12	0	0	0

Drug Utilization Review Board

Motions Votes

Follow-Up Class Review

September 20, 2012

Statins - High Potency

Brand Name	PDL Status	Recommendation
Atorvastatin	P	**P**
Crestor Tab	P/PA	**NP/PA**
Lipitor Tab	NP	**NP**
Livalo Tab	NP/PA	**NP/PA**
Simvastatin Tab (except 80mg)	P	**P**
Simvastatin Tab 80mg	P/PA	**P/PA**
Vytorin Tab	NP/PA	**NP/PA**

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Ashworth, Laurel E. Pharm.D. - Vice Chair	N/A					
2	Bona, Joseph R. M.D.			√			
3	Carter, Karen L., M.D.			√			
4	Carter, Melissa D., J.D.			√			
5	Greeson, John D., M.D., MBA			√			
6	Jaggers, Rondell C., Pharm.D.			√			
7	Jones, Edwina, Pharm.D., MBA	√		√			
8	Lorys, Robyn Pharm.D.			√			
9	May, J. Russell, Pharm.D.			√			
10	Miller, Osgood (Drew) A. R.Ph.			√			
11	O'Connor, Michael S., Pharm.D.			√			
12	White, Sandra L., M.D., MBA, FACR		√	√			
13	Yates, Mary Virginia "Ginny", Pharm.D.			√			
			TOTAL	12	0	0	0

Attachment A

Drug Utilization Review Board

Motions Votes

Follow-Up Class Review

September 20, 2012

Statins - Low Potency

Brand Name	PDL Status	Recommendation
Fluvastatin	NP/PA	**NP/PA**
Lescol Cap	P	**P**
Lescol XL Tab	P	**P**
Lovastatin Tab	P	**P**
Pravastatin Tab	P	**P**

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Ashworth, Laurel E. Pharm.D. - Vice Chair	N/A					
2	Bona, Joseph R. M.D.			√			
3	Carter, Karen L., M.D.			√			
4	Carter, Melissa D., J.D.			√			
5	Greeson, John D., M.D., MBA			√			
6	Jaggers, Rondell C., Pharm.D.			√			
7	Jones, Edwina, Pharm.D., MBA			√			
8	Lorys, Robyn Pharm.D.			√			
9	May, J. Russell, Pharm.D.	√		√			
10	Miller, Osgood (Drew) A. R.Ph.			√			
11	O'Connor, Michael S., Pharm.D.			√			
12	White, Sandra L., M.D., MBA, FACR		√	√			
13	Yates, Mary Virginia "Ginny", Pharm.D.			√			
			TOTAL	12	0	0	0

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Manufacturers' Forum
Manufacturer Presentations

Dates: November 1, 2012

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

Attendees
Department of Community Health
Linda Wiant, PharmD, Director of Pharmacy

NorthStar HealthCare Consulting
Tara R. Cockerham, PharmD, Clinical Programs Director
Dan Alday, RPh, Director, Clinical Programs & Analytics
Emily Baker, PharmD, BCPS, MBA, MHA, President
Amy Baker, PharmD, Pharmacist

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 that were submitted for or presented at the Forum, the summaries of the presentations on new drugs or new information of existing drugs since last presented are 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. Bristol-Myers Squibb
Heidi Googe, PharmD, Executive Medical Science Liaison, Virology
Sarah Faas, District Business Manager, Virology and Transplant

Reyataz® (atazanavir)

Indication and Usage
- Reyataz (atazanavir sulfate, ATV) is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection.
- This indication is based on analyses of plasma HIV-1 RNA levels and CD4+ cell counts from controlled studies of 96 weeks duration in antiretroviral-naive and 48 weeks duration in antiretroviral-treatment-experienced adult and pediatric patients at least 6 years of age.
- The following points should be considered when initiating therapy with Reyataz:
    - In Study 045, Reyataz/ritonavir and lopinavir/ritonavir were similar for the primary efficacy outcome measure of time-averaged difference in change from baseline in HIV RNA level. This study was not large enough to reach a definitive conclusion that Reyataz/ritonavir and lopinavir/ritonavir are equivalent on the secondary efficacy outcome measure of proportions below the HIV RNA lower limit of detection.
    - The number of baseline primary protease inhibitor mutations affects the virologic response to Reyataz/ritonavir.

Efficacy and Safety
Treatment-Naïve Patients
- ***Ritonavir-Boosted Atazanavir*:** Study AI424-138 was a 96-week, open-label, randomized, multicenter study which compared atazanavir/ritonavir (ATV/r) 300/100 mg once daily (n=441) to lopinavir/ritonavir (LPV/r) 400/100 mg twice daily (n=437), each with fixed-dose tenofovir (TDF)/emtricitabine (FTC) 300/200 mg, once daily over 96 weeks.

    - The proportion of patients achieving HIV-1 RNA <50 copies/mL: ATV/r 75%; LPV/r 68%. Similar response rates were observed in patients with high baseline viral loads (i.e. baseline HIV RNA ≥ 100,000 copies/mL): ATV/r 74%; LPV/r 67%
    - Median increase from baseline in CD4 cell count over 96 weeks: ATV/r 261 cells/mm3; LPV/r 273 cells/mm3
- ***Unboosted Atazanavir***: Study AI424-034 was a randomized, double-blind, multicenter study which compared ATV 400 mg once daily (n=405) to efavirenz (EFV) 600 mg once daily (n=405), each with fixed-dose lamivudine (3TC) 150 mg and zidovudine (ZDV) 300 mg, given twice daily over 48 weeks.
    - The proportion of patients achieving HIV-1 RNA <400 copies/mL: ATV 67%; EFV 62%
    - Mean increase from baseline in CD4+ cell count over 48 weeks: ATV 176 cells/mm3; EFV 160 cells/mm3
- ***Treatment-emergent adverse events*** of moderate or severe intensity reported in ≥2% of ATV-treated HIV-1-infected treatment-naïve patients in clinical trials: headache, nausea, jaundice/scleral icterus, vomiting, diarrhea, abdominal pain, dizziness, insomnia, peripheral neurologic symptoms, and rash.

Treatment-Experienced Patients
- ***Ritonavir-Boosted Atazanavir****:* Study AI424-045 was a randomized, multicenter trial which compared ATV/r 300/100 mg once daily to LPV/r 400/100 mg twice daily, each with TDF and one nucleoside reverse transcriptase inhibitor (NRTI) over 48 weeks, in 347 patients who experienced virologic failure on highly active ARV therapy (HAART) regimens containing PIs, NRTIs, and non-nucleoside reverse transcriptase inhibitors (NNRTIs).1
    - Primary Efficacy endpoint (time-averaged-difference (TAD) in change from baseline in HIV-1 RNA through Week 48): ATV/r and LPV/r arms achieved similar results (ATV/r -1.58 log10 copies/mL; LPV/r -1.70 log10 copies/mL; TAD=+0.12 [97.5% CI, -0.17, 0.41]).
    - Mean increase from baseline in CD4+ cell count through 48 weeks: ATV/r 116 cells/mm3; LPV/r 123 cells/mm3
- ***Treatment-emergent adverse events*** of moderate or severe intensity reported in ≥2% of ATV-treated HIV-1 infected treatment-experienced patients in clinical trials: fever, jaundice/scleral icterus, diarrhea, nausea, depression, and myalgia.

Contraindications
- Reyataz is contraindicated in patients with previously demonstrated hypersensitivity (e.g., Stevens-Johnson syndrome, erythema multiforme, or toxic skin eruptions) to any of the components of this product.
- Coadministration with alfuzosin, triazolam, orally administered midazolam, ergot derivatives, rifampin, irinotecan, lovastatin, simvastatin, indinavir, cisapride, pimozide, St. John's Wort, and sildenafil when dosed as Revatio®.

Warnings and Precautions
- Cardiac conduction abnormalities: PR interval prolongation may occur in some patients. Use with caution in patients with preexisting conduction system disease or when administered with other drugs that may prolong the PR interval.
- Rash: Discontinue if severe rash develops.
- Hyperbilirubinemia: Most patients experience asymptomatic increases in indirect bilirubin, which is reversible upon discontinuation. Do not dose reduce. If a concomitant transaminase increase occurs, evaluate for alternative etiologies.
- Hepatotoxicity: Reyataz should be used with caution in patients with hepatic impairment. Patients with hepatitis B or C infection are at risk of increased transaminases or hepatic decompensation. Monitor hepatic laboratory tests prior to therapy and during treatment.
- Nephrolithiasis has been reported. Consider temporary interruption or discontinuation.
- Patients receiving Reyataz may develop new onset or exacerbations of diabetes mellitus/hyperglycemia, immune reconstitution syndrome, and redistribution/accumulation of body fat.
- Hemophilia: Spontaneous bleeding may occur and additional factor VIII may be required.
- Various degrees of cross-resistance among protease inhibitors have been observed. Resistance to ATV may not preclude the subsequent use of other protease inhibitors.

Questions and Answers
Q: What is the life expectancy of HIV patients?
A: Similar rate to general population but slightly lower due to not all HIV patients are being treated.

Q: What were the reasons for discontinuation of medication?
A: Increase in bilirubin and jaundice, which will normalize with removal of medication.

Q: Do you know of any plans managing this class?
A: No plans as of yet as class is usually protected due to importance of individual patient needs and treatment.

Sustiva® (efavirenz)

Indication and Usage
Sustiva (efavirenz, EFV) is a non-nucleoside reverse transcriptase inhibitor (NNRTI) indicated in combination with other antiretroviral agents for the treatment of human immunodeficiency virus type 1 (HIV-1) infection. This indication is based on two phase III clinical trials of at least one year duration that demonstrated prolonged suppression of HIV RNA.

Efficacy and Safety
Study 006 (NNRTI- and protease inhibitor- [PI-] naïve patients)
- Design: Randomized, open-label, 168-week study (n=1266) comparing EFV 600 mg once daily + zidovudine (ZDV) 300 mg q12h + lamivudine (3TC) 150 mg q12h or EFV 600 mg once daily + indinavir (IDV) 1000 mg q8h with IDV 800 mg q8h + ZDV 300 mg q12h + 3TC 150 mg q12h
- Virologic response:
    - HIV-1 RNA <400 copies/mL at Week 48: 69%, 57%, and 50% and at Week 168: 48%, 40%, and 29% in the EFV + ZDV + 3TC, EFV + IDV, and IDV + ZDV + 3TC arms, respectively
    - HIV-1 RNA <50 copies/mL at Week 48: 65%, 50%, and 45% and at Week 168: 43%, 31%, and 23%, in the EFV + ZDV + 3TC, EFV + IDV, and IDV + ZDV + 3TC arms, respectively
- Immunologic response (mean change from baseline in CD4+ cell count) at Week 48: 190, 191, and 180 cells/mm3 and at Week 168: 329, 319, and 329 cells/mm3 in the EFV + ZDV + 3TC, EFV + IDV, and IDV + ZDV + 3TC arms, respectively
- A Kaplan-Meier analysis of time to loss of virologic response (HIV-1 RNA <400 copies/mL) suggests that both the trends of virologic response and differences in response continue through 4 years.
- The most common (>5%) adverse reactions of at least moderate severity among patients treated with EFV in combination with ZDV/3TC or IDV were rash, dizziness, nausea, headache, fatigue, insomnia, and vomiting.

Study ACTG 364 (nucleoside reverse transcriptase inhibitor- [NRTI-] experienced patients)
- Design: Randomized, double-blind, placebo-controlled, 48-week study (n=196) comparing EFV 600 mg once daily + nelfinavir (NFV) 750 mg three times daily + NRTIs, EFV 600 mg once daily + NRTIs, and NFV 750 mg three times daily + NRTIs
- HIV-1 RNA <500 copies/mL at Week 48: 71%, 63%, and 41% in the EFV + NFV + NRTIs, EFV + NRTIs, and NFV + NRTIs arms, respectively
- There was no significant difference in the mean CD4+ cell count among treatment groups; the overall mean increase was approximately 100 cells at 48 weeks among patients who continued on study regimens.
- A Kaplan-Meier analysis of time to treatment failure through 72 weeks demonstrates a longer duration of virologic suppression (HIV-1 RNA <500 copies/mL) in the EFV-containing arms.
- The most common (>5%) adverse reactions of at least moderate severity among patients treated with EFV in combination with NRTIs or NFV + NRTIs were pain, dizziness, diarrhea, rash, and pruritus.

Contraindications
- Sustiva is contraindicated in patients with previously demonstrated clinically significant hypersensitivity (e.g., Stevens-Johnson syndrome, erythema multiforme, or toxic skin eruptions) to any of the components of this product.
- Coadministration with bepridil, cisapride, midazolam, pimozide, triazolam, or ergot derivatives is contraindicated, since competition for CYP3A by efavirenz could result in inhibition of their metabolism and create the potential for serious and/or life-threatening adverse reactions.
- Concomitant use of EFV and St. John's wort (*Hypericum perforatum*) or St. John's wort-containing products is not recommended.

Warnings and Precautions
- Drug Interactions: EFV plasma concentrations may be altered by substrates, inhibitors, or inducers of CYP3A. Likewise, EFV may alter plasma concentrations of drugs metabolized by CYP3A or CYP2B6
- Resistance: EFV should not be used as a single agent to treat HIV-1 infection or add on as a sole agent to a failing regimen. Consider potential for cross-resistance when choosing other agents.

- Coadministration with Related Products: Coadministration of EFV with Atripla® (efavirenz 600 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg) is not recommended unless needed for dose adjustment (e.g., with rifampin), since EFV is one of its active ingredients.
- Psychiatric Symptoms: Immediate medical evaluation is recommended for serious psychiatric symptoms such as severe depression or suicidal ideation.
- Nervous System Symptoms (NSS): NSS are frequent; usually begin 1-2 days after initiating therapy and resolve in 2-4 weeks. Dosing at bedtime may improve tolerability. NSS are not predictive of onset of psychiatric symptoms.
- Reproductive Risk Potential: Pregnancy Category D. Fetal harm can occur when administered to a pregnant woman during the first trimester. Women should be apprised of the potential harm to the fetus. Pregnancy registry is available.
- Rash: Rash usually begins within 1-2 weeks after initiating therapy and resolves within 4 weeks. Discontinue if severe rash develops.
- Hepatotoxicity: Monitor liver function tests before and during treatment in patients with underlying hepatic disease, including hepatitis B or C coinfection, marked transaminase elevations, or who are taking medications associated with liver toxicity. Among reported cases of hepatic failure, a few occurred in patients with no pre-existing hepatic disease.
- Convulsions: Use caution in patients with a history of seizures.
- Lipid Elevations: Total cholesterol and triglyceride elevations. Monitor before therapy and periodically thereafter.
- Immune Reconstitution Syndrome: May necessitate further evaluation and treatment.
- Fat Redistribution: Observed in patients receiving antiretroviral therapy.

Questions and Answers
Q: What are the incidences of psychiatric adverse events and what is the recommendation if patient has at baseline?
A: Depression – 2.4%, suicidal – 0.7%, aggression – 0.5%, psychosis – 2%; if patient is not controlled at baseline, BMS recommends not using drug until patient is stable. However, these are not contraindications to use of Sustiva.

Q: Is a supplemental rebate being offered on Reyataz or Sustiva?
A: Not sure as BMS Government Affairs handles supplemental rebate offers.

II. Merck

Emile Jean-Baptiste, MD, PhD, Regional Medical Director
Lisa Bishop, Senior Region Account Executive, Managed Markets and Policy

Isentress® (raltegravir)

Indication
Isentress is a human immunodeficiency virus integrase strand transfer inhibitor (HIV-1 INSTI) indicated in combination with other antiretroviral agents for the treatment of human immunodeficiency virus (HIV-1) infection.

Efficacy
- *Adults:* This indication is based on analyses of plasma HIV-1 RNA levels in three double-blind controlled studies of Isentress. Two of these studies were conducted in clinically advanced, 3-class antiretroviral (NNRTI, NRTI, PI) treatment-experienced adults through 96 weeks, and one conducted in treatment naive adults through 156 weeks.
- *Pediatrics:* Isentress is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in children and adolescents 2 years of age and older and weighing at least 10 kg. This indication is based on the evaluation of safety, tolerability, pharmacokinetic parameters and efficacy of Isentress through at least 24-weeks in a multi-center, open-label, non-comparative study in HIV-1 infected children and adolescents 2 to 18 years of age. The use of other active agents with Isentress is associated with a greater likelihood of treatment response.
- *Treatment-Naïve Subjects:* STARTMRK (Protocol 021) is a Phase 3 study to evaluate the safety and antiretroviral activity of Isentress 400 mg twice daily + emtricitabine (+) tenofovir versus efavirenz 600 mg at bedtime plus emtricitabine (+) tenofovir in treatment-naïve HIV- 1-infected subjects with HIV-1 RNA >5000 copies/mL. The percent of subjects with HIV-1 RNA copies less than 50 copies/mL were 76% and 68% for Isentress and Efavirenz, respectively. The percent of virologic failures (which includes subjects who discontinued prior to Week 156 for lack of efficacy, subjects changed OBT due to lack of efficacy prior to Week 156, or subjects who are ≥50 copies in the 156 week window) were 9% and 13% for Isentress and Efavirenz, respectively. The mean changes in CD4 count from baseline were 281 cells/mm3 in the group receiving Isentress 400 mg twice daily and 241 cells/mm3 in the group receiving Efavirenz 600 mg at bedtime.

- *Treatment-Experienced Subjects:* BENCHMRK 1 and BENCHMRK 2 are Phase 3 studies to evaluate the safety and antiretroviral activity of Isentress 400 mg twice daily in combination with an optimized background therapy (OBT), versus OBT alone, in HIV-1-infected subjects, 16 years or older, with documented resistance to at least 1 drug in each of 3 classes (NNRTIs, NRTIs, PIs) of antiretroviral therapies. OBT was selected by the investigator based on genotypic/phenotypic resistance testing and prior ART history. The percent of subjects with HIV-1 RNA copies less than 50 copies/mL were 55% and 27% for Isentress and Placebo + OBT respectively. The percent of virologic failures (Includes subjects who switched to open-label raltegravir after Week 16 due to the protocol-defined virologic failure, subjects who discontinued prior to Week 96 for lack of efficacy, subjects changed OBT due to lack of efficacy prior to Week 96, or subjects who were ≥50 copies in the 96 week window) were 35% and 66% for Isentress and Placebo + OBT respectively.
- *Pediatric Subjects:* IMPAACT P1066 is a Phase I/II open label multicenter trial to evaluate the pharmacokinetic profile, safety, tolerability, and efficacy of raltegravir in HIV infected children. Subjects received either the 400 mg film-coated tablet formulation (6 to 18 years of age) or the chewable tablet formulation (2 to less than 12 years of age) with an optimized background regimen. At Week 24, 54% of subjects achieved HIV RNA <50 copies/mL; 72% achieved HIV RNA <400 copies/mL or ≥1 log10 HIV RNA drop from baseline. The mean CD4 count (percent) increase from baseline to Week 24 was 119 cells/mm3 (3.8%).

Safety

Warnings and Precautions

- *Immune reconstitution syndrome:* During the initial phase of combination antiretroviral treatment, patients whose immune systems respond may develop an inflammatory response to indolent or residual opportunistic infections, which may necessitate further evaluation and treatment. Autoimmune disorders (such as Graves' disease, polymyositis, and Guillain-Barré syndrome) have also been reported to occur in the setting of immune reconstitution; however, the time to onset is more variable, and can occur many months after initiation of treatment.
- *Phenylketonurics:* Isentress chewable tablets contain phenylalanine, a component of aspartame, which may be harmful to patients with phenylketonuria.
- *Drug Interactions:* Raltegravir does not inhibit (IC50>100 μM) CYP1A2, CYP2B6, CYP2C8, CYP2C9, CYP2C19, CYP2D6 or CYP3A in vitro. Moreover, in vitro, raltegravir did not induce CYP1A2, CYP2B6 or CYP3A4. Raltegravir is not a substrate of cytochrome P450 (CYP) enzymes. Based on in vivo and in vitro studies, raltegravir is eliminated mainly by metabolism via a UGT1A1-mediated glucuronidation pathway. Coadministration of Isentress with drugs that are strong inducers of uridine diphosphate glucuronosyltransferase (UGT) 1A1 may result in reduced plasma concentrations of raltegravir. The impact of other inducers of drug metabolizing enzymes, such as phenytoin and phenobarbital, on UGT1A1 is unknown. In drug interaction studies, raltegravir did not have a clinically meaningful effect on the pharmacokinetics of the following: hormonal contraceptives, methadone, lamivudine, tenofovir, etravirine, and darunavir/ritonavir. Coadministration of Isentress with drugs that inhibit UGT1A1 may increase plasma levels of raltegravir.
- *Adverse Reactions:* The most commonly reported (≥2% in either treatment group) drug-related clinical adverse events (AE) of moderate to severe intensity in treatment-naïve patients receiving Isentress compared with efavirenz were insomnia (4% vs 4%), headache (4% vs 5%), nausea (3% vs 4%), and fatigue (2% vs 3%), respectively. In treatment-experienced patients receiving Isentress, the most commonly reported (≥2% in either treatment group) drug-related clinical adverse event (AE) of moderate to severe intensity and at a higher incidence compared with placebo was headache (2% vs <1%). Intensities were defined as follows: Moderate (discomfort enough to cause interference with usual activity); or Severe (incapacitating with inability to work or do usual activity). Grade 2–4 creatine kinase laboratory abnormalities were observed in subjects treated with Isentress. Myopathy and rhabdomyolysis have been reported. Use with caution in patients at increased risk of myopathy or rhabdomyolysis, such as patients receiving concomitant medications known to cause these conditions. Cancers were reported in treatment-experienced subjects who initiated Isentress or placebo, both with optimized background therapy (OBT), and in treatment-naïve subjects who initiated Isentress or efavirenz, both with emtricitabine (+) tenofovir; several were recurrent. The risk of developing cancer in clinical studies was similar in the group receiving Isentress and the group receiving the comparator. Rash occurred more commonly in treatment-experienced subjects receiving regimens containing Isentress + darunavir/ritonavir compared to subjects receiving Isentress without darunavir/ritonavir or darunavir/ritonavir without Isentress. However, rash that was considered drug related occurred at similar rates for all 3 groups. These rashes were mild to moderate in severity and did not limit therapy; there were no discontinuations due to rash.

Questions and Answers

Q: How is the medication supplied?

A: 25mg and 100mg chewable tablets which contain phenylalanine, 100mg tablets

Q: Is the 5-year data published?
A: Not yet; available as data on file and shows similar results as 3-year data.

Q: What is life expectancy of patients with HIV?
A: If treated, similar to general population. If co-morbid condition exists, most patients die from the co-morbid condition instead of HIV/AIDS.

Q: Is a supplemental rebate being offered?
A: It is being considered.

III. GlaxoSmithKline

Ken Linsky, PharmD, Scientific Account Liaison
Eileen Baranowski, PharmD, Director, Scientific Account Liaisons
Vivian Lee Ryan, Account Executive

Potiga™ (ezogabine), CV

Indication and Mechanism of Action

- Potiga is a potassium channel opener indicated as adjunctive treatment of partial-onset seizures in patients aged 18 years and older. The mechanism by which ezogabine exerts its therapeutic effects has not been fully elucidated.
- In vitro studies indicate that ezogabine enhances transmembrane potassium currents mediated by the KCNQ (Kv7.2 to 7.5) family of ion channels. By activating KCNQ channels, ezogabine is thought to stabilize the resting membrane potential and reduce brain excitability. In vitro studies suggest that ezogabine may also exert therapeutic effects through augmentation of GABA-mediated currents.

Efficacy

- Potiga was effective in patients with inadequately controlled partial onset seizures (POS) with or without secondary generalization despite receiving one to three antiepileptic drugs (AEDs), as demonstrated in three multicenter, randomized, double-blind, placebo-controlled studies involving 1,239 adult patients.
- In these trials, relative to placebo, Potiga significantly reduced the frequency of seizures, and demonstrated significantly higher responder rates. Specifically, in a 16-week dose-ranging study in adults with POS, Potiga 900 and 1,200 mg/day significantly reduced the total partial seizure rate compared to placebo (600 mg/day dosing did not reach statistical significance).
- In another 16-week study in adults with POS, patients taking Potiga 600 and 900 mg/day had significantly greater reduction in 28–day total partial seizure frequency compared to placebo.
- In an 18-week study in adults with POS, patients taking Potiga 1,200 mg/day experienced significantly greater reduction in 28–day total partial seizure frequency compared to patients taking placebo. In addition, Potiga consistently demonstrated significantly higher responder rates (defined as ≥ 50% reduction in 28–day rate of seizures from the baseline phase to end of double-blind phase) relative to placebo, ranging from 20% to more than 40%.
- In particular, in the dose-ranging trial, significantly greater responder rates compared to placebo were reported for the 900 and 1200 mg/day doses (600 mg/day dosing did not reach statistical significance).
- In the second and third studies, responder rates were also significantly improved relative to placebo for all three doses.

Safety

- The most frequently reported (≥4% and occurring approximately twice the placebo rate) adverse reactions in controlled studies evaluating Potiga as adjunctive therapy in partial-onset seizures included the following:
    - dizziness (23%), somnolence (22%), fatigue (15%), confusional state (9%), vertigo (8%), tremor (8%), abnormal coordination (7%), diplopia (7%), disturbance in attention (6%), memory impairment (6%), asthenia (5%), blurred vision (5%), gait disturbance (4%), aphasia (4%), dysarthria (4%), and balance disorder (4%).
- Potiga is a Schedule V controlled substance.
- A Risk Evaluation and Mitigation Strategy (REMS) program is in place for Potiga to inform health care professionals of the risk of urinary retention and the symptoms of acute urinary retention in patients taking Potiga. Patients receiving Potiga should be carefully monitored for urologic symptoms.

- In addition, the following should be monitored: confusional state, psychotic symptoms, and hallucinations; dizziness and somnolence; QT interval in patients taking concomitant medications known to increase the QT interval or with certain heart conditions; and suicidal thoughts or behaviors.

Questions and Answers
Q: Are other indications, such as initial treatment or other types of epilepsy, being sought?
A: No. With newer AEDs agents, pivotal trials are not being conducted as initial treatment.

Q: Is a pediatric indication being sought?
A: A study in patients aged 12-18 years recently started.

Q: Are there any head-to-head trials being planned?
A: No.

Q: Are there any health outcomes studies being conducted?
A: There are health outcomes studies being considered but not yet determined.

Q: What strengths are available and are other formulations being developed?
A: Available as 50mg, 100mg, 200mg and 300mg tablets, and titration pack. No XR formulation being studied in US but is in Japan.

Q: Is Potiga specific to only potassium channels in central nervous system?
A: No, it can affect other potassium channels such as in heart with a potential QT prolongation by 7.7 milliseconds.

Q: What are considered the advantages of Potiga?
A: Unique mechanism of action as potassium channel opener, effective in patients who have tried other AEDs, no CYP450 drug-drug interactions.

IV. Gilead

Ray E. Lancaster, BS, PharmD, Associate Director, Medical Sciences
Judy Buchanan, RN, Executive Manager, National Accounts

Atripla® (efavirenz/emtricitabine/tenofovir disoproxil fumarate)

Indication and Usage
- Single Tablet Regimen (STR)-based therapies provide:
    - Regimen simplification & lower pill burden as recommended by DHHS/IAS-USA Treatment Guidelines
    - Single co-pay
    - Increased adherence via
        - Simultaneous dosing of the antiretroviral regimen
        - Avoidance of prescription refill misalignment
        - Improved quality of life
    - An association with better outcomes and lower healthcare costs
- Atripla is a once-daily STR and preferred initial regimen by both the DHHS and IAS-USA guidelines
- Atripla is indicated for use alone as a complete regimen or in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients 12 years of age and older.
    - This indication is for both treatment-naïve patients and virologically suppressed patients with no history of virologic failure who switch to Atripla.
    - Atripla is not approved for the treatment of chronic hepatitis B virus (HBV) infection and the safety and efficacy of Atripla have not been established in patients coinfected with HBV and HIV-1.

Efficacy and Safety
- BLACK BOX WARNING: Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogs, including tenofovir disoproxil fumarate, a component of Atripla, in combination with other antiretrovirals.
- Severe acute exacerbations of hepatitis B have been reported in patients who have discontinued Emtriva or Viread, which are components of Atripla. Hepatic function should be monitored closely with both clinical and laboratory follow-up for at least several months in patients who are coinfected with HIV-1 and HBV and discontinue Atripla. If appropriate, initiation of anti-hepatitis B therapy may be warranted.

- Atripla (or its components) demonstrated non-inferior efficacy and comparable tolerability in the following studies:
    - Non-inferior to Sustiva® (efavirenz) + Combivir® (lamivudine/zidovudine) in treatment-naïve adult patients in Study 934: 81% vs. 58% achieved <400 copies/mL at Week 144 (TLOVR analysis)
        - Virologic suppression rate was superior with Atripla; however, this largely results from the higher number of discontinuations due to adverse events and other reasons in the Combivir arm
        - Similar overall safety and resistance profile with fewer discontinuations due to adverse events with Atripla: 5% vs. 12%
    - Non-inferior to staying on baseline regimen in stable, virologically suppressed adult patients with no history of virologic failure in Study 073: 89% vs. 88% achieved <200 copies/mL at Week 48 (TLOVR analysis)
        - Renal function (measured by estimated glomerular filtration rate [eGFR]) remained unchanged
        - Development of resistance was uncommon
    - Stribild™ (elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate) was non-inferior to Atripla in Study 102: 84% on Atripla vs. 88% achieved <50 copies/mL at Week 48 (SNAPSHOT analysis)
        - Compared to Stribild, Atripla demonstrated lower rate of nausea (Grade 1), higher rates of dizziness, abnormal dreams and insomnia, and similar rate of discontinuation due to adverse events (5% vs. 4%)
        - Similar rates of virologic failure (7% in both arms) and resistance development (2% in both arms)
    - Isentress® (raltegravir) + Truvada® (emtricitabine/tenofovir disoproxil fumarate) was non-inferior to the components of Atripla in the STARTMRK study
        - Suppression <50 copies/mL was 82% for Atripla vs. 86% at Week 48 and 61% for Atripla vs. 71% at Week 240 (non-completer = failure [NC=F] analysis)
        - No significant difference in discontinuations due to adverse events and rates of resistance development were similar through 240 weeks
- Atripla was associated with improved adherence and a reduction in hospitalization costs in several pharmacoeconomic analyses.
- Atripla is the first STR and based on data from 2 pivotal trials provides:
    - An STR option for providers wanting to initiate a one pill once a day option for naïve patients
    - An STR option for providers who wish to switch patients from an NNRTI- or PI-based regimen, which can reduce pill burden and potentially improve tolerability

Questions and Answers
Q: When does the patent expire?
A: 2018.

Q: What was the increase in adherence with single tablet regimen?
A: Do not have the exact numbers and difference, but the increase in adherence with single tablet regimen was significant.

Stribild™ (cobicistat/elvitegravir/emtricitabine/tenofovir disoproxil fumarate)

Indication and Usage
- Single Tablet Regimens (STR) based therapies provide:
    - Regimen Simplification & lower pill burden as recommended by DHHS/IAS-USA Treatment Guidelines
    - Single co-pay
    - Increased adherence via
        - Simultaneous dosing of the ARV Regimen
        - Avoidance of prescription refill misalignment
        - And Improved Quality of Life
    - An association with better outcomes and lower healthcare costs
- Stribild, a combination of 1 integrase strand transfer inhibitor, 1 pharmacokinetic enhancer, and 2 nucleos(t)ide analog HIV-1 reverse transcriptase inhibitors is an alternative regimen in the DHHS and IAS-USA guidelines and combines the DHHS preferred backbone NRTI Truvada, with Elvitegravir, an integrase inhibitor and Cobicistat, a pharmacokinetic boosting agent with no antiviral activity in a once daily STR.
- Stribild is indicated as a complete regimen for the treatment of HIV-1 infection in adults who are antiretroviral treatment-naïve

Efficacy and Safety

- Stribild has a Black Boxed Warning that the drug can cause a buildup of lactic acid in the blood and severe liver problems, both of which can be fatal. The Boxed Warning also states that Stribild is not approved to treat chronic hepatitis B virus infection.
- Stribild demonstrated non-inferior efficacy via Snapshot analysis compared to:
    - Reyataz-Study 103 : 90% vs. 87%
    - Atripla- Study 102 : 88% vs. 84%
    - Non-inferior virologic suppression across protocol-specified subgroups, including HIV-1 RNA >100,000 copies/mL at baseline
- Stribild was well tolerated with similar low-rates of treatment discontinuation to the comparator arms of:
    - Reyataz
        - Fewer reports of ocular icterus
        - Discontinuations due to renal adverse events were: 0.3% in each arm
        - Cobicistat increased serum Cr 0.12mg/dL for Stribild
        - RTV increased serum Cr 0.08mg/dL for Reyataz
            - This impact on eGFR is consistent with MATE-1 inhibition on active tubular secretion by COBI and RTV but does not affect aGFR, therefore
            - Stribild should be initiated in patients with CrCL > 70ml/min and discontinued in patients with CrCL < 50ml/min to minimize the risk of TDF related renal issues in patients with moderate to severe renal impairment.
        - Smaller increases in triglycerides with Stribild
- Stribild was well tolerated with similar low-rates of treatment discontinuation to the comparator arms of:
    - Atripla
        - Fewer reports of abnormal dreams, insomnia, dizziness, and rash
        - Higher rate of nausea (Grade 1)
        - 1.4% discontinuing due to renal events in the Stribild arm
            - Median 0.14 mg/dL increase in serum creatinine with Stribild compared to 0.01mg/dL for Atripla ($p<0.001$)
            - Stribild should be initiated in patients with CrCL > 70ml/min and discontinued in patients with CrCL < 50ml/min to reduce the risk of TDF related renal issues in patients with moderate to severe renal impairment.
    - Smaller increases in total cholesterol and LDL with Stribild compared to Atripla
- Stribild is the first integrase based STR and based on data from 2 pivotal registration trials provides:
    - An STR option for providers that initiate treatment naïve HIV-1 patients with either a Protease Inhibitor or an Integrase Inhibitor based regimen
    - An STR option for providers with concerns around treatment naive HIV-1 patients with high viral loads and who may not consider an NNRTI based STR option due to efficacy/safety concerns
    - An STR option for treatment naïve HIV-1 patients with CV or neuropsychiatric co-morbidities or concerns around NNRTI based therapy CV or neuropsychiatric ADEs

Questions and Answers

Q: Was the compliance data conducted with a HIV medication?
A: Yes, Study 073 was conducted with Atripla, but no compliance studies yet with Complera or Stribild.

Q: What is considered the place in therapy for Stribild?
A: When considering a protease inhibitor or integrase inhibitor, no concerns of use in patients with increased viral load as with Complera, if patient has neuropsychiatric issues, if patient is pregnant.

Q: Do the guidelines state that Stribild should be used over Atripla in patients with depression or mental health issues since difference in depression was only 2 percentage points in the clinical trial?
A: No, not the current guidelines.

Q: Are studies in treatment-experienced patients being conducted?
A: Yes, switch studies are being conducted.

Q: How are the Care Management Organizations (CMOs) covering?
A: Complera is preferred without prior authorization (PA) with the 3 CMOs, Stribild is preferred with the 3 CMOs, with WellCare not requiring PA, and Amerigroup and Peach State requiring new product PA until reviewed.

V. Corcept

Michelle Watson, PhD, Medical Science Liaison
Thom S. Martin, Associate Vice-President, VCG & Associates

Korlym™ (mifepristone)

Indication and Usage

- Korlym (mifepristone) 300 mg Tablets is a cortisol receptor blocker indicated to control hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery.
- Korlym is the only approved medical treatment for patients with Cushing's syndrome.
- Cushing's syndrome is rare endocrine disorder (10-15 in 1 million people) caused by prolonged exposure of the body's tissues to excessive concentrations of circulating free glucocorticoids (cortisol analogs). Korlym directly blocks the cortisol receptor and the progesterone receptor.

Efficacy and Safety

- Korlym has a black box warning for termination of pregnancy. Mifepristone is a potent antagonist of progesterone and cortisol via the progesterone and glucocorticoid (GR-II) receptors, respectively. The antiprogestational effects will result in the termination of pregnancy.
- Data from a Phase 3 trial (Fleseriu et al. 2012) demonstrated that refractory Cushing's syndrome patients receiving Korlym experienced significant clinical and metabolic improvements over baseline measurements. Based on this study, the FDA approved Korlym on Feb 17 to treat the clinical and metabolic effects of hypercortisolism in patients with endogenous Cushing's syndrome.
- The open-label trial enrolled 50 Cushing's syndrome patients examined at 17 clinical sites across the United States. A majority of the patients had undergone unsuccessful surgery. Of the 50 patients, 43 had Cushing's disease, four had ectopic tumors and three had adrenal tumors. Patients were divided into two groups: a glucose-intolerant group (n=29) and a hypertension group (n=21).
- The primary analysis was a responder analysis. In the glucose-intolerant group, a responder was defined as a patient who achieved a 25% or greater improvement in glucose tolerance as measured by a standard two-hour glucose-tolerance test after 24 weeks of treatment (or at the early termination visit) compared to baseline. In the hypertension group, a responder was defined as a patient who achieved a 5 millimeter or greater improvement in diastolic blood pressure after 24 weeks of treatment (or at the early termination visit) compared to baseline. Based on the modified intent-to-treat analysis (≥30 days of Korlym; N=46), the primary endpoints were met in both patient groups, with 15 of 25 (60%) patients in the glucose-intolerant group and 8 of 21 (38%) patients in the hypertension group responding to treatment with Korlym.
- Secondary endpoints were assessed for the broader clinical benefit of Korlym based on global clinical improvement evaluated by a Data Review Board, comprised of three academic physicians who specialize in the evaluation and treatment of patients with Cushing's syndrome. The Data Review Board evaluated efficacy data available for each patient at six weeks of the trial and determined whether the patient's clinical manifestations of Cushing's syndrome had worsened, stayed the same, or improved compared to baseline. Additional data used to determine clinical improvement included changes in diabetes and hypertension medications, hemoglobin A1c, insulin sensitivity, metabolic function, weight, body composition, Cushingoid appearance, cognitive/psychiatric evaluations, and quality of life. At least two Data Review Board members were required to determine that a patient had made a clinically significant improvement at each visit for the patient to qualify as a responder. The secondary endpoint was met with a response rate of 87%.
- Based on the intent-to-treat population (N=50), adverse events among the trial patients were mostly mild to moderate. Fatigue and nausea were the most commonly reported adverse events attributed to Korlym. Of 16 patients who experienced serious adverse events; six were believed to be related to Korlym treatment. Of 16 patients who withdrew from the study (not necessarily the same patients), seven discontinued the treatment because of adverse events and seven withdrew consent or discontinued for other reasons. In addition, two patients died of underlying metastatic disease. No deaths were attributed to treatment with Korlym.
- Existing evidence has demonstrated the efficacy and safety of Korlym or mifepristone for the treatment of Cushing's syndrome. Of note, approximately 90% of the patients who completed the Phase 3 trial chose to continue as part of the ongoing extension study. Data collected from the extension study will be submitted to FDA to support the efficacy and long-term safety of Korlym use in patients with Cushing's syndrome.

Questions and Answers

Q: Is a REMS program required?

A: The FDA does not require a REMS program. There is a patient guide and Korlym is only available through Curascript.

Q: What treatment alternatives were available to patients before the availability of Korlym?
A: Surgery, ketoconazole, adrenalectomy. Ketoconazole was the pharmacologic therapy that may have been used, but is not FDA-indicated and can be associated with adrenal insufficiency and liver toxicity.

Q: Are higher strengths of tablets being developed?
A: No, the strength available is to ensure its difference from RU-486.

Q: Are other indications being sought?
A: Use before surgery and use in psychotic depression are being studied.

Q: Is a supplemental rebate being offered?
A: A supplemental rebate of $0 was submitted.

VI. Abbott

Abbott did not present at the Forum but provided the summary information below on Kaletra for review.

Kaletra (lopinavir/ritonavir)

Indication and Usage

- Kaletra is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatrics ages 14 days and older.
- Kaletra contains lopinavir and is the only protease inhibitor co-formulated with low-dose ritonavir.
- Kaletra can be dosed either once-daily (QD) or twice-daily (BID). Kaletra tablets and oral solution should not be administered once daily in pediatric patients < 18 years of age. Kaletra tablets and oral solution should not be administered as a once daily regimen in combination with efavirenz, nevirapine, amprenavir, or nelfinavir.

Efficacy and Safety

- Kaletra has demonstrated efficacy in both adult antiretroviral-naïve and treatment-experienced patients, and in pediatrics.
- The M97-720 is the longest follow-up for a prospective controlled study of a defined antiretroviral regimen evaluating efficacy and safety in HIV infected antiretroviral-naïve adult patients. In this study, 100 antiretroviral-naïve patients with viral loads >5000 copies/mL and no CD4 restrictions were randomized to receive one of 3 Kaletra doses (200/100 mg BID, 400/100 mg BID, or 400/200 mg BID) plus stavudine 40 mg BID and lamivudine 150 mg BID. After 48 weeks, all patients received open-label Kaletra 400/100 mg BID and continued stavudine and lamivudine. After 6 years on study, patients were permitted to replace stavudine with tenofovir DF. The original primary endpoint of the study, the proportion of subjects with HIV RNA levels <400 copies/mL at Week 24, was extended for the 7-year follow-up analysis. Thus, the primary endpoint for the 7-year analysis, was the proportion of subjects with plasma HIV RNA <400 copies/mL at Week 360 by intent-to-treat analysis, with missing values considered failures. At 7 years, 61% of subjects had plasma HIV RNA levels <400 copies/mL and 59% had <50 copies/mL. In the on-treatment analysis, 98% of subjects had plasma HIV RNA levels <400 copies/mL and 95% had <50 copies/mL. Among the 60 subjects with baseline and Week 360 measurements, the mean CD4 cell count increased from 275 cells/mm3 at baseline to 776 cells/mm3 at Week 360. This increase appeared to be consistent regardless of baseline levels with mean increases through 360 weeks between 410-556 cells/mm3. Overall, 39 subjects discontinued treatment due to adverse events (n=16), personal/other reasons (10), loss to follow-up (9), and noncompliance (4). No lopinavir or stavudine resistance was observed in subjects experiencing loss of virologic response while lamivudine resistance was detected in 4 of 19 subjects. The most common drug-related moderate or severe adverse events were diarrhea (28%), nausea (16%), and abdominal pain (11%). Patients who received stavudine and switched to tenofovir TD experienced significant improvements in total cholesterol and triglycerides: Total cholesterol reduced by 26 mg/dL and triglycerides by 185 mg/dL after 24 weeks following the switch from stavudine to tenofovir DF.
- Resistance: Studies in antiretroviral-naïve patients have shown an absence of primary mutations to lopinavir at viral rebound. Of the 1,318 patients treated with Kaletra during antiretroviral-naïve patient trials ranging from 48 weeks through 360 weeks of therapy, no patients developed primary resistance to Kaletra. In addition, an analysis from M97-720 showed there was no change in phenotypic susceptibility to any other protease inhibitors between baseline and virologic rebound in the patients that qualified for resistance testing during the study. Studies in the antiretroviral-naïve patients have also shown a low incidence of mutations associated with the accompanying

nucleosides. Of the patients in these studies eligible for resistance testing and with available results, 28% (32/114) developed resistance to lamivudine or emtricitabine, 0% (0/40) developed resistance to tenofovir, and 0% (0/74) developed TAMs or resistance to stavudine. Kaletra has a high genetic barrier to resistance and requires the accumulation of several mutations to result in phenotypic failure. The accumulation of protease inhibitor resistance prior to the initiation of Kaletra will subsequently reduce the virologic response to Kaletra. However, despite the presence of some mutations, Kaletra can be active in patients with previous virologic failure as demonstrated in the antiretroviral-experienced clinical trials.

- Kaletra is contradicted in patients with previously demonstrated clinically significant hypersensitivity (e.g., toxic epidermal necrolysis, Stevens-Johnson syndrome, erythema multiforme) to any of its ingredients, including ritonavir.
- Co-administration of KALETRA is contraindicated with drugs that are highly dependent on CYP3A for clearance and for which elevated plasma concentrations are associated with serious and/or life-threatening reactions.
- The potential for drug-drug interactions must be considered prior to and during therapy with Kaletra. Preterm neonates may be at increased risk of propylene glycol-associated adverse events due to diminished ability to metabolize propylene glycol, thereby leading to accumulation and potential adverse events.
- Pancreatitis has been observed in patients receiving KALETRA therapy, including those who developed marked triglyceride elevations. Although a causal relationship to KALETRA has not been established, marked triglyceride elevations are a risk factor for development of pancreatitis.
- Lopinavir/ritonavir prolongs the PR interval in some patients. Cases of second or third degree atrioventricular block have been reported. Kaletra should be used with caution in patients with underlying structural heart disease, pre-existing conduction system abnormalities, ischemic heart disease or cardiomyopathies, as these patients may be at increased risk for developing cardiac conduction abnormalities. Avoid use in patients with congenital long QT syndrome, those with hypokalemia, and with other drugs that prolong the QT interval.
- There have been post-marketing reports of hepatic dysfunction, including some fatalities. These have generally occurred in patients with advanced HIV-1 disease taking multiple concomitant medications in the setting of underlying chronic hepatitis or cirrhosis. A causal relationship with Kaletra therapy has not been established. Elevated transaminases with or without elevated bilirubin levels have been reported in HIV-1 mono-infected and uninfected patients as early as 7 days after the initiation of Kaletra.
- Patients may develop new onset or exacerbations of diabetes mellitus, hyperglycemia, immune reconstitution syndrome, elevation in cholesterol and redistribution/accumulation of body fat.

Place in Therapy

- Kaletra is consistently recommended as a preferred protease inhibitor (PI) in combination therapy by the Department of Health and Human Services (DHHS) within the various treatment guidelines. Specifically, in the adult and adolescent guidelines, Kaletra administered either QD or BID is among the preferred PI options rated AI (i.e., strong recommendation based on randomized trials with either clinical or validated laboratory outcomes) for the first antiretroviral regimen for treatment-naïve patients. Other preferred AI-rated PI options include atazanavir + ritonavir once daily and darunavir + ritonavir once daily and raltegravir + tenofovir/emtricitabine. The DHHS designates regimens as “preferred” when clinical trial data suggest optimal and durable efficacy with acceptable tolerability and ease of use. The International AIDS Society US Panel has also recommended Kaletra as a component of therapy for the initial treatment regimen in adults based upon substantial clinical trial data, including long-term outcomes. Other recommended ritonavir-boosted PI regimens include the following: atazanavir, fosamprenavir, darunavir, and saquinavir. The DHHS has also issued guidelines for the management of HIV infection in pediatrics. The preferred initial therapy for all infants and children ages ≥14 days to <3 years is lopinavir/ritonavir plus two nucleoside reverse transcriptase inhibitors (NRTIs), with nevirapine-based regimens now considered an alternative regimen for initial therapy in this age group. For initial therapy for children age >6 years, atazanavir with low-dose ritonavir boosting has been added as a second preferred PI choice, joining lopinavir/ritonavir. The DHHS has also provided recommendations for the management of HIV in pregnant women. Specifically, the DHHS lists Kaletra as the recommended PI for use in combination regimens with 2 NRTI drugs for pregnant women. Kaletra is also recommended as the preferred PI in a combination regimen by the Public Health Service for the management of both occupational (expanded regimen only) and non-occupational post-exposure prophylaxis.

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, February 7, 2013, with an overflow day on Tuesday, February 12, 2013 if needed.

Date: **Thursday, February 7, 2013 from 9am to 5pm EST**
Tuesday, February 12, 2013 from 9am to 5pm EST (overflow day if needed)

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, therapeutic classes and/or supplemental rebate classes up for review are 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 Forum. Manufacturers with drugs up for review at the current DURB meeting will be granted preference when seeking appointments. All requests for appointments must be made in writing to **GAMedicaid@nhc-llc.com**.

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 shall be limited to 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.
- For existing drugs, manufacturers are highly encouraged to present ***only*** 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, 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 **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.

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.

Presentation Opportunity:

Manufacturers' Forum: A forum prior to each relevant DURB meeting whereby manufacturers may present:

1) Clinical information relevant to either a new drug on the market or a drug that is part of a supplemental rebate class under review by the DURB at the next meeting.

2) Clinical information relevant to ongoing NHC/Catamarn Clinical Management Strategy development (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.

Upon review of the NHC clinical information and based upon its expertise and discussions, the DURB makes recommendations to GDCH.

Opportunity to Appeal to GDCH:

GDCH Review Process: DURB recommendations are reviewed by GDCH for final decisions. Manufacturers may request an appeal meeting for review directly with GDCH within 10 business days following DURB meetings. **Contact: Rose Marie Duncan 404-657-7247**

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, March 19, 2013:	9:00am – 4:00pm
Thursday, June 6, 2013:	10:00am – 2:00pm
Thursday, September 19, 2013:	10:00am – 2:00pm
Tuesday, December 10, 2013:	10:00am – 2:00pm

Manufacturers' Forum

NorthStar HealthCare Consulting

1121 Alderman Drive

Suite 112

Alpharetta, Georgia 30005

Thursday, February 7, 2013:	9:00am – 5:00pm
(Overflow day is Tuesday, February 12, 2013 if needed)	
Thursday, May 2, 2013:	9:00am – 5:00pm
Thursday, August 1, 2013:	9:00am – 5:00pm
Thursday, November 7, 2013:	9:00am – 5:00pm