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 20, 2012

NorthStar
HealthCare Consulting
Let Us Be Your Guide

This page intentionally left blank

GEORGIA DEPARTMENT OF COMMUNITY HEALTH

DRUG UTILIZATION REVIEW BOARD MEETING
AGENDA

2 Peachtree Street - 5th Floor DCH Board Room
Atlanta, Georgia 30303
September 20, 2012 – 10:00 a.m. to 2:00 p.m.

CALL TO ORDER	*Gary Williams, MD, Chairman*
COMMON PDL	*Jerry Dubberly, PharmD, MBA, Chief*
COMMENTS FROM THE DEPARTMENT	*Linda Wiant, PharmD, Director*
MINUTES FROM PREVIOUS MEETING	*Chairman*
NORTHSTAR HEALTHCARE CONSULTING	*Emily Baker, PharmD, BCPS, MBA, MHA* *Tara R. Cockerham, PharmD*

PDL MANAGEMENT

- **Manufacturers' Forum**
- **New Drug Reviews**
  - Arcapta™
  - Erivedge™
  - Inlyta™
  - Kalydeco™
  - Onfi™
  - Picato™
  - Rectiv™
  - Zioptan™
- **Clinical Utilization Reviews**
  - Long-Acting Beta-Agonist Containing Products for Asthma
  - Oral Progesterone
  - Simvastatin 80mg Containing Products
- **Follow-Up Class Reviews – Clinical Updates**
  - Antihyperkinesis Agents
  - Long-Acting Beta-Agonist Inhalers
  - Statins

FUTURE AGENDA ITEMS	*Chairman*
CONSUMER COMMENTS SESSION	
ADJOURNMENT OF OPEN SESSION	*Chairman*
EXECUTIVE SESSION	
RECONVENING OF OPEN SESSION	
➢ Board's Voting for Recommendations to DCH	*Chairman*
ADJOURNMENT OF MEETING	*Chairman*

NorthStar HealthCare Consulting
Let Us Be Your Guide

This page intentionally left blank

Department of Community Health
Drug Utilization Review Board (DURB)
MINUTES
Thursday, June 21, 2012

MEMBERS PRESENT

Gary M. Williams, M.D., Chairman
Laurel E. Ashworth, Pharm.D., Vice-Chairperson
Joseph R. Bona, M.D., MBA
Melissa D. Carter, J.D.
Carl Ellis, R.Ph.
Arvind Gupta, M.D.
Robyn Lorys, Pharm.D.
J. Russell May, Pharm.D.
Osgood (Drew) A. Miller, R.Ph.
Matthew Perri, III, R.Ph., Ph.D.

MEMBERS ABSENT

Paul D. Boyce, M.D.
Karen L. Carter, M.D.
Truddie Darden, M.D.
Rondell C. Jaggers, Pharm.D.
Michael S. O'Connor, Pharm.D.

Staff

Jerry Dubberly, Pharm.D., MBA, Chief Medical Assistance Plans
David Schuster, Interim Deputy 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., Clinical Manager, Pharmacy Services
Lori Garner, MHS, MBA, R.Ph., Pharmacist, Pharmacy Services
Rose Marie Duncan, MBA, Program Associate, Pharmacy Services
William Kitson, Pharm.D. Candidate
Afzal Mistry, Pharm.D. Candidate

Office of General Counsel

Woody Dahmer, J.D., Senior Staff Attorney
Richard Greene, J.D., General Counsel
Alison Earles, J.D., Ethics Officer

NorthStar HealthCare Consulting

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

SXC Health Solutions, Inc.

Susan McCreight, Account Manager
Mark Hall, Sr. Manager
Talmahjia “Tami” Sweat, Pharm.D., Clinical Systems Product Manager

Goold Health Services
Jeff Barkin, M.D., Associate Medical Director
Steve Liles, Pharm.D., Sr. Director, Pharmacy Services
Doug Martin, Pharm.D., Pharmacy Project Manager

University of Georgia Pharmacy School
Elizabeth Ensley
Eunice Kim
Sarah Evans

Mercer University Pharmacy School
Indu Shekar
Mitansu A. Patel
Tuyen Lam Nguyen

Call to Order
The Drug Utilization Review Board (DURB/DUR Board/Board) held its second meeting for the calendar year on June 21, 2012. The Chairman, Gary M. Williams, M.D., called the meeting to order at 10:00am. A new Board member, Melissa Carter, J.D., was welcomed. It was noted that the meeting format will include an ethics presentation by Woody Dahmer from the DCH Office of General Counsel. The presentation will address ethics and compliance of all federal and state open meeting statutes and guidelines and permanent changes on how the executive session will be conducted. Voting on compounds/compound classes will occur in the reconvened open session and all Board members should attend to assure 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. Additional presentations will be made by Jerry Dubberly, Pharm.D., MBA, Chief Medical Assistance Plans, Christine Bruno, M.D., and former DCH Pharmacy intern, Afzal Mistry.

Comments from the Chief
Jerry Dubberly, Pharm.D., MBA, Chief Medical Assistance Plans, commented on the Medicaid Redesign Project. The Department worked with a consultant, Navigant, to review the current Medicaid program. A final report was delivered in January and is posted on the DCH website. The Department has been working with task forces to receive additional feedback based on previous stakeholder meetings and findings from the Navigant report. Among the goals and objectives DCH wanted to accomplish were: improving health outcomes for members, long-term sustainable program savings, appropriate utilization services, access, an operationally and fiscally feasible solution, payment reform, member engagement and a scalable solution. The Department is currently looking at several options from the strategy report and will come to a decision later in the summer prior to the next DURB meeting.

Ethics Presentation
Woody Dahmer, J.D., Senior Staff Attorney, Office of General Counsel, introduced Richard Greene, General Counsel, and Alison Earles, Ethics Officer, and presented an ethics overview to the Board (Attachment A). Items included in the presentation were the DCH statement of ethics, conflicts of interest and confidentiality requirements.

Comments from the Department

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

1. Pharmacy Students –Students from the University of Georgia and Mercer Pharmacy Schools were welcomed.
2. Open Meetings Act – Updates to this Act requires the Board to vote in the open session (reconvened after the executive session).
3. Resignation - Kimberly S. Carroll, M.D., has resigned from the DUR Board. Appreciation for her service to the Board was expressed.
4. New Member – Melissa Carter, J.D., was welcomed as the newest Board member in the Consumer Advocate role. She received a B.S. degree in Psychology and a Juris Doctor degree from the University of Illinois. She is a member of the bar in the States of Georgia and Illinois. She has served as the Director in the Office of the Child Advocate for the Protection of Children for the State of Georgia and currently serves as the Director of the Barton Child Law and Policy Center at the Emory School of Law.
5. Osgood A. Miller, R.Ph. – Osgood A. "Drew" Miller, R.Ph. was congratulated on his award, The Innovative Practice Award, given by the Georgia Pharmacy Association (GPhA). He currently has an active Diabetes practice, teaches immunizations and has a 'Green' practice where he recycles plastic bottles and vials.

Minutes from the Previous Meeting

Board members reviewed the minutes from the March 15, 2012 meeting. There were no corrections. A motion was made by J. Russell May, Pharm.D., and seconded by Osgood A. Miller, R.Ph.. The motion carried unanimously to approve the minutes as written.

Manufacturers' Forum

Tara R. 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 seven (7) manufacturers participated and provided information regarding the following drugs.

Manufacturers	Drugs
Dyax	Kalbitor
Teva	Tev-Tropin
Merck	Victrelis, Saphris
Sunovion	Latuda
Shire	Firazyr, Vpriv
DepoMed	Gralise
Vertex	Incivek

There were no comments or questions. The next forum is Thursday, August 9, 2012 from 9am-5pm at the NorthStar Healthcare Consulting office: 1121 Alderman Drive, Suite 112, Alpharetta, GA 30005.

Therapeutic Class Reviews

Clinical information for the following therapeutic classes was presented for discussion by Dr. Tara Cockerham. The complete detailed therapeutic class reviews were provided in the

Therapeutic Class Review section of the June DUR Board binder. Additional discussion, comments and questions were noted as follows:

- Protease Inhibitors for Hepatitis C – A letter from Dr. Carlos Franco (see Attachment B) requesting addition of telaprevir to the PDL was read. Afzal Mistry, Pharm.D. Candidate, gave an overview of utilization trends for Incivek and Victrelis (Attachment C). A question was asked about the long-term effect of partial therapy on treatment resistance. Dr. Christine Bruno, a Hepatologist at Atlanta Gastroenterology Associates, discussed using Incivek and Victrelis in clinical practice. She provided feedback and answered questions regarding product selection, adverse events/side effects, and relapse.
- Agents for Hereditary Angioedema – A question was asked regarding average monthly dosing and frequency of attacks.
- Atypical Antipsychotics – There were no comments or questions.
- Growth Hormones – There were no comments or questions.

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 June 2012 DUR Board binder.

Therapeutic Class	Drugs	Presenter
Antihemophilic Products	*Corifact (factor XIII concentrate)*	Emily Baker, Pharm.D., BCPS
Chelating Agents	*Ferriprox (deferiprone)*	Emily Baker, Pharm.D., BCPS
Antineoplastics	*Jakafi (ruxolitinib)*	Emily Baker, Pharm.D., BCPS
Agents for Gaucher Disease	*Vpriv (velaglucerase)*	Emily Baker, Pharm.D., BCPS

There were no comments or questions from the Board.

Non-Supplemental Rebate Drugs – Clinical Updates Review

Clinical updates to the Non-Supplemental Rebate categories were listed in the Non-Supplemental Review section of the DURB binder. The following therapeutic categories had updates:

Drug Class/Name
Analgesics-Miscellaneous
Anaphylaxis Therapy
Angiotensin Converting Enzyme Inhibitors and Calcium Channel Blockers Combinations
Antifungals
Diabetic – Meglitinides

Diabetic – Thiazolidinediones
Fibromyalgia Agents
Fluoroquinolones
Gastrointestinal – Proton Pump Inhibitors
Immunosuppressants – Renal Transplant Rejection Agents
Narcotics – Miscellaneous
Osteoporosis Agents
Parkinson's Disease – Selective Dopamine Agonists

There were no comments or questions from the Board.

Follow-Up from Last Meeting

- Narcotics – A prescription limit is being implemented for 9/1/2012 and a Retro-DUR intervention is being conducted.
- Suboxone – A Retro-DUR intervention will be conducted to look at its concomitant use with benzodiazepines and narcotics.

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:

- Prometrium – agenda topic for September meeting

Consumer Comments Session

Consumer comments were presented to the Board from the following:

- Mr. Camden Pace (member of NAMI) spoke on behalf of himself regarding his illness.
- Dr. Cockerham presented consumer comments to the Board from a letter from Dr. Karen Schultz, Pediatric Endocrine Associates (see Attachment D).

A disclosure form was completed by Mr. Pace and Dr. Schultz and was reviewed by the Department.

Note: Dr. Brian Pearlman with the Center for Hepatitis C - Atlanta Medical Center signed in with the intent to speak before the Board, but he was not available or left the meeting before he was able to do so.

Upcoming Meetings

The following upcoming meetings were published in the DURB binder:

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

  Thursday, September 20, 2012
  Tuesday, December 11, 2012

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

  Thursday, August 9, 2012
  Thursday, November 1, 2012

Disclosure Forms

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

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, SXC Health Solutions and University of Georgia and Mercer students attended the closed session with the Board members. A motion was made by Robyn Lorys, Pharm.D., and seconded by J. Russell May, Pharm.D., 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 12.15 pm**,** at which time members took a break then reconvened for the executive (closed) session.

Executive Session

The executive session was held from 12:28pm to 2:35pm.

Board's Recommendations to the Department

After all clinical and financial evaluations and discussions, the DUR Board reconvened in the open session, 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 E.

New Drug Reviews

Antihemophilic Agent

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

Chelating Agent

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

Antineoplastic

The DUR Board recommended ***Preferred*** status for ***Jakafi™***.

Agent for Gaucher Disease

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

Therapeutic Class Reviews

Protease Inhibitors for Hepatitis C

The DUR Board recommended ***Preferred*** status with ***Prior Authorization*** for ***Incivek®*** and ***Victrelis®***.

Agents for Hereditary Angioedema

The DUR Board recommended ***Preferred*** status for ***Berinert®***, ***Cinryze®*** and ***Firazyr®*** and ***Non-Preferred*** status for ***Kalbitor®***.

Atypical Antipsychotics

The DUR Board recommended ***Preferred*** status for ***Equetro®***; ***Preferred*** status with ***Prior Authorization*** for ages less than FDA-approved for all generics, ***olanzapine, quetiapine, risperidone*** and ***ziprasidone***; ***Preferred*** status with ***Prior Authorization*** for ages less than FDA-approved and trial of one generic for ***Abilify®*** and ***Latuda®***; and ***Non-Preferred*** status with ***Prior Authorization*** for all other atypical antipsychotics.

Growth Hormones

The DUR Board recommended ***Preferred*** status with ***Prior Authorization*** for ***Genotropin®, Norditropin® and Nutropin®*** and ***Non-Preferred*** status with ***Prior Authorization*** for ***Humatrope®, Omnitrope®, Saizen®*** and ***Tev-Tropin®***.

Non-Supplemental Rebate Class Reviews

The DUR Board recommended ***No Changes*** from the current PDL status, which is noted in the Preferred Drug List section of the DURB binder.

Conclusion

At the conclusion of the executive session, the open session reconvened at 2:58pm and audience participants were invited back in to hear the Board's recommendations submitted to the Department. Dr. Williams presided over the voting and presented the recommendations from the Board to the Department.

With no other business for discussion, Chairman Williams adjourned the meeting at 3:07pm.

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

_____

Gary Williams, M.D., Chairman

Georgia Department of Community Health

Attachment A

Ethics - Guidelines

Presentation to: Drug Utilization Review Board

Presented by: Woody Dahmer

Date: 6/21/2012

Georgia Department of Community Health

Purpose

Drug Utilization Review Board

Make recommendations to DCH intended to promote patient safety in the Georgia Medicaid fee-for-service program through prospective drug review, retrospective drug use review, and educational intervention programs.

Georgia Department of Community Health

Ethics – Conflicts of Interest

DCH – General Counsel

Richard Greene – General Counsel

Alison Earles – Ethics Officer

Woody Dahmer – Sr. Staff Attorney

DCH – Statement of Ethics

- Accomplishing the mission and goals of DCH hinges on the commitment to strong business and personal ethics.
- DCH employees:
  - Are expected to maintain the highest moral and ethical standards in carrying out their responsibilities;
  - Must prevent all forms of impropriety, including self-interest, partiality, favoritism and undue influence; and

DCH – Statement of Ethics

- Should always avoid situations which constitute a conflict of interest or the perception that a conflict of interest exists.

Drug Utilization Review Board Guidelines

- Conflict of Interest Section
  - Recently revised
  - To be reviewed by Board members prior to Board activities
  - Disclosure Statement to be reviewed and completed by Board members prior to Board activities

Conflict of Interest (from Guidelines)

A “conflict of interest” exists when a Board member possesses personal, financial or professional interests that compete, conflict or otherwise interfere with Board member’s ability to address in a fair and impartial manner any matter under consideration by the DUR Board.

Conflict of Interest (from Guidelines)

- Board members shall not meet with pharmaceutical manufacturers, distributors or retailers or their representatives with respect to any matters which are known to be under review by the Board. (new)
- Other conflicts of interest could arise when a Board member has a relationship with those likely to be impacted by DUR Board decisions, such as:

Conflict of Interest (from Guidelines)

- Being the recipient of a grant;
- Being hired as a paid consultant;
- Participating in a speakers bureau;
- Being a significant stockholder of a corporation;

Conflict of Interest (from Guidelines)

- Being the recipient of financial support from an organization; and
- Being the recipient of gifts in excess of $ 25.00 (including meals, travel, tickets for events, etc.) (new)

Disclosure of Conflicts of Interest

- Board members are expected to disclose the existence of any Conflicts of Interest.
  - Each Board member should complete and sign the Disclosure Statement and submit it to the DUR Board Coordinator one week prior to each meeting.
  - A Board member must disclose any conflicts to the Board Chairperson and to DCH.

Intent

- The intent is <u>not</u> to discourage Board member participation, but to identify those relationships that may create the appearance of or an actual conflict of interest so that issues can be identified and addressed in a timely manner.
- When a Board member is unsure of whether or not a conflict of interest exists, err on the side of disclosure rather than non-disclosure.

Review of Disclosures

- Disclosures of the appearance of or actual conflicts of interest will be reviewed by the Board Chairperson, with assistance as needed from DCH.
- Based on his/her review, the Chairperson will determine the appropriate action, which may include recusal on related matters under consideration by the Board.

Failure to Disclose a Conflict of Interest

Based on any appearance of or an actual conflict of interest or any failure to disclose a conflict of interest, the DCH Commissioner, at his sole discretion, may terminate a member's Board membership at any time.

Confidentiality

- Materials provided to Board members are "confidential" and should not be disclosed to any party not participating on the Board.
- Examples of information that should be kept confidential are:
  - Names of providers and recipients reviewed by the Board; and
  - Circumstances related to specific cases.

PHOEBE
INFECTIOUS DISEASES
AND TRAVEL MEDICINE

CARLOS FRANCO, M.D.

Attachment B

June 8, 2012

Georgia Medicaid -State of Georgia

Linda Wyant

Dear Ms. Wyant,

I am writing this letter to request your support to use the antiviral telaprevir (incivek) in patients suffering from chronic hepatitis C with the genotype 1a/1b. Unfortunately, this infectious disease is quite frequent with devastating consequences, if untreated. With the availability of directly acting antiviral agents for treating hepatitis C offers a new window of opportunity to care for these patients. Additionally, we prevent long-term consequences such as cirrhosis, and or hepatocellular carcinoma with substantial impact in the quality of life of patients with this infection.

The currently available drug boceprevir through GA Medicaid is cumbersome to use and its efficacy in African America population is suboptimal.

Please consider adding telaprevir to be used in this patient population. It is a better drug and it will end up saving money from long-term complications associated with hepatitis C. I am writing this letter out of my own interest and I have no commercial ties to any pharmaceutical company or any conflicts of interest to report to you.

Sincerely,

Carlos Franco, MD, MPH

Infectous Diseases Clinician

507 THIRD AVENUE, SUITES 2-3 ■ ALBANY, GEORGIA 31701 ■ PHONE 229-312-1680 ■ FAX 229-312-1685

Victrelis and Incivek

Cost Comparison and Data Analysis of Hepatitis C Treatment in Medicaid Patients

Fez Mistry
PharmD Candidate
University of Georgia
Department of Community Health

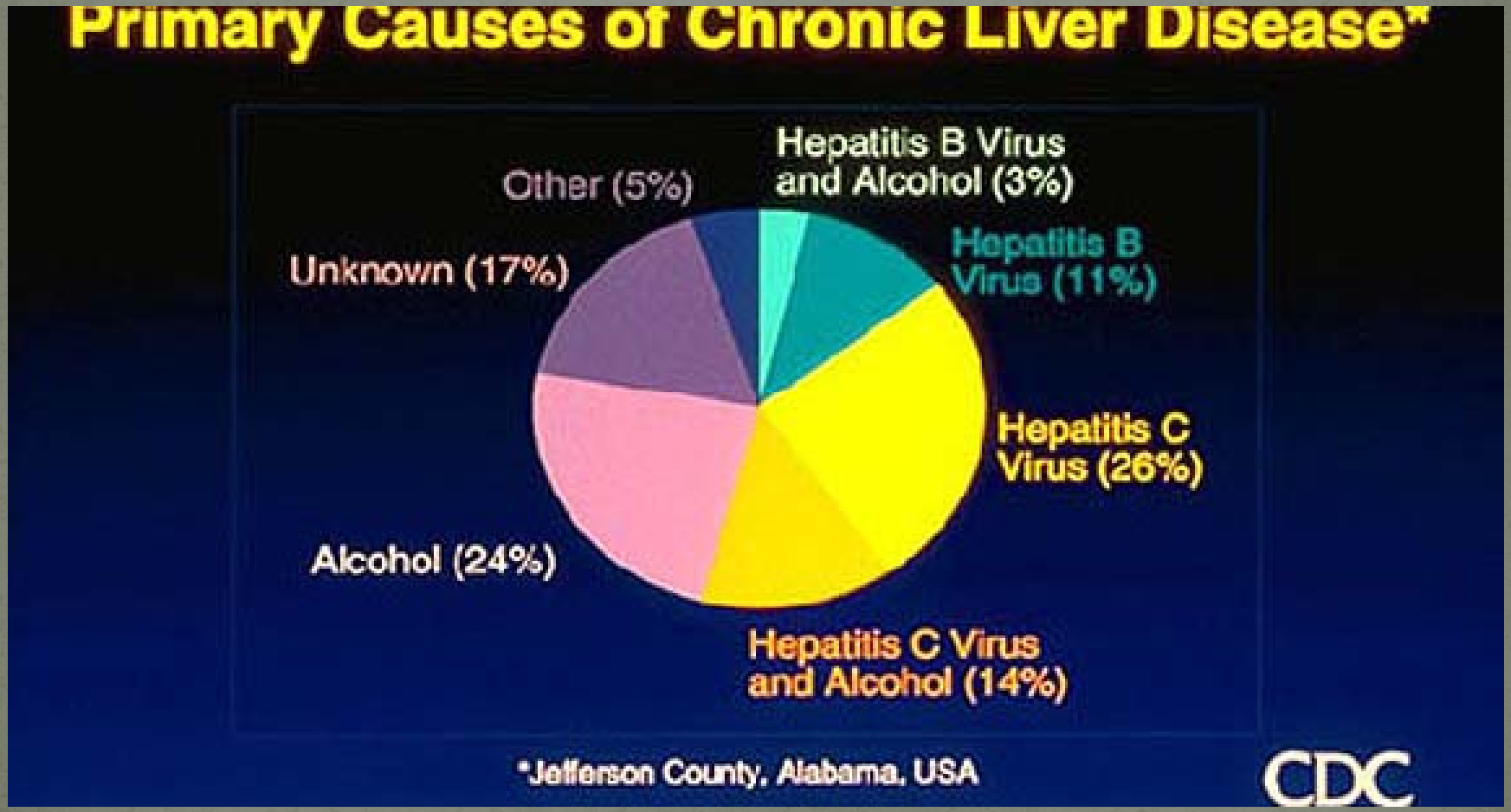
OBJECTIVES

- Briefly explore the disease state, including the incidence, prevalence, and pathophysiology of Hepatitis C Virus (HCV)
- Examine current treatment guidelines
- Discuss the cost of therapy for Victrelis and Incivek
- Evaluate Medicaid patients on each therapy
- Review current formulary status and discuss potential changes prior to the DURB meeting

BACKGROUND

- World Health Organization (WHO) estimates *170 million* people infected with HCV worldwide
- Approximately *2.7 million* Americans with active HCV infection
- 8,000-10,000 deaths each year in the U.S.
- >75% of patients develop chronic hepatitis
  - Common cause of chronic liver disease, which can lead to cirrhosis (25-50%) and hepatocellular carcinoma (11-19%)
  - Most frequent indication for liver transplantation

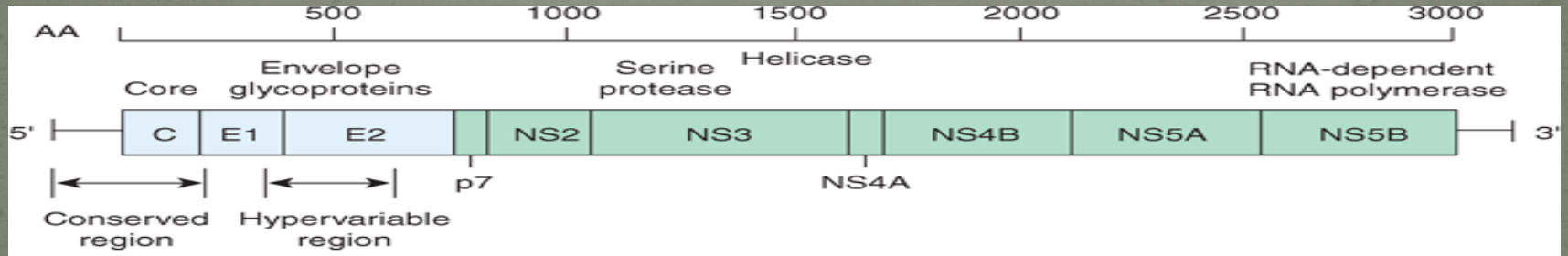
BACKGROUND



Hepatitis C. Causes of chronic liver disease. Courtesy of the US Centers for Disease Control and Prevention.

BACKGROUND

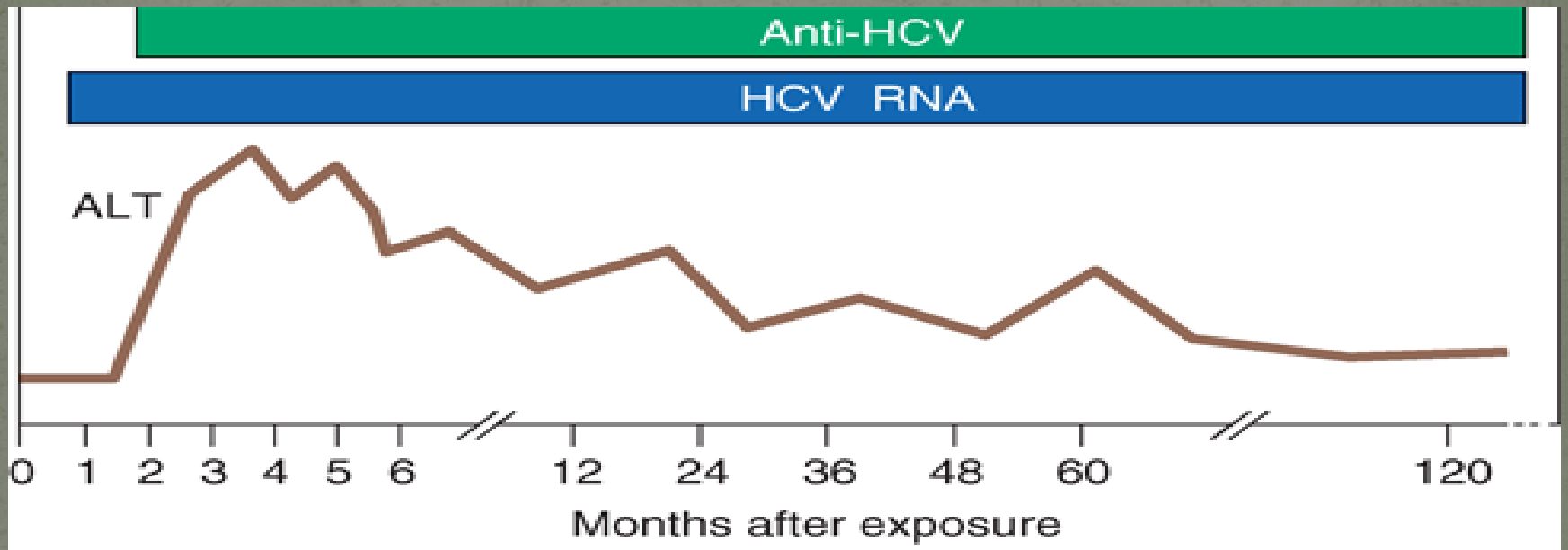
- Linear single-stranded (SS) RNA virus



Source: Longo DL, Fauci AS, Kasper DL, Hauser SL, Jameson JL, Loscalzo J: *Harrison's Principles of Internal Medicine, 18th Edition*: www.accessmedicine.com

- 3000 amino acids yield 10 viral proteins after translation
- This HCV RNA most sensitive indicator of HCV infection
  - Can be detected within days after exposure
  - Reported as international units (IUs) per milliliter

BACKGROUND



Source: Longo DL, Fauci AS, Kasper DL, Hauser SL, Jameson JL, Loscalzo J: *Harrison's*

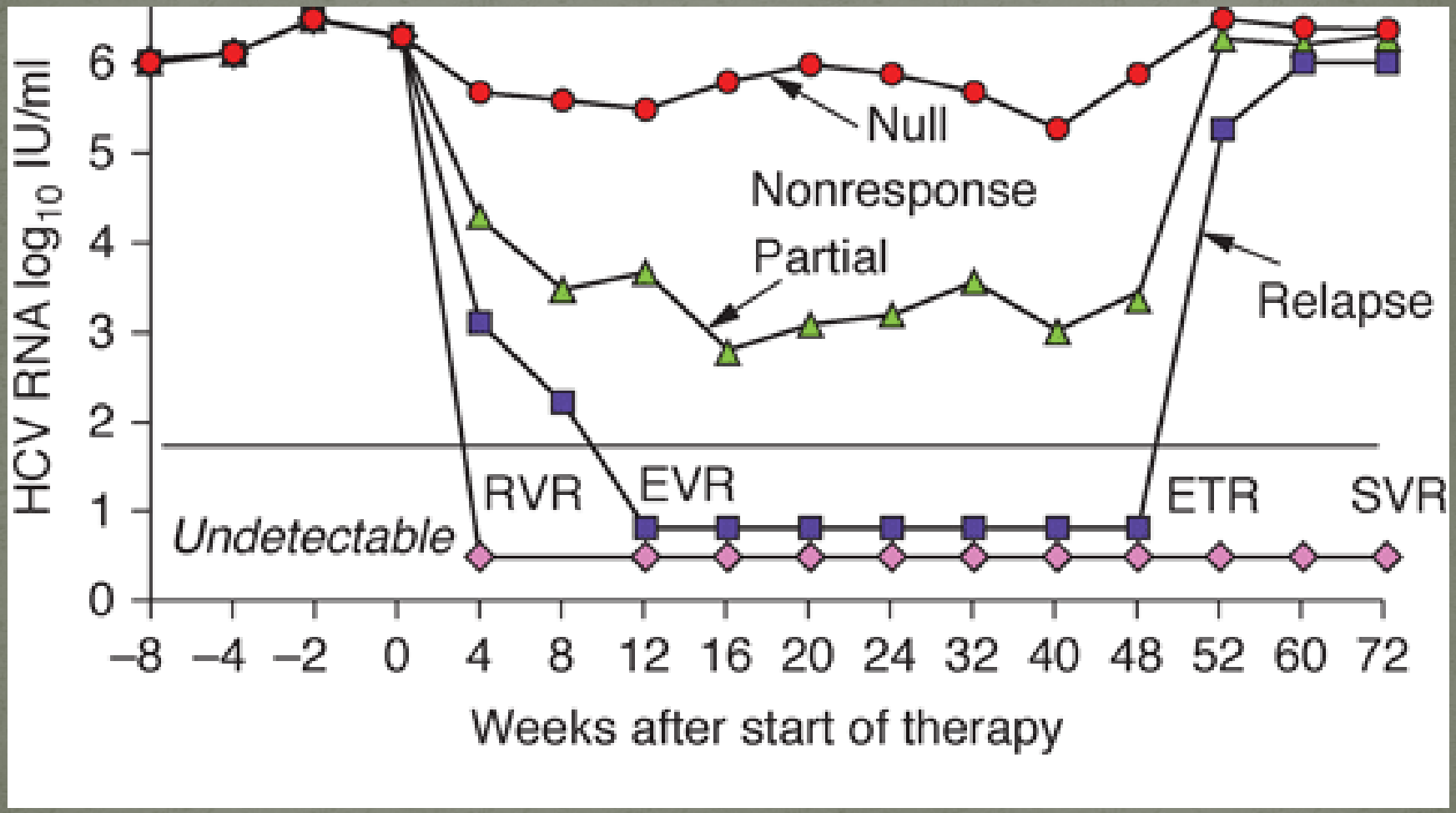
BACKGROUND

- Various genotypes:
  - Type 1 occurs in approximately 70% of infected Americans
    - 90% of infected African Americans
  - Types 2 and 3 make up the other 30%
  - Other genotypes more common in different parts of the world

KEY DEFINITIONS

- **End of Treatment Response (ETR):** HCV RNA negative 24 or 48 weeks at end of therapy
- **Sustained Viral Response (SVR):** HCV RNA negative 24 weeks after completion of therapy
- **Treatment Failures**:
  - **Nonresponder**: Failure to clear HCV RNA after 24 weeks of therapy
    - **Null responder**: HCV RNA decline <2 log IU/mL after 24 weeks of therapy
    - **Partial responder**: HCV RNA decline >2 log IU/ml after 24 weeks but virus still detectable
  - **Relapser**: Reappearance of HCV RNA after therapy is discontinued

KEY DEFINITIONS



UPDATED TREATMENT GUIDELINES

- Current recommended therapy:
  - Addition of *boceprevir (Victrelis)* or *telaprevir (Incivek)* (Class I, Level A) to *pegylated interterferon alfa (PegA)* and *ribavirin* (Rib)
  - *Boceprevir* or *telaprevir* may not be used as monotherapy (Class I, Level A)
  - *Boceprevir* treatment must be preceded by 4 weeks of lead-in with PegA and Rib (Class I, Level A)

AMERICAN ASSOCIATION FOR THE STUDY OF LIVER DISEASES

AASLD

CLAIMS DATA

- Telaprevir
  - Only 3 patients
    - 1 completed 12 weeks of therapy with success
    - 2 stopped treatment before 12 weeks due to unknown reasons
- Boceprevir
  - Approximately 60 patients
    - 6 required more than 24 weeks of therapy
    - 20 currently at less than 24 weeks but may require additional treatment
    - 35 stopped treatment prior to 24 weeks due to various reasons
      - Non-compliance
      - Adverse drug reactions
      - Inadequate decreases in viral load

CONVERSATIONS WITH NURSES

- Compliance issues not drug-related
  - Function of patient and physician personalities
    - Few reports of no-show patients
  - MDs with stringent monitoring requirements (weekly) had better compliance and outcomes
- Slight preference for telaprevir over boceprevir
  - Length of therapy
  - Ease of administration
  - Early monitoring

POTENTIAL CHANGES

- Tighter regulation
  - Decrease prior authorization time period to 1 month
  - MDs must report viral counts monthly (in order to have PA approved)
    - High d/c rate and known cases of inadequate viral count reduction indicates boceprevir treatment may have been initiated in patients who were null responders to PegA and Rib
- Allow therapy to be initiated with telaprevir?
  - High d/c rate with boceprevir
  - Shorter treatment
  - Easier to administer and monitor
  - Greater physician satisfaction
  - Cons
- Patients must pick up the medication from the pharmacy
  - No “white-bagging” allowed

QUESTIONS & DISCUSSION

-----Original Message-----
From: K Schultz [mailto:kschultz@pedendo.com]
Sent: Thu 6/14/2012 4:34 PM
To: Linda Wiant
Cc: K Schultz
Subject: GH formulary

Pediatric Endocrine Associates

1100 Lake Hearn Sr

Atlanta, GA 30342

Peachcare

Dear Ms Wiant,

This letter is to ask you to consider placing Tev-tropin on the Peachcare formulary. We have many families who are in the managed Medicaid plans and for different reasons are placed in Peachcare for a month, usually while paperwork gets straightened out. They are all on Tev-tropin, but then must change to a different medication for that short period of time. The office has to apply for the new formulary and to arrange for training. It involves a lot of paperwork and is extremely time consuming. Adding Tev-tropin would simplify the changes immensely and be so much easier on the families.

Thank you for your time,

Karen Schultz

Drug Utilization Review Board

Motions - Votes

New Drugs

June 21, 2012

New Drug	Drug	PDL Status	Motion/Recommendation			
Antihemophilic Products	Corifact™	P	P/PA			
Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES			
			YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1 Ashworth, Laurel E. Pharm.D.			√			
2 Bona, Joseph R. M.D.		√	√			
3 Carter, Melissa D., J.D.			√			
4 Ellis, Carl, R.Ph.			√			
5 Gupta, Arvind, M.D.			√			
6 Lorys, Robyn Pharm.D.			√			
7 May, J. Russell, Pharm.D.	√		√			
8 Miller, Osgood (Drew) A. R.Ph.			√			
9 Perri, III, Matthew, R.Ph., Ph.D.			√			
10 Williams, Gary M., M.D. - Chair			N/A			
TOTAL			9	0	0	0

Drug Utilization Review Board

Motions - Votes

New Drugs

June 21, 2012

New Drug	Drug	PDL Status	Motion/Recommendation			
Chelating Agents	Ferriprox	NP/PA	NP/PA			
Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES			
			YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1 Ashworth, Laurel E. Pharm.D.			√			
2 Bona, Joseph R. M.D.			√			
3 Carter, Melissa D., J.D.			√			
4 Ellis, Carl, R.Ph.			√			
5 Gupta, Arvind, M.D.			√			
6 Lorys, Robyn Pharm.D.			√			
7 May, J. Russell, Pharm.D.	√		√			
8 Miller, Osgood (Drew) A. R.Ph.		√	√			
9 Perri, III, Matthew, R.Ph., Ph.D.			√			
10 Williams, Gary M., M.D. - Chair			N/A			
TOTAL			9	0	0	0

Drug Utilization Review Board

Motions - Votes

New Drugs

June 21, 2012

New Drug	Drug	PDL Status	Motion/Recommendation			
Antineoplastics	Jakafi	P	P			
Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES			
			YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1 Ashworth, Laurel E. Pharm.D.			√			
2 Bona, Joseph R. M.D.	√		√			
3 Carter, Melissa D., J.D.			√			
4 Ellis, Carl, R.Ph.			√			
5 Gupta, Arvind, M.D.			√			
6 Lorys, Robyn Pharm.D.			√			
7 May, J. Russell, Pharm.D.			√			
8 Miller, Osgood (Drew) A. R.Ph.		√	√			
9 Perri, III, Matthew, R.Ph., Ph.D.			√			
10 Williams, Gary M., M.D. - Chair			N/A			
TOTAL			9	0	0	0

Drug Utilization Review Board

Motions - Votes

New Drugs

June 21, 2012

New Drug	Drug	PDL Status	Motion/Recommendation			
Agents for Gaucher Disease	Vpriv	P/PA	P/PA			
Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES			
			YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1 Ashworth, Laurel E. Pharm.D.			√			
2 Bona, Joseph R. M.D.		√	√			
3 Carter, Melissa D., J.D.			√			
4 Ellis, Carl, R.Ph.			√			
5 Gupta, Arvind, M.D.			√			
6 Lorys, Robyn Pharm.D.			√			
7 May, J. Russell, Pharm.D.			√			
8 Miller, Osgood (Drew) A. R.Ph.	√		√			
9 Perri, III, Matthew, R.Ph., Ph.D.			√			
10 Williams, Gary M., M.D. - Chair			N/A			
TOTAL			9	0	0	0

Drug Utilization Review Board

Motions Votes

Therapeutic Class Review

June 21, 2012

Therapeutic Class	Drug	PDL Status	Motion/Recommendation
Protease Inhibitors for Hepatitis C	Incivek	NP/PA	P/PA
	Victrelis	NP/PA	P/PA

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Ashworth, Laurel E. Pharm.D.			√			
2	Bona, Joseph R. M.D.	√		√			
3	Carter, Melissa D., J.D.			√			
4	Ellis, Carl, R.Ph.			√			
5	Gupta, Arvind, M.D.			√			
6	Lorys, Robyn Pharm.D.			√			
7	May, J. Russell, Pharm.D.		√	√			
8	Miller, Osgood (Drew) A. R.Ph.			√			
9	Perri, III, Matthew, R.Ph., Ph.D.			√			
10	Williams, Gary M., M.D. -Chair			N/A			
	TOTAL			9	0	0	0

Drug Utilization Review Board

Motions Votes

Therapeutic Class Review

June 21, 2012

Therapeutic Class	Drug	PDL Status	Motion/Recommendation
Agents for Hereditary Angioedema	Berinert	P	P
	Cinryze	P	P
	Firazyr	P	P
	Kalbitor	P	NP

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Ashworth, Laurel E. Pharm.D.			√			
2	Bona, Joseph R. M.D.			√			
3	Carter, Melissa D., J.D.			√			
4	Ellis, Carl, R.Ph.			√			
5	Gupta, Arvind, M.D.			√			
6	Lorys, Robyn Pharm.D.			√			
7	May, J. Russell, Pharm.D.	√		√			
8	Miller, Osgood (Drew) A. R.Ph.			√			
9	Perri, III, Matthew, R.Ph., Ph.D.		√	√			
10	Williams, Gary M., M.D. -Chair			N/A			
	TOTAL			9	0	0	0

Drug Utilization Review Board

Motions Votes

Therapeutic Class Review

June 21, 2012

Therapeutic Class	Drug	PDL Status	Motion/Recommendation
Atypical Antipsychotic	Abilify	NP/PA	P/PA
	olanzapine generic	NP/PA	P/PA<13yo
	Zyprexa/Zydis	NP/PA	NP/PA
	quetiapine generic	NP/PA	P/PA<10yo
	Seroquel	P/PA <10yo	NP/PA
	Seroquel XR	NP/PA	NP/PA
	risperidone generic	P/PA <10yo	P/PA<10yo
	ziprasidone generic	NP/PA	P/PA<18yo
	Geodon	P/PA <18yo	NP/PA
	Saphris	NP/PA	NP/PA
	Fanapt	NP/PA	NP/PA
	Latuda	NP/PA	P/PA
	Invega	NP/PA	NP/PA
	Equetro	P	P

Motion (Verbiage): The DUR Board recommended that generics be given preferred (P) status with PA for age, and preferred (P) status with PA for Latuda and Ability after one (1) generic step. All other drugs should maintain the current PDL status.

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Ashworth, Laurel E. Pharm.D.			√			
2	Bona, Joseph R. M.D.	√		√			
3	Carter, Melissa D., J.D.			√			
4	Ellis, Carl, R.Ph.			√			
5	Gupta, Arvind, M.D.			√			
6	Lorys, Robyn Pharm.D.				√		
7	May, J. Russell, Pharm.D.			√			
8	Miller, Osgood (Drew) A. R.Ph.			√			
9	Perri, III, Matthew, R.Ph., Ph.D.		√	√			
10	Williams, Gary M., M.D. -Chair			N/A			
	TOTAL			8	1	0	0

Drug Utilization Review Board

Motions Votes

Therapeutic Class Review

June 21, 2012

Therapeutic Class	Drug	PDL Status	Motion/Recommendation
Long Acting Injectables	InvegaSustenna	NP/PA	NP/PA
	Risperdal Consta	NP/PA	NP/PA
	Zypexa Relprevv	NP/PA	NP/PA

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Ashworth, Laurel E. Pharm.D.			√			
2	Bona, Joseph R. M.D.	√		√			
3	Carter, Melissa D., J.D.			√			
4	Ellis, Carl, R.Ph.			√			
5	Gupta, Arvind, M.D.			√			
6	Lorys, Robyn Pharm.D.			√			
7	May, J. Russell, Pharm.D.			√			
8	Miller, Osgood (Drew) A. R.Ph.			√			
9	Perri, III, Matthew, R.Ph., Ph.D.		√	√			
10	Williams, Gary M., M.D. - Chair			N/A			
	TOTAL			9	0	0	0

Drug Utilization Review Board

Motions Votes

Therapeutic Class Review

June 21, 2012

Therapeutic Class	Drug	PDL Status	Motion/Recommendation
Growth Hormones	Genotropin	P/PA	P/PA
	Humatrope	NP/PA	NP/PA
	Norditropin	P/PA	P/PA
	Nutropin/AQ	P/PA	P/PA
	Omnitrope	NP/PA	NP/PA
	Saizen	NP/PA	NP/PA
	Tev-Tropin	NP/PA	NP/PA

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Ashworth, Laurel E. Pharm.D.			√			
2	Bona, Joseph R. M.D.			√			
3	Carter, Melissa D., J.D.			√			
4	Ellis, Carl, R.Ph.			√			
5	Gupta, Arvind, M.D.			√			
6	Lorys, Robyn Pharm.D.			√			
7	May, J. Russell, Pharm.D.			√			
8	Miller, Osgood (Drew) A. R.Ph.		√	√			
9	Perri, III, Matthew, R.Ph., Ph.D.	√		√			
10	Williams, Gary M., M.D. - Chair			N/A			
	TOTAL			9	0	0	0

Drug Utilization Review Board

Motions Votes

Non-Supplemental Rebate Classes

June 21, 2012

Drug Class	Clinical Updates	Motion/Recommendation
Analgesics-Miscellaneous	DUR Board Binder - Page 169	LEAVE AS IS

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Ashworth, Laurel E. Pharm.D.			√			
2	Bona, Joseph R. M.D.			√			
3	Carter, Melissa D., J.D.			√			
4	Ellis, Carl, R.Ph.			√			
5	Gupta, Arvind, M.D.		√	√			
6	Lorys, Robyn Pharm.D.			√			
7	May, J. Russell, Pharm.D.	√		√			
8	Miller, Osgood (Drew) A. R.Ph.			√			
9	Perri, III, Matthew, R.Ph., Ph.D.			√			
10	Williams, Gary M., M.D. -Chair			N/A			
	TOTAL			9	0	0	0

Drug Utilization Review Board

Motions Votes

Non-Supplemental Rebate Classes

June 21, 2012

Drug Class	Clinical Updates	Motion/Recommendation
Anaphylaxis Therapy	DUR Board Binder - Page 169	LEAVE AS IS

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Ashworth, Laurel E. Pharm.D.			√			
2	Bona, Joseph R. M.D.			√			
3	Carter, Melissa D., J.D.			√			
4	Ellis, Carl, R.Ph.			√			
5	Gupta, Arvind, M.D.		√	√			
6	Lorys, Robyn Pharm.D.			√			
7	May, J. Russell, Pharm.D.	√		√			
8	Miller, Osgood (Drew) A. R.Ph.			√			
9	Perri, III, Matthew, R.Ph., Ph.D.			√			
10	Williams, Gary M., M.D. -Chair			N/A			
	TOTAL			9	0	0	0

Drug Utilization Review Board

Motions Votes

Non-Supplemental Rebate Classes

June 21, 2012

Drug Class	Clinical Updates	Motion/Recommendation
Angiotensin Converting Enzyme Inhibitors and Calcium Channel Blockers Combination	DUR Board Binder - Page 169	LEAVE AS IS

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Ashworth, Laurel E. Pharm.D.			√			
2	Bona, Joseph R. M.D.			√			
3	Carter, Melissa D., J.D.			√			
4	Ellis, Carl, R.Ph.			√			
5	Gupta, Arvind, M.D.		√	√			
6	Lorys, Robyn Pharm.D.			√			
7	May, J. Russell, Pharm.D.	√		√			
8	Miller, Osgood (Drew) A. R.Ph.			√			
9	Perri, III, Matthew, R.Ph., Ph.D.			√			
10	Williams, Gary M., M.D. -Chair			N/A			
	TOTAL			9	0	0	0

Drug Utilization Review Board

Motions Votes

Non-Supplemental Rebate Classes

June 21, 2012

Drug Class	Clinical Updates	Motion/Recommendation
Antifungals	DUR Board Binder - Page 169	LEAVE AS IS

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Ashworth, Laurel E. Pharm.D.			√			
2	Bona, Joseph R. M.D.			√			
3	Carter, Melissa D., J.D.			√			
4	Ellis, Carl, R.Ph.			√			
5	Gupta, Arvind, M.D.		√	√			
6	Lorys, Robyn Pharm.D.			√			
7	May, J. Russell, Pharm.D.	√		√			
8	Miller, Osgood (Drew) A. R.Ph.			√			
9	Perri, III, Matthew, R.Ph., Ph.D.			√			
10	Williams, Gary M., M.D. -Chair			N/A			
	TOTAL			9	0	0	0

Drug Utilization Review Board

Motions Votes

Non-Supplemental Rebate Classes

June 21, 2012

Drug Class Beta Adrenergics Long-Acting Nebulizers	Clinical Updates				Motion/Recommendation	
	DUR Board Binder - Page 169				LEAVE AS IS	
	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES			
				YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Ashworth, Laurel E. Pharm.D.			√			
2	Bona, Joseph R. M.D.			√			
3	Carter, Melissa D., J.D.			√			
4	Ellis, Carl, R.Ph.			√			
5	Gupta, Arvind, M.D.		√	√			
6	Lorys, Robyn Pharm.D.			√			
7	May, J. Russell, Pharm.D.	√		√			
8	Miller, Osgood (Drew) A. R.Ph.			√			
9	Perri, III, Matthew, R.Ph., Ph.D.			√			
10	Williams, Gary M., M.D. -Chair			N/A			
TOTAL				9	0	0	0

Drug Utilization Review Board

Motions Votes

Non-Supplemental Rebate Classes

June 21, 2012

Drug Class Beta Adrenergics Short-Acting Nebulizers	Clinical Updates				Motion/Recommendation	
	DUR Board Binder - Page 169				LEAVE AS IS	
	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES			
				YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Ashworth, Laurel E. Pharm.D.			√			
2	Bona, Joseph R. M.D.			√			
3	Carter, Melissa D., J.D.			√			
4	Ellis, Carl, R.Ph.			√			
5	Gupta, Arvind, M.D.		√	√			
6	Lorys, Robyn Pharm.D.			√			
7	May, J. Russell, Pharm.D.	√		√			
8	Miller, Osgood (Drew) A. R.Ph.			√			
9	Perri, III, Matthew, R.Ph., Ph.D.			√			
10	Williams, Gary M., M.D. -Chair			N/A			
TOTAL				9	0	0	0

Drug Utilization Review Board

Motions Votes

Non-Supplemental Rebate Classes

June 21, 2012

Drug Class	Clinical Updates	Motion/Recommendation
Diabetic -Meglitinides	DUR Board Binder - Page 170	LEAVE AS IS

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Ashworth, Laurel E. Pharm.D.			√			
2	Bona, Joseph R. M.D.			√			
3	Carter, Melissa D., J.D.			√			
4	Ellis, Carl, R.Ph.			√			
5	Gupta, Arvind, M.D.		√	√			
6	Lorys, Robyn Pharm.D.			√			
7	May, J. Russell, Pharm.D.	√		√			
8	Miller, Osgood (Drew) A. R.Ph.			√			
9	Perri, III, Matthew, R.Ph., Ph.D.			√			
10	Williams, Gary M., M.D. -Chair			N/A			
	TOTAL			9	0	0	0

Drug Utilization Review Board

Motions Votes

Non-Supplemental Rebate Classes

June 21, 2012

Drug Class	Clinical Updates	Motion/Recommendation
Diabetic -Thiazolidinediones	DUR Board Binder - Page 170	LEAVE AS IS

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Ashworth, Laurel E. Pharm.D.			√			
2	Bona, Joseph R. M.D.			√			
3	Carter, Melissa D., J.D.			√			
4	Ellis, Carl, R.Ph.			√			
5	Gupta, Arvind, M.D.		√	√			
6	Lorys, Robyn Pharm.D.			√			
7	May, J. Russell, Pharm.D.	√		√			
8	Miller, Osgood (Drew) A. R.Ph.			√			
9	Perri, III, Matthew, R.Ph., Ph.D.			√			
10	Williams, Gary M., M.D. -Chair			N/A			
	TOTAL			9	0	0	0

Drug Utilization Review Board

Motions Votes

Non-Supplemental Rebate Classes

June 21, 2012

Drug Class	Drug	PDL Status	Motion Recommendation
Fibromyalgia Agents	Cymbalta	NP/PA	NP/PA
	Savella	NP/PA	NP/PA
	Lyrica	P	P

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Ashworth, Laurel E. Pharm.D.			√			
2	Bona, Joseph R. M.D.			√			
3	Carter, Melissa D., J.D.		√	√			
4	Ellis, Carl, R.Ph.			√			
5	Gupta, Arvind, M.D.			√			
6	Lorys, Robyn Pharm.D.			√			
7	May, J. Russell, Pharm.D.			√			
8	Miller, Osgood (Drew) A. R.Ph.	√		√			
9	Perri, III, Matthew, R.Ph., Ph.D.			√			
10	Williams, Gary M., M.D. -Chair			N/A			
	TOTAL			9	0	0	0

Drug Utilization Review Board

Motions Votes

Non-Supplemental Rebate Classes

June 21, 2012

Drug Class	Clinical Updates	Motion/Recommendation
Fluoroquinolones	DUR Board Binder - Page 170	LEAVE AS IS

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Ashworth, Laurel E. Pharm.D.			√			
2	Bona, Joseph R. M.D.			√			
3	Carter, Melissa D., J.D.			√			
4	Ellis, Carl, R.Ph.			√			
5	Gupta, Arvind, M.D.		√	√			
6	Lorys, Robyn Pharm.D.			√			
7	May, J. Russell, Pharm.D.	√		√			
8	Miller, Osgood (Drew) A. R.Ph.			√			
9	Perri, III, Matthew, R.Ph., Ph.D.			√			
10	Williams, Gary M., M.D. -Chair			N/A			
	TOTAL			9	0	0	0

Drug Utilization Review Board

Motions Votes

Non-Supplemental Rebate Classes

June 21, 2012

Drug Class	Clinical Updates	Motion/Recommendation
Gastrointestinal - Proton Pump Inhibitors	DUR Board Binder - Page 170	LEAVE AS IS

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Ashworth, Laurel E. Pharm.D.			√			
2	Bona, Joseph R. M.D.			√			
3	Carter, Melissa D., J.D.			√			
4	Ellis, Carl, R.Ph.			√			
5	Gupta, Arvind, M.D.		√	√			
6	Lorys, Robyn Pharm.D.			√			
7	May, J. Russell, Pharm.D.	√		√			
8	Miller, Osgood (Drew) A. R.Ph.			√			
9	Perri, III, Matthew, R.Ph., Ph.D.			√			
10	Williams, Gary M., M.D. -Chair			N/A			
	TOTAL			9	0	0	0

Drug Utilization Review Board

Motions Votes

Non-Supplemental Rebate Classes

June 21, 2012

Drug Class	Clinical Updates	Motion/Recommendation
Herpes Agents - Oral	DUR Board Binder - Page 170	LEAVE AS IS

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Ashworth, Laurel E. Pharm.D.			√			
2	Bona, Joseph R. M.D.			√			
3	Carter, Melissa D., J.D.			√			
4	Ellis, Carl, R.Ph.			√			
5	Gupta, Arvind, M.D.		√	√			
6	Lorys, Robyn Pharm.D.			√			
7	May, J. Russell, Pharm.D.	√		√			
8	Miller, Osgood (Drew) A. R.Ph.			√			
9	Perri, III, Matthew, R.Ph., Ph.D.			√			
10	Williams, Gary M., M.D. -Chair			N/A			
	TOTAL			9	0	0	0

Drug Utilization Review Board

Motions Votes

Non-Supplemental Rebate Classes

June 21, 2012

Drug Class	Clinical Updates	Motion/Recommendation
Immunosuppressants - Renal Transplant Rejection Agents	DUR Board Binder - Page 171	LEAVE AS IS

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Ashworth, Laurel E. Pharm.D.			√			
2	Bona, Joseph R. M.D.			√			
3	Carter, Melissa D., J.D.			√			
4	Ellis, Carl, R.Ph.			√			
5	Gupta, Arvind, M.D.		√	√			
6	Lorys, Robyn Pharm.D.			√			
7	May, J. Russell, Pharm.D.	√		√			
8	Miller, Osgood (Drew) A. R.Ph.			√			
9	Perri, III, Matthew, R.Ph., Ph.D.			√			
10	Williams, Gary M., M.D. -Chair			N/A			
	TOTAL			9	0	0	0

Drug Utilization Review Board

Motions Votes

Non-Supplemental Rebate Classes

June 21, 2012

Drug Class	Clinical Updates	Motion/Recommendation
Narcotics - Miscellaneous	DUR Board Binder - Page 171	LEAVE AS IS

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Ashworth, Laurel E. Pharm.D.			√			
2	Bona, Joseph R. M.D.			√			
3	Carter, Melissa D., J.D.			√			
4	Ellis, Carl, R.Ph.			√			
5	Gupta, Arvind, M.D.		√	√			
6	Lorys, Robyn Pharm.D.			√			
7	May, J. Russell, Pharm.D.	√		√			
8	Miller, Osgood (Drew) A. R.Ph.			√			
9	Perri, III, Matthew, R.Ph., Ph.D.			√			
10	Williams, Gary M., M.D. -Chair			N/A			
	TOTAL			9	0	0	0

Drug Utilization Review Board

Motions Votes

Non-Supplemental Rebate Classes

June 21, 2012

Drug Class	Clinical Updates	Motion/Recommendation
Ophthalmics - Miscellaneous	DUR Board Binder - Page 171	LEAVE AS IS

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Ashworth, Laurel E. Pharm.D.			√			
2	Bona, Joseph R. M.D.			√			
3	Carter, Melissa D., J.D.			√			
4	Ellis, Carl, R.Ph.			√			
5	Gupta, Arvind, M.D.		√	√			
6	Lorys, Robyn Pharm.D.			√			
7	May, J. Russell, Pharm.D.	√		√			
8	Miller, Osgood (Drew) A. R.Ph.			√			
9	Perri, III, Matthew, R.Ph., Ph.D.			√			
10	Williams, Gary M., M.D. -Chair			N/A			
	TOTAL			9	0	0	0

Drug Utilization Review Board

Motions Votes

Non-Supplemental Rebate Classes

June 21, 2012

Drug Class	Clinical Updates	Motion/Recommendation
Osteoporosis Agents	DUR Board Binder - Page 171	LEAVE AS IS

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Ashworth, Laurel E. Pharm.D.			√			
2	Bona, Joseph R. M.D.			√			
3	Carter, Melissa D., J.D.			√			
4	Ellis, Carl, R.Ph.			√			
5	Gupta, Arvind, M.D.		√	√			
6	Lorys, Robyn Pharm.D.			√			
7	May, J. Russell, Pharm.D.	√		√			
8	Miller, Osgood (Drew) A. R.Ph.			√			
9	Perri, III, Matthew, R.Ph., Ph.D.			√			
10	Williams, Gary M., M.D. -Chair			N/A			
	TOTAL			9	0	0	0

Drug Utilization Review Board

Motions Votes

Non-Supplemental Rebate Classes

June 21, 2012

Drug Class	Clinical Updates	Motion/Recommendation
Parkinson's Disease - Selective Dopamine Agonists	DUR Board Binder - Page 171	LEAVE AS IS

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Ashworth, Laurel E. Pharm.D.			√			
2	Bona, Joseph R. M.D.			√			
3	Carter, Melissa D., J.D.			√			
4	Ellis, Carl, R.Ph.			√			
5	Gupta, Arvind, M.D.		√	√			
6	Lorys, Robyn Pharm.D.			√			
7	May, J. Russell, Pharm.D.	√		√			
8	Miller, Osgood (Drew) A. R.Ph.			√			
9	Perri, III, Matthew, R.Ph., Ph.D.			√			
10	Williams, Gary M., M.D. -Chair			N/A			
	TOTAL			9	0	0	0

Drug Utilization Review Board

Motions Votes

Non-Supplemental Rebate Classes

June 21, 2012

Drug Class	Clinical Updates	Motion/Recommendation
Topical - Antivirals	DUR Board Binder - Page 171	LEAVE AS IS

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Ashworth, Laurel E. Pharm.D.			√			
2	Bona, Joseph R. M.D.			√			
3	Carter, Melissa D., J.D.			√			
4	Ellis, Carl, R.Ph.			√			
5	Gupta, Arvind, M.D.		√	√			
6	Lorys, Robyn Pharm.D.			√			
7	May, J. Russell, Pharm.D.	√		√			
8	Miller, Osgood (Drew) A. R.Ph.			√			
9	Perri, III, Matthew, R.Ph., Ph.D.			√			
10	Williams, Gary M., M.D. -Chair			N/A			
	TOTAL			9	0	0	0

Drug Utilization Review Board

Motions Votes

Non-Supplemental Rebate Classes

June 21, 2012

Drug Class	Clinical Updates	Motion/Recommendation
Topical - Genital Warts	DUR Board Binder - Page 171	LEAVE AS IS

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Ashworth, Laurel E. Pharm.D.			√			
2	Bona, Joseph R. M.D.			√			
3	Carter, Melissa D., J.D.			√			
4	Ellis, Carl, R.Ph.			√			
5	Gupta, Arvind, M.D.		√	√			
6	Lorys, Robyn Pharm.D.			√			
7	May, J. Russell, Pharm.D.	√		√			
8	Miller, Osgood (Drew) A. R.Ph.			√			
9	Perri, III, Matthew, R.Ph., Ph.D.			√			
10	Williams, Gary M., M.D. -Chair			N/A			
	TOTAL			9	0	0	0

Drug Utilization Review Board

Motions Votes

Non-Supplemental Rebate Classes

June 21, 2012

Drug Class	Clinical Updates	Motion/Recommendation
Urinary Antiinfectives	DUR Board Binder - Page 171	LEAVE AS IS

	Board Members - Present	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Ashworth, Laurel E. Pharm.D.			√			
2	Bona, Joseph R. M.D.			√			
3	Carter, Melissa D., J.D.			√			
4	Ellis, Carl, R.Ph.			√			
5	Gupta, Arvind, M.D.		√	√			
6	Lorys, Robyn Pharm.D.			√			
7	May, J. Russell, Pharm.D.	√		√			
8	Miller, Osgood (Drew) A. R.Ph.			√			
9	Perri, III, Matthew, R.Ph., Ph.D.			√			
10	Williams, Gary M., M.D. -Chair			N/A			
	TOTAL			9	0	0	0

Manufacturers' Forum
Manufacturer Presentations

Dates: August 9, 2012

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

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

SXC 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 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. Kalydeco
Michelle Mattox, PharmD, Managed Care Liaison II, Medical Affairs
Dan Petty, PharmD, MBA, Regional Account Manager, Managed Markets

Kalydeco™ (ivacaftor)
Kalydeco is classified as a cystic fibrosis transmembrane conductance regulator (CFTR) potentiator. Kalydeco is indicated for the treatment of cystic fibrosis (CF) in patients age 6 years and older who have a *G551D* mutation in the *CFTR* gene. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the *G551D* mutation. *Limitations of Use:* Kalydeco is not effective in patients with CF who are homozygous for the *F508del* mutation in the *CFTR* gene. Kalydeco has not been studied in other populations of patients with CF.

Efficacy
Trials in Patients with CF who have a *G551D* Mutation in the *CFTR* Gene

- The efficacy of Kalydeco in patients with CF who have a *G551D* mutation in the *CFTR* gene was evaluated in two randomized, double-blind, placebo-controlled clinical trials in 213 clinically stable patients with CF. Trial 1 evaluated 161 patients with CF who were 12 years of age or older (mean age 26 years) with baseline FEV1 between 40-90% predicted [mean FEV1 64% predicted (range: 32% to 98%)]. Trial 2 evaluated 52 patients who were 6 to 11 years of age (mean age 9 years) with baseline FEV1 between 40-105% predicted [mean FEV1 84% predicted (range: 44% to 134%)]. Patients in both trials were randomized 1:1 to receive either 150 mg of Kalydeco or placebo every 12 hours with food containing fat for 48 weeks in addition to their prescribed CF therapies. The use of inhaled hypertonic saline was not permitted.
- The primary efficacy endpoint in both studies was improvement in lung function as determined by the mean absolute change from baseline in percent predicted pre-dose FEV1 through 24 weeks of treatment. In both studies, treatment with Kalydeco resulted in a significant improvement in FEV1. The treatment difference between Kalydeco and placebo for the mean absolute change in percent predicted FEV1 from baseline through Week 24 was 10.6 percentage points ($P<0.0001$) in Trial 1 and 12.5 percentage points ($P<0.0001$) in Trial 2. These changes persisted through 48 weeks. Improvements in percent predicted FEV1 were observed regardless of age, disease severity, sex and geographic region.

- Secondary efficacy variables included time to first pulmonary exacerbation through Week 48 (Trial 1 only), absolute change in weight from baseline to Week 48, and improvement in cystic fibrosis symptoms including relevant respiratory symptoms such as cough, sputum production and difficulty breathing. In Trial 1, treatment with Kalydeco resulted in improvements in the risk of pulmonary exacerbations (relative risk of pulmonary exacerbation through Week 48: treatment difference of 0.46, *P*=0.0012). Trials 1 and 2 also demonstrated a statistically significant mean absolute change from baseline in body weight with Kalydeco (treatment difference at week 48: Trial 1=2.7 kg, *P*=0.0001; Trial 2=2.8 kg, *P*=0.0002). Patients treated with Kalydeco also demonstrated statistically significant improvements in CF symptoms (*P*<0.0001; Trial 1 only).

Trial in Patients Homozygous for the *F508del* Mutation in the *CFTR* Gene

- Trial 3 was a 16-week, randomized, double-blind, placebo-controlled, parallel-group trial in 140 patients with CF age 12 years and older who were homozygous for the *F508del* mutation in the *CFTR* gene and who had FEV1 ≥40% predicted. Patients were randomized 4:1 to receive Kalydeco 150 mg every twelve hours or placebo in addition to their prescribed CF therapies. The use of inhaled hypertonic saline was not permitted. The mean age of patients enrolled was 23 years and the mean baseline FEV1 was 79% predicted (range 40% to 129%).
- The primary endpoint was improvement in lung function as determined by the mean absolute change from baseline through Week 16 in percent predicted FEV1. Treatment with Kalydeco resulted in no improvement in FEV1 relative to placebo in patients with CF homozygous for the *F508del* mutation in the *CFTR* gene [mean absolute change from baseline through Week 16 in percent predicted FEV1 was 1.5% and -0.2% for patients in the Kalydeco and placebo-treated groups, respectively (*p*=0.15)]. There were no meaningful differences between patients treated with Kalydeco compared to placebo for secondary endpoints (change in CF symptoms, change in weight, or change in sweat chloride concentration).

Safety

- *Contraindications:* There are no known contraindications to Kalydeco.
- *Warnings and Precautions:*
    - Elevated transaminases (ALT or AST) have been reported in patients with CF receiving Kalydeco. It is recommended that ALT and AST be assessed prior to initiating Kalydeco, every 3 months during the first year of treatment, and annually thereafter. Patients who develop increased transaminase levels should be closely monitored until the abnormalities resolve. Dosing should be interrupted in patients with ALT or AST of greater than 5 times the upper limit of normal (ULN). Following resolution of transaminase elevations, consider the benefits and risks of resuming Kalydeco dosing.
    - Use of Kalydeco with strong CYP3A inducers may reduce the therapeutic effectiveness of Kalydeco. Co-administration of Kalydeco with strong CYP3A inducers such as rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin and St. John's Wort is not recommended.
- *Drug Interactions:* Use of Kalydeco with strong CYP3A inducers substantially decreases the exposure of Kalydeco. Co-administration of Kalydeco with strong CYP3A inducers such as rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin and St. John's Wort is not recommended. Use of Kalydeco with a strong CYP3A inhibitor significantly increased Kalydeco exposure. Reduction of the Kalydeco dose to 150 mg twice a week is recommended for co-administration with strong CYP3A inhibitors, such as ketoconazole, itraconazole, posaconazole, voriconazole, telithromycin, and clarithromycin. Use of Kalydeco with a moderate CYP3A inhibitor increased Kalydeco exposure. Reduction of the Kalydeco dose to 150 mg once daily is recommended for co-administration with moderate CYP3A inhibitors, such as fluconazole and erythromycin. Food containing grapefruit or Seville oranges should be avoided during treatment with Kalydeco. Kalydeco and its M1 metabolite have the potential to inhibit CYP3A and P-gp. Administration of Kalydeco may increase systemic exposure of drugs that are substrates of CYP3A and/or P-gp, which may increase or prolong their therapeutic effect and adverse events. Caution and monitoring is recommended when co-administering Kalydeco with CYP3A and or P-gp substrates, such as digoxin, cyclosporine, tacrolimus, midazolam, alprazolam, diazepam, and triazolam.
- *Adverse Reactions:* In phase 2b/3 trials conducted in patients with CF with a *G551D* mutation in the *CFTR* gene or homozygous for the *F508del* mutation, the proportion of patients who prematurely discontinued study drug due to adverse reactions was 2% for patients treated with Kalydeco and 5% for placebo-treated patients. Serious adverse reactions, whether considered drug-related or not by the investigators, which occurred more frequently in patients treated with Kalydeco included abdominal pain, increased hepatic enzymes, and hypoglycemia. In phase 3 trials of patients with CF with a *G551D* mutation, the most common adverse events occurring in ≥8% of patients treated with Kalydeco and higher than in patients receiving placebo were headache (24% vs 16%), oropharyngeal pain (22% vs 18%), upper respiratory tract infection (22% vs 14%), nasal congestion (20% vs 15%), abdominal pain (16% vs 13%), nasopharyngitis (15% vs 12%), diarrhea (13% vs 10%), rash (13% vs 7%), nausea (12% vs 11%), and dizziness (9% vs 1%).

Questions and Answers
Q: Were all completed and analyzed studies in cystic fibrosis presented today?
A: Yes.

Q: What percentage of cystic fibrosis patients has the *G551D* mutation?
A: 4%.

Q: What percentage of patients in clinical trials was already tested for mutation?
A: 92%; standard practice is to test for 23 standard genotypes then expand.

Q: What is the recommendation for monitoring ALT/AST and how many patients discontinued in clinical trials due to elevation?
A: Recommendation for monitoring is every 3 months for the 1st year and then yearly. Two patients discontinued due to elevations in ALT/AST.

Q: Has hyperglycemia or metabolic syndrome occurred due to weight gain? What is the mechanism that causes the weight gain?
A: Hyperglycemia and metabolic syndrome have not occurred since the weight gain will plateau and thus patients do not continue to gain weight. Kalydeco helps to correct islet cells thus increases insulin.

Q: Are long-term outcomes being studied?
A: An ongoing open-label study is being conducted to evaluate exacerbations, mortality, discontinuation of supportive medications and weight gain since most of these patients need to increase their weight. Interim data is not yet available but 74 patients have completed 96 weeks and 25 patients have completed 72 weeks.

Q: Are any other studies being conducted?
A: Combination use in *F5081del* mutation is being conducted.

II. Merck
Vicki L. Star, MD, FACR, Senior Regional Medical Director
Lisa Bishop, Account Executive

Zioptan™ (tafluprost)
Zioptan (tafluprost ophthalmic solution) 0.0015% is a prostaglandin analog indicated for reducing elevated intraocular pressure (IOP) in patients with open-angle glaucoma (OAG) or ocular hypertension (OHT). It has no contraindications. Zioptan is supplied as a sterile solution of tafluprost in single-use containers. Zioptan does not contain a preservative. The recommended dose is one drop of Zioptan in the conjunctival sac of the affected eye(s) once daily in the evening. The solution from one individual unit is to be used immediately after opening for administration to one or both eyes. Since sterility cannot be maintained after the individual unit is opened, the remaining contents should be discarded immediately after administration.

Efficacy
In three phase III clinical studies up to 24 months in duration, patients with OAG or OHT and baseline pressure of 23-26 mmHg who were treated with Zioptan dosed once daily in the evening demonstrated reductions in IOP at 3 and 6 months of 6-8 mmHg and 5-8 mmHg, respectively. A pharmacodynamic study demonstrated the equivalence of the two formulations Efficacy and safety levels of preserved and preservative-free tafluprost are equivalent in patients with glaucoma or ocular hypertension: results from a pharmacodynamics analysis.

- *Preservative-Free Tafluprost Versus Preservative-Free Timolol:* A 12-week, prospective, randomized, double-masked, active-controlled, parallel-group phase III study compared the efficacy and safety of PF tafluprost and PF timolol in 643 patients with OAG or OHT. The primary efficacy endpoint was the change from baseline in mean IOP at 9 time points. The primary hypothesis was that PF tafluprost would be noninferior to PF timolol based on a non-inferiority margin of 1.5 mmHg at each of the 9 time points assessed. Results demonstrated that the IOP-lowering effect of PF tafluprost was non-inferior to PF timolol at all visits and time points. At 4 of the 9 time points, the upper limits of the 95% confidence intervals (CIs) were less than 0, in favor of tafluprost. Randomized clinical trial of the efficacy and safety of preservative-free tafluprost and timolol in patients with open-angle glaucoma or ocular hypertension.
- *Preservative-Containing Tafluprost Versus Preservative-Containing Timolol:* A 12-month, prospective, randomized, double-masked, active-controlled, parallel-group phase III study compared the efficacy and safety of PC tafluprost and PC timolol in 458 patients with OAG or OHT. The primary efficacy endpoint was the change from baseline in

mean IOP at 8:00, 10:00, and 16:00 at Weeks 2 and 6 and Months 3, 6, 9, and 12. The primary hypothesis was that PC tafluprost would be noninferior to PC timolol based on a non-inferiority margin of 1.5 mmHg at each of the time points assessed. Results demonstrated that the IOP-lowering effect of PC tafluprost was non-inferior to PC timolol at all visits and time points, with the upper 95% CI ranging from –0.2 to 0.9 mmHg.

- *Preservative-Containing Tafluprost Versus Preservative-Containing Latanoprost:* A prospective, randomized, double-masked, active-controlled, parallel-group phase III study compared the efficacy and safety of PC tafluprost and PC latanoprost in 533 patients with OAG or OHT. The primary efficacy endpoint was the change from baseline in overall diurnal IOP at 6 months. Results showed a time wise IOP-lowering effect from baseline of 6.3–7.8 mmHg with PC tafluprost as compared to 7.1–9.1 mmHg with PC latanoprost at 6 months.{Merck internal data} At 24 months, the mean decrease in IOP from baseline was 7.1 mmHg (29.1%) for PC tafluprost and 7.7 mmHg (32.2%) for PC latanoprost. At the completion of the study, the noninferiority of PC tafluprost to PC latanoprost over all diurnal IOP measurements was not demonstrated with RM ANCOVA but was reached with RM ANOVA (noninferiority limit was 1.5 mmHg). Efficacy and safety of tafluprost 0.0015% versus latanoprost 0.005% eye drops in open-angle glaucoma and ocular hypertension: 24-month results of a randomized, double-masked phase III study.

Safety

- *Warnings and Precautions:* Pigmentation of the iris, periorbital tissue and eyelashes can occur in patients treated with Zioptan. Zioptan may gradually change eyelashes and vellus hair including increased length, thickness and number of lashes. Zioptan should be used with caution in patients with active intraocular inflammation because the inflammation may be exacerbated. Macular edema, including cystoid macular edema, has been reported during treatment with prostaglandin F2ά analogs. Zioptan should be used with caution in aphakic patients, in pseudophakic patients with a torn posterior lens capsule, or in patients with known risk factors for macular edema. Use of Zioptan in pediatric patients is not recommended because of potential safety concerns related to increased pigmentation following long-term chronic use.
- *Selected Tolerability Information:* PC or PF tafluprost 0.0015% was evaluated in 905 patients in five controlled clinical studies of up to 24-months' duration.
    - The most common adverse reaction observed in patients treated with tafluprost was conjunctival hyperemia which was reported in a range of 4% – 20% of patients.
    - Approximately 1% of patients discontinued therapy due to ocular events.
    - Ocular adverse reactions reported at an incidence of ≥2% in these clinical studies included ocular stinging/irritation (7%), ocular pruritus including allergic conjunctivitis (5%), cataract (3%), dry eye (3%), ocular pain (3%), eyelash darkening (2%), growth of eyelashes (2%) and vision blurred (2%).
    - Nonocular adverse reactions reported at an incidence of 2% – 6% in these clinical studies in patients treated with tafluprost 0.0015% were headache (6%), common cold (4%), cough (3%) and urinary tract infection (2%).

Questions and Answers

Q: Were all completed and analyzed studies for reducing elevated intraocular pressure presented today?
A: Yes.

Q: Were the comparator studies head-to-head or non-inferiority trials?
A: Head-to-head.

Q: Is there a head-to-head study being conducted that evaluates PF tafluprost vs. another PF prostaglandin analogue?
A: Not at this time since the power needs to be large and the duration long for this type of study.

Q: What is the place in therapy for the product?
A: Alternative for patients with sensitivities to preservatives.

III. Genentech

Thomas Morrow, MD, Director, Medical Affairs, Payer Support
Dusti Prisock, PharmD, Regional General Manager, Managed Care and Customer Operations
Michael Zymowski, Managed Care

Erivedge™ (vismodegib)

Erivedge (vismodegib) capsule is the only FDA-approved oral therapy for the treatment of adults with metastatic basal cell carcinoma, or with locally advanced basal cell carcinoma (BCC) that has recurred following surgery or who are not candidates for surgery, and who are not candidates for radiation. Erivedge is an inhibitor of the Hedgehog pathway. It

binds to and inhibits Smoothened, a transmembrane protein involved in Hedgehog signal transduction.

Efficacy

- International, single-arm, multicenter, two-cohort, open-label Phase II study (N=104) included patients with both metastatic and locally advanced BCC, defined as follows:
    - Metastatic BCC (mBCC): BCC that had spread beyond the skin to other parts of the body, including the lymph nodes, lung, bones, and/or internal organs
    - Locally advanced BCC (laBCC): lesions that had recurred after radiotherapy, unless radiotherapy was contraindicated or inappropriate (e.g., Gorlin syndrome, limitations because of location of tumor, or cumulative prior radiotherapy dose), and where the lesions were either unresectable or surgical resection would result in substantial deformity
- Erivedge demonstrated response rates in patients treated with 150 mg Erivedge daily until disease progression or unacceptable toxicity.
- The median duration of treatment was 10.2 months (range 0.7 to 18.7 months).

Objective Response Rate: Efficacy-Evaluable Patients*

	mBCC (n = 33)	laBCC (n = 63)
IRF†-Confirmed ORR, n (%)	10 (30.3)	27 (42.9)
(95% CI)	(15.6, 48.2)	(30.5, 56.0)
Complete Response‡	0 (0.0)	13 (20.6)
Partial Response	10 (30.3)	14 (22.2)
Median Response Duration (months)	7.6	7.6
(95% CI)	(5.6, Not estimable)	(5.7, 9.7)

*Patients who received at least one dose of Erivedge with independent pathologist-confirmed diagnosis of BCC. †IRF=Independent Review Facility ‡For laBCC, complete response was defined as objective response with no residual BCC on sampling tumor biopsy. An objective response in laBCC required at least one of the following criteria and absence of any criterion for disease progression: (1) ≥ 30% reduction in lesion size [sum of the longest diameter [SLD)] from baseline in target lesions by radiographic assessment; (2) ≥ 30% reduction in SLD from baseline in externally visible dimension of target lesions; (3) complete resolution of ulceration in all target lesions.

Safety

- **Black Box Warning-Embryo-Fetal Death and Severe Birth Defects:** Erivedge capsule can cause fetal harm when administered to a pregnant female based on its mechanism of action. Erivedge is embryotoxic and teratogenic in animals. Teratogenic effects included severe midline defects, missing digits, and other irreversible malformations. Verify pregnancy status prior to the initiation of Erivedge. Advise male and female patients of these risks. Advise female patients of the need for contraception during and after treatment and advise male patients of the potential risk of Erivedge exposure through semen. Advise patients to contact their healthcare provider immediately if they suspect they (or, for males, their female partner) may be pregnant. Female and male patients of reproductive potential should be counseled regarding pregnancy prevention and planning.
- *Female patients:* Determine pregnancy status within 7 days prior to initiation of treatment in females of reproductive potential. For females with a negative pregnancy test, initiate a highly effective form of contraception (failure rate of less than 1%) prior to the first dose. Continue highly effective contraception during therapy and for 7 months after the last dose of Erivedge.
- *Male patients:* Male patients should use condoms with spermicide, even after a vasectomy, during sexual intercourse with female partners while being treated with Erivedge and for 2 months after the last dose to avoid exposing an embryo or fetus to vismodegib.
- *Blood Donation:* Advise patients not to donate blood or blood products while receiving Erivedge and for at least 7 months after the last dose of Erivedge
- *Nursing Mothers:* It is not known whether vismodegib is excreted in human breast milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from Erivedge, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.
- *Adverse Reactions:* The most common adverse reactions (≥10%) were muscle spasms, alopecia, dysgeusia, weight loss, fatigue, nausea, diarrhea, decreased appetite, constipation, arthralgias, vomiting, and ageusia. Amenorrhea has been observed in clinical trials in females of reproductive potential. Reversibility of fertility impairment is unknown. In clinical trials, a total of 3 of 10 premenopausal women developed amenorrhea while receiving Erivedge. Treatment-emergent grade 3 laboratory abnormalities observed in clinical trials were hyponatremia in 6 patients (4%), hypokalemia in 2 patients (1%), and azotemia in 3 patients (2%).

Questions and Answers

Q: Were all completed and analyzed studies conducted in basal cell carcinoma presented today?

A: Yes; the product was approved based on phase II results.

Q: Will a phase III study in basal cell carcinoma be conducted?
A: No, but phase IV studies will most likely be conducted.

Q: Is there a study evaluating overall survival being conducted?
A: Patients in the phase II study are being followed for overall survival analysis.

IV. **Novartis**
Julia Compton, PharmD, Medical Science Liaison
Fred McClellan, Senior Regional Account Manager

Arcapta™ (indacaterol)
Arcapta Neohaler is a long-acting beta2-adrenergic agonist indicated for long-term, once-daily maintenance bronchodilator treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema. *Important Limitations of Use:* Arcapta Neohaler is NOT indicated to treat acute deteriorations of COPD. Arcapta Neohaler is NOT indicated for asthma.

Efficacy
- The Arcapta Neohaler COPD development program included 6 confirmatory trials that were randomized, double-blinded, placebo and active-controlled design of 12-week, 26-week, or 52-week duration. These 6 trials enrolled 5474 COPD patients who were 40 years or older, had a smoking history of at least 10 pack years, had a post-bronchodilator FEV1 of <80% and at least 30% of the predicted normal value, and a post-bronchodilator ratio of FEV1/FVC of <70%. The primary efficacy endpoint was 24-hour post-dose trough FEV1 after 12 weeks of treatment in all 6 trials. A summary of the 6 trials is as follows:
  - Arcapta Neohaler 75 mcg once-daily and placebo [two 12-week trials]
  - Indacaterol 150 mcg and 300 mcg once-daily, tiotropium (an active comparator), and placebo [one 26-week trial] - conducted after an initial 2-week dose ranging portion of the design
  - Indacaterol 150 mcg once-daily and placebo [one 12-week trial]
  - Indacaterol 150 mcg once-daily, salmeterol (an active comparator), and placebo [one 26-week trial]
  - Indacaterol 300 mcg and 600 mcg once-daily, formoterol (an active comparator), placebo [one 52-week trial]
- In the 2 trials (N=323 and N=318) that compared Arcapta Neohaler 75 mcg once-daily vs. placebo, the least-squares mean trough FEV1 at week 12 was 1.38 L vs. 1.26 L (treatment difference: 0.12 [95% CI: 0.08, 0.15]), respectively, and 1.49 L vs. 1.35 L (treatment difference: 0.14 [95% CI: 0.10, 0.18]).
- Serial FEV1 measurements in patients treated with Arcapta Neohaler demonstrated a bronchodilatory treatment effect after the first dose compared to placebo at 5 minutes post-dose of 0.09 L and 0.10 L in the 2 trials, respectively. The mean peak improvement relative to baseline after the first dose (Day 1) was 0.19 L and 0.22 L, respectively. Improvement in lung function observed at week 2 was consistent over the 12-week treatment.
- In both COPD clinical trials that included Arcapta Neohaler 75 mcg, patients treated with Arcapta Neohaler used less daily rescue albuterol during the trial compared to patients treated with placebo.
- In all 6 COPD trials, all doses of indacaterol (75 mcg, 150 mcg, 300 mcg, and 600 mcg) showed statistically significantly greater 24-hour post-dose trough FEV1 compared to placebo at 12 weeks.
- Health-related quality of life was measured in all 6 efficacy COPD clinical trials using the St. George's Respiratory Questionnaire (SGRQ), a disease-specific patient reported instrument which measures symptoms, activities, and impact on daily life. At week 12, pooled data from these trials demonstrated an improvement over placebo in SGRQ total score of –3.8 with a 95% CI of (–5.3, –2.3) for the Arcapta Neohaler 75 mcg dose, –4.6 with a 95% CI of (–5.5, –3.6) for 150 mcg, and –3.8 with a 95% CI of (–4.9, –2.8) for 300 mcg.
- Tolerance to the effects of inhaled beta-agonists can occur with regularly-scheduled, chronic use. In two 12-week clinical efficacy trials in 323 and 318 adult patients with COPD, Arcapta Neohaler improvement in lung function (as measured by the forced expiratory volume in one second, FEV1) observed at week 4 with Arcapta Neohaler was consistently maintained over the 12-week treatment period in both trials.

Safety
- **Black Box Warning-Asthma-Related Death**
- The Arcapta Neohaler safety database reflects exposure of 2516 patients at doses of 75 mcg or greater for at least 12 weeks in 6 clinical trials. In these trials, 449 patients were exposed to the recommended dose of 75 mcg for up to 3 months, and 144, 583 and 425 COPD patients were exposed to a dose of 150 mcg, 300 mcg or 600 mcg for 1 year, respectively.
  - In these 6 clinical trials, 48% of patients treated with any dose of indacaterol reported an adverse reaction compared with 43% of patients treated with placebo.

- The proportion of patients who discontinued treatment due to adverse reaction was 5% for Arcapta Neohaler treated patients and 5% for placebo-treated patients. The most common adverse reactions that led to discontinuation of Arcapta Neohaler were COPD and dyspnea.
- The most common serious adverse reactions were COPD exacerbation, pneumonia, angina pectoris, and atrial fibrillation, which occurred at similar rates across treatment groups.
- Most common adverse reactions (>2% and more common than placebo) during 3-month exposure at the recommended 75 mcg once-daily dose were nasopharyngitis, cough, oropharyngeal pain, headache and nausea.
- In the clinical trials, healthcare providers observed during clinic visits that an average of 24% of patients experienced a cough on at least 20% of visits following inhalation of Arcapta Neohaler 75 mcg compared to 7% of patients receiving placebo. The cough usually occurred within 15 seconds following inhalation and lasted for no more than 15 seconds. Cough following inhalation in clinical trials was not associated with bronchospasm, exacerbations, deteriorations of disease, or loss of efficacy.

- All LABAs are contraindicated in patients with asthma without use of a long-term asthma control medication.
- Do not initiate Arcapta Neohaler in acutely deteriorating COPD patients. Do not use Arcapta Neohaler for relief of acute symptoms. Concomitant short-acting beta2-agonists can be used as needed for acute relief.
- Do not exceed the recommended dose. Excessive use of Arcapta Neohaler, or use in conjunction with other medications containing long-acting beta2-agonist can result in clinically significant cardiovascular effects and may be fatal.
- Life-threatening paradoxical bronchospasm can occur. If paradoxical bronchospasm occurs, Arcapta Neohaler should be discontinued immediately and alternative therapy instituted.
- Use with caution in patients with cardiovascular or convulsive disorders, thyrotoxicosis, or sensitivity to sympathomimetic drugs.
- Beta2-agonist medications may produce significant hypokalemia in some patients. Inhalation of high doses of beta2-adrenergic agonists may produce increases in plasma glucose. Clinically notable decreases in serum potassium or changes in blood glucose were infrequent during long-term clinical studies with the rates similar to those for placebo controls. Arcapta Neohaler has not been investigated in patients whose diabetes mellitus is not well controlled.

Questions and Answers
Q: Were all completed and analyzed studies in COPD presented today?
A: Yes.

Q: Are any studies being conducted without use of an inhaled corticosteroid?
A: A study in combination with an antimuscarinic is being conducted.

Q: Are the plans to formulate with an inhaled corticosteroid (ICS)?
A: No.

Q: Is there a head-to-head trial being conducted with the 75 mcg daily dose?
A: Not at this time.

Q: Is higher dosing being studied in the US?
A: No, 75 mcg is the lowest effective dose so no need for higher dosing.

Q: What considered the advantages of Arcapta?
A: Once daily dosing to improve adherence, rapid effect within first 5 minutes, available as single agent without ICS, improved quality of life data in labeling that is not in labeling for other LABA products, decreases use of rescue medication.

V. Pfizer
Tom Heard, RPh, CGP, Associate Director, Medical Outcomes Specialist
Lonnie Wen, RPh, PhD, Director, US Regional Outcomes Research, Oncology

Inlyta™ (axitinib)
Axitinib (Inlyta) is indicated for the treatment of advanced renal cell carcinoma (RCC) after failure of one prior systemic therapy. Axitinib has been shown to inhibit receptor tyrosine kinases including vascular endothelial growth factor receptors (VEGFR)-1, VEGFR-2, and VEGFR-3 at therapeutic plasma concentrations. These receptors are implicated

in pathologic angiogenesis, tumor growth, and cancer progression. VEGF-mediated endothelial cell proliferation and survival were inhibited by axitinib *in vitro* and in mouse models. Axitinib was shown to inhibit tumor growth and phosphorylation of VEGFR-2 in tumor xenograft mouse models.

Efficacy

- The safety and efficacy of axitinib were evaluated in a randomized, open-label, multicenter Phase 3 study. Patients (N=723) with advanced RCC whose disease had progressed on or after treatment with 1 prior systemic therapy, including sunitinib-, bevacizumab-, temsirolimus-, or cytokine-containing regimens were randomized (1:1) to receive axitinib (N=361) or sorafenib (N=362). Progression-free survival (PFS) was assessed by a blinded independent central review committee. Other endpoints included objective response rate (ORR) and overall survival (OS).
- There was a statistically significant advantage for axitinib over sorafenib for the endpoint of PFS. Axitinib median PFS was 6.7 months (95% confidence interval (CI), 6.3-8.6) versus 4.7 months (95% CI, 4.6-5.6) for sorafenib (HR 0.665; p<0.0001) as determined by independent review. There was no statistically significant difference between the arms in OS. Based on blinded independent review committee assessment, the median duration of response in the axitinib arm was 11 months (95% CI, 7.4 months to not estimable) compared with 10.6 months in the sorafenib arm (95% CI, 8.8 to 11.5 months).

Cost Analysis (Budget Impact Model))

- Axitinib is the first VEGFR-TKI proven to be superior to an active comparator in the second-line treatment of advanced RCC. An incidence-based budget impact model has been developed to assist payers in understanding the potential annual budget impact of adding axitinib to a health plan formulary as a second-line treatment for patients with mRCC. The model estimates the incremental budget impact of adopting axitinib as a treatment option for patients who have been diagnosed with mRCC and have received a previous line of systemic treatment by comparing drug-related costs after introduction of axitinib (i.e., the “world-with-axitinib” scenario) compared with the “world-without-axitinib” scenario, over a period of 3 years. The results of this analysis demonstrate that treating mRCC patients with axitinib has a minimal incremental budget impact.

Safety

- The most common (≥20%) adverse events (AEs) occurring in patients receiving axitinib (all grades, vs sorafenib) were diarrhea (55% vs 53%), hypertension (40% vs 29%), fatigue (39% vs 32%), decreased appetite (34% vs 29%), nausea (32% vs 22%), dysphonia (31% vs 14%), hand-foot syndrome (27% vs 51%), weight decreased (25% vs 21%), vomiting (24% vs 17%), asthenia (21% vs 14%), and constipation (20% vs 20%). The most common (≥10%) grade 3/4 AEs occurring in patients receiving axitinib (vs sorafenib) were hypertension (16% vs 11%), diarrhea (11% vs 7%), and fatigue (11% vs 5%). The most common (≥20%) lab abnormalities occurring in patients receiving axitinib (all grades, vs sorafenib) included increased creatinine (55% vs 41%), decreased bicarbonate (44% vs 43%), hypocalcemia (39% vs 59%), decreased hemoglobin (35% vs 52%), decreased lymphocytes (absolute) (33% vs 36%), increased ALP (30% vs 34%), hyperglycemia (28% vs 23%), increased lipase (27% vs 46%), increased amylase (25% vs 33%), increased ALT (22% vs 22%), and increased AST (20% vs 25%). Hypertension including hypertensive crisis has been observed. Blood pressure should be well controlled prior to initiating axitinib. Patients should be monitored for hypertension and treated as necessary. For persistent hypertension, despite use of antihypertensive medications, reduce the dose. Discontinue axitinib if hypertension is severe and persistent despite use of antihypertensive therapy and dose reduction of axitinib, and discontinuation should be considered if there is evidence of hypertensive crisis. Arterial and venous thrombotic events have been observed and can be fatal. Use with caution in patients who are at increased risk or who have a history of these events. Hemorrhagic events, including fatal events, have been reported. Axitinib has not been studied in patients with evidence of untreated brain metastasis or recent active gastrointestinal bleeding and should not be used in those patients. If any bleeding requires medical intervention, temporarily interrupt the axitinib dose. Gastrointestinal perforation and fistula, including death, have occurred. Use with caution in patients at risk for gastrointestinal perforation or fistula. Patients should be monitored for symptoms of gastrointestinal perforation or fistula periodically throughout treatment. Hypothyroidism requiring thyroid hormone replacement has been reported. Monitoring of thyroid function before initiation of, and periodically throughout, treatment is recommended. Stop axitinib at least 24 hours prior to scheduled surgery. Reversible Posterior Leukoencephalopathy Syndrome (RPLS) has been observed. If signs or symptoms occur, permanently discontinue treatment. Monitoring for proteinuria before initiation of, and periodically throughout, treatment is recommended. For moderate to severe proteinuria, reduce the dose or temporarily interrupt treatment. Liver enzyme elevation has been observed during treatment with axitinib. ALT, AST, and bilirubin levels should be monitored before initiation of, and periodically throughout, treatment. For patients with moderate hepatic impairment, the starting dose should be decreased. Axitinib has not been studied in patients with severe hepatic impairment. Women of childbearing potential should be advised of potential hazard to the fetus and to avoid becoming pregnant while receiving axitinib. Avoid strong

CYP3A4/5 inhibitors. If unavoidable, reduce the dose of axitinib. Grapefruit or grapefruit juice may also increase axitinib plasma concentrations and should be avoided. Avoid strong CYP3A4/5 inducers and, if possible, avoid moderate CYP3A4/5 inducers.

Questions and Answers
Q: Were all completed and analyzed studies in RCC presented today?
A: Yes.

Q: Are other indications being sought?
A: Use in hepatocellular and solid tumor cancers is being studied.

Q: Is there a study being conducted evaluating overall survival as a primary endpoint?
A: No.

Q: Is there a long-term study being conducted?
A: No.

VI. Aptalis

Anita Hays, RN, PhD, Medical Science Liaison, Global Affairs
George Kitchens, RPh

Rectiv™ (nitroglycerin ointment 0.4%)
Rectiv (nitroglycerin) ointment 0.4% for intra-anal use is indicated for the treatment of moderate to severe pain associated with chronic anal fissure (CAF).

Current Treatment Options for Chronic Anal Fissure
- Chronic anal fissures are an extremely painful condition associated with significant morbidity.
- Practice parameters from the American Society of Colorectal Surgeons (ASCRS) and 2 position papers state that conservative therapy should be the first step in treatment for all fissure types.
- Nitroglycerin (NTG) ointment forms free radical nitric oxide, resulting in vasodilatation and anal sphincter relaxation. The use of topical nitroglycerin significantly decreases pain during the therapy period.
- Rectiv is the only FDA approved nitroglycerin treatment for moderate to severe pain associated with CAF. Other commonly used topical therapies for CAF must be compounded locally for intra-anal application. Direct prescribing information comparisons are not currently available for products now used in general clinical practice for treating pain associated with CAF.
- Rectiv does not need to be compounded and offers a uniform, standardized formulation that has been tested in clinical trials. Rectiv provides a consistent standardized dose delivery with documented efficacy, stability and safety for those patients with pain from a CAF.

Efficacy
The pivotal clinical trial was a 3-week, phase 3, multi-center, randomized, double-blind, placebo-controlled study in 247 adults with a chronic anal fissure that determined the efficacy and safety of Rectiv (nitroglycerin) Ointment 0.4% on the pain associated with a CAF.
- The primary endpoint was the absolute change from baseline visual analog scale (VAS) scores in 24-hour average pain, as assessed by patient-reported VAS averaged over Days 14–18 of treatment.
- Time to improvement in pain intensity, measured by: a) 50% decrease and b) at least 10 mm decrease in 24-hour average pain intensity (VAS) and the patients' global assessment of therapy at Day 21.
- Rectiv demonstrated a statistically significant improvement in patient-reported pain compared to placebo.
- The most common treatment-emergent adverse events for RECTIV versus placebo were headache (69.9% vs 47.6%), dizziness (4.9% vs 1.6%), diarrhea (3.3% vs 3.2%), and nausea (1.6 % vs 4.0%).

Safety
- Rectiv is contraindicated in patients:
    - Taking phosphodiesterase type 5 (PDE5) inhibitors (e.g., sildenafil, vardenafil, and tadalafil), which can potentiate the hypotensive effect of organic nitrates
    - With severe anemia
    - With increased intracranial pressure
    - With known hypersensitivity to nitroglycerin, other nitrates and nitrites, or any components of the ointment

- Patients with cardiovascular disorders should be closely monitored while using Rectiv. Venous and arterial dilation as a consequence of nitroglycerin treatment can result in hypotension.
- Exercise caution in patients with any of the following conditions: blood volume depletion, existing hypotension, cardiomyopathies, congestive heart failure, acute myocardial infarction, or poor cardiac function for other reasons.
- The adverse reactions of Rectiv are likely to be more pronounced in the elderly.
- Nitroglycerin produces dose-related headaches, which may be severe.
- The following drug interactions may occur in patients taking Rectiv:
    - PDE5 inhibitors: potentiation of hypotensive effects of organic nitrates; concomitant use is contraindicated
    - Antihypertensives: possible additive hypotensive effects
    - Aspirin: increased nitroglycerin levels
    - Tissue-type plasminogen activator (t-PA): decreased thrombolytic effect
    - Heparin: anticoagulant effect of heparin may be reduced. Monitor activated partial thromboplastin time (APTT)
    - Ergotamine: increased bioavailability of ergotamine
    - Alcohol: additive vasodilatory effects to nitroglycerin. Consumption of alcohol should be avoided.
- The most common adverse reactions (≥2%) are headache and dizziness.

Questions and Answers

Q: Were all completed and analyzed studies in chronic anal fissures presented today?
A: Yes.

Q: What were the most common reasons for study discontinuation?
A: Headache and not being compliant with recording score.

Q: How many days supply is the 30 gram tube?
A: 60 days supply.

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 (previously SXC), announces the Manufacturers' Forum occurring on Thursday, November 1, 2012.

Date: **Thursday, November 1, 2012 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, 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
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

This page intentionally left blank

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

This page intentionally left blank

2012

Upcoming Meetings

Drug Utilization Review Board Meeting

2 Peachtree Street, N.W.

5th Floor Board Room

Atlanta, Georgia 30303

Tuesday, December 11, 2012: 10:00am – 2:00pm

Manufacturers' Forum

NorthStar HealthCare Consulting

1121 Alderman Drive

Suite 112

Alpharetta, Georgia 30005

Thursday, November 1, 2012: 9:00am – 5:00pm