



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

June 21, 2012



**GEORGIA DEPARTMENT
OF COMMUNITY HEALTH**

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**DRUG UTILIZATION REVIEW BOARD MEETING
AGENDA**

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

June 21, 2012 – 10:00 a.m. to 2:00 p.m.

CALL TO ORDER	<i>Gary Williams, MD, Chairman</i>
ETHICS PRESENTATION	<i>Woody Dahmer, JD, Senior Staff Attorney, Office of General Counsel</i>
COMMENTS FROM THE DEPARTMENT	<i>Linda Wiant, PharmD, Director</i>
MINUTES FROM PREVIOUS MEETING	<i>Chairman</i>
NORTHSTAR HEALTHCARE CONSULTING	<i>Emily Baker, PharmD, BCPS, MBA, MHA Tara R. Cockerham, PharmD</i>
PDL MANAGEMENT	
➤ Manufacturers' Forum	
➤ Therapeutic Class Reviews	
▪ Protease Inhibitors for Hepatitis C	
▪ Agents for Hereditary Angioedema	
▪ Atypical Antipsychotics	
▪ Growth Hormones	
➤ New Drug Reviews	
▪ Corifact™	
▪ Ferriprox™	
▪ Jakafi™	
▪ Vpriv™	
➤ Non-Supplemental Rebate Classes - Clinical Updates Review	
➤ Follow-Up from Last Meeting	
FUTURE AGENDA ITEMS	<i>Chairman</i>
CONSUMER COMMENTS SESSION	
ADJOURNMENT OF OPEN SESSION	<i>Chairman</i>
EXECUTIVE SESSION	
RECONVENING OF OPEN SESSION	
➤ Board's Voting for Recommendations to DCH	<i>Chairman</i>
ADJOURNMENT OF MEETING	<i>Chairman</i>



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**Department of Community Health
Drug Utilization Review Board (DURB)
MINUTES
Thursday, March 15, 2012**

MEMBERS PRESENT

Gary M. Williams, M.D., Chairman
Laurel E. Ashworth, Pharm.D., Vice-Chairperson
Joseph R. Bona, M.D., MBA
Paul D. Boyce, M.D.
Karen L. Carter, M.D.
Truddie Darden, M.D.
Carl Ellis, R.Ph.
Rondell C. Jagers, Pharm.D.
Robyn Lorys, Pharm.D.
J. Russell May, Pharm.D.
Osgood A. Miller, R.Ph.
Michael S. O'Connor, Pharm.D.

MEMBERS ABSENT

Kimberly S. Carroll, M.D.
Arvind Gupta, M.D.
Matthew Perri, III, R.Ph., Ph.D.

Staff

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

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
Talmahjia "Tami" Sweat, Pharm.D., Clinical Systems Product Manager

Goold Health Services

Timothy Clifford, M.D., Medical Director
Doug Martin, Pharm.D., Pharmacy Project Manager
Shelley White, Senior Rebate Specialist

University of Georgia Pharmacy School

Christina Kim, Pharm.D. Candidate
Nicole Shumiloff, Pharm.D. Candidate

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Brett Hall, Pharm.D. Candidate
Laura Stoudenmire, Pharm.D.

Call to Order

The Drug Utilization Review Board (DURB/DUR Board/Board) held its first meeting for the calendar year on March 15, 2012. The Chairman, Gary M. Williams, M.D., called the meeting to order at 9:02am.

Comments from the Department

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

1. Resignations – Ryan Beddingfield, R.Ph. and Mary Rhee, M.D., M.S. have resigned from the DUR Board. Appreciation for their service to the Board was expressed. There is an opening for a consumer advocate on the DURB. Applications are being accepted.
2. Pharmacy Students –Students and a pharmacy practice resident from the University of Georgia Pharmacy School were welcomed.

Minutes from the Previous Meeting

Dr. Williams asked for comments regarding the minutes from the December 13, 2011 meeting. There were no corrections. A motion was made, seconded, and carried to approve the minutes as written.

Manufacturers’ Forum

Emily Baker, Pharm.D., BCPS, reviewed information regarding the Manufacturers’ Forum that was provided in the Manufacturer Information section in the DUR Board binder. A total of twenty-three (23) manufacturers participated and provided information regarding the following drugs discussed at the March 2012 DURB meeting:

Manufacturers	Drugs
Janssen	Xarelto
Novo Nordisk	Victoza, Norditropin Flexpro
Shire	Intuniv
Merck	Januvia, Juvisync, Victrelis, Singulair
Pfizer	Xalkori, Lyrica, Prestiq, Toviaz
GlaxoSmithKline	Advair
Novartis	Tekturna, Tekturna HCT, Amturnide, Tekamlo, Valturna, Gilenya
UCB	Cimzia, Vimpat
AstraZeneca	Brilinta
Kadmon	RibaPak
Romark	Alinia
Gilead	Complera, Truvada, Letairis
Actelion	Tracleer
Covidien-Mallinckrodt	Pennsaid, Exalgo
Astellas	Protopic, VESIcare
Nephron	Albuterol Inhalation Solution 0.042%, 1.25mg/3ml
Amgen	Aranesp, Epogen, Enbrel
Biogen	Avonex

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Manufacturers	Drugs
Bristol-Myers Squibb	Onglyza
Genentech	Zelboraf
Forest	Viibryd
Purdue	Butrans
Ferring	Lysteda

Comments were made on the Direct Renin Inhibitors. The next forum is Thursday, May 3, 2012 from 9am-5pm at the NorthStar Healthcare Consulting office: 1121 Alderman Drive, Suite 112, Alpharetta, GA 30005.

New Drug Reviews

Clinical information for the following new drugs, in the market six months or more, was presented for discussion and recommendations. The complete detailed drug summary is in the New Drugs for Review section of the March 2012 DUR Board binder.

Therapeutic Class	Drugs	Presenter
Antiplatelet Drugs	<i>Brilinta</i>	Emily Baker, Pharm.D., BCPS
Antiinfectives	<i>Difucid</i>	Emily Baker, Pharm.D., BCPS
Antidepressants – Miscellaneous	<i>Viibryd</i>	Emily Baker, Pharm.D., BCPS
Antineoplastics	<i>Xalkori</i>	Emily Baker, Pharm.D., BCPS
Anticoagulants	<i>Xarelto</i>	Emily Baker, Pharm.D., BCPS
Antineoplastics	<i>Zelboraf</i>	Emily Baker, Pharm.D., BCPS

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

- Brilinta-observational finding of decreased effectiveness of Brilinta with aspirin
- Xalkori-comparison to standard therapy for ALK-positive patients
- Xarelto-difference from antiplatelet drugs; consideration for acute coronary syndrome; withdrawal cautions

Supplemental Rebate Drugs – New Clinical Information Review

Clinical updates to the Supplemental Rebate categories were listed in the Supplemental Rebate section of the DURB binder. Tara R. Cockerham, Pharm.D., highlighted significant safety updates at the request of the DURB. The following therapeutic categories had updates:

Drug Class/Name
Androgens/Anabolics
Anticoagulants

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Drug Class/Name - continued
Antidepressants - Miscellaneous
Antihyperkinesia Agents
Contraceptives
Diabetic – Non-Insulin Injectables
Direct Renin Inhibitors and Combinations
Hepatitis C Agents
Insulins/Insulin Penfills
Lipid-Other
Nasal Steroids
Phosphate Binders
Tumor Necrosis Factor (TNF) Blockers
Adrenergic Combinations
Angiotensin II Receptor Antagonist (ARBs) and Combinations
Anticonvulsants
Antiemetic Drugs
Antihistamines – Non-sedating
Antineoplastics
Antispasmodics
Benign Prostatic Hyperplasia (BPH) Agents
Beta Blockers
Cardiac – Other
Diabetic – Dipeptidyl Peptidase IV (DPP-IV) Inhibitors
Drugs for Gout
Endothelin Receptor Agonists
Erythropoiesis Stimulating Agents (ESAs)
Gastrointestinal – Digestive Enzymes
Gastrointestinal – Inflammatory Bowel Agents
Growth Hormones
Hemostatics
Human Immunodeficiency Virus (HIV) Drugs
Hyperparathyroid – Vitamin D Analogs and Calcimimetics
Leukotriene Modifiers
Lipid - Niacin
Migraine – Selective Serotonin Agents
Multiple Sclerosis (MS) Agents
Nonsteroidal Antiinflammatory Agents
Nonsteroidal Antiinflammatory Cyclooxygenase-2 Selective Agents
Ophthalmic Nonsteroidal Antiinflammatory Agents
Ophthalmic Prostaglandins
Opioid Agonists
Opioid Partial Agonists
Platelet Aggregate Inhibitors/Combinations - Miscellaneous
Progestins
Pulmonary Antihypertensives

Drug Class/Name - continued
Respiratory Agents - Miscellaneous
Topical Antipsoriatics
Topical – Corticosteroids
Topical – Immunomodulators
Topical – Scabicides and Pediculicides
Triglyceride Lowering Agents

Comments were provided from the Board.

Utilization Trend Review

Utilization trends for Georgia Medicaid Fee-for-Service were provided in detail in the Utilization Trends section of the March 2012 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:

1. Drosperinone-containing products (e.g. Yaz)
2. Sedative Hypnotics

Consumer Comments Session

Dr. Cockerham presented consumer comments to the Board from the following:

Letters (see Attachment A): Dr. Christine J. Bruno, Atlanta Gastroenterology Associates

A disclosure form was completed by Dr. Bruno and was reviewed by the Department.

Comments from the Chairman

Dr. Gary Williams gave comments on the Texas Medication Algorithm Project, as noted in Attachment B. Dr. Wiant commented for clarification that DCH doesn't believe there has been any wrongdoing on behalf of the State, DCH or the Board, and that every decision made is unbiased and done in the best interest of the State and its patients.

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

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Thursday, March 15, 2012

Thursday, June 21, 2012

Thursday, September 20, 2012

Tuesday, December 11, 2012

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

Thursday, May 3, 2012

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 except for Dr. Truddie Darden.

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 students attended the closed session with the Board members. There was a unanimous vote approving the closed session. The Chairman, Dr. Gary Williams, adjourned the open session at approximately 9.56 am, at which time members took a break then reconvened for the executive (closed) session.

Executive Session

The executive session was held from 10:05am to 2:20pm.

Board's Recommendations to the Department

After all clinical and financial evaluations and discussions, the DUR Board presented the Department with the following recommendations for changes to the Preferred Drug List (PDL):

New Drug Reviews

Antiplatelet

The DUR Board recommended *Non-Preferred* status with *Prior Authorization* for *Brilinta*[™].

Antiinfective

The DUR Board recommended *Non-Preferred* status with *Prior Authorization* for *Dificid*[™].

Antidepressant

The DUR Board recommended *Non-Preferred* status with *Prior Authorization* for *Vuibryd*[™].

Antineoplastics

The DUR Board recommended *Preferred* status with *Prior Authorization* for *Xalkori*[™] and *Zelboraf*[™].

Anticoagulants

The DUR Board recommended *Non-Preferred* status with *Prior Authorization* for *Xarelto*[™].

Supplemental Rebate Class Reviews

Androgens/Anabolics

The DUR Board recommended *Non-Preferred* status with *Prior Authorization* for *Androgel*[®] 1.62%.

Anticoagulants

The DUR Board recommended *Non-Preferred* status with *Prior Authorization* for *Arixtra*[®].

Antihyperkinesia

The DUR Board recommended no changes at this time and to reevaluate the class in 6 months.

Asthma and Bronchodilator Agents

The DUR Board recommended *Non-Preferred* status for *Theophylline Elixir*.

Contraceptives

The DUR Board recommended *Non-Preferred* status with *Prior Authorization* for *Drospirenone-Containing Products* (*Beyaz*[®], *Gianvi*[®], *Loryna*[®], *Ocella*[®], *Safryal*[®], *Syeda*[®], *Yasmin*[®], *Yaz*[®], *Zarah*[®]) and for *Ortho Evra*[®].

Diabetic – Non-Insulin Injectables

The DUR Board recommended *Preferred* status with *Prior Authorization* for *Victoza*[®].

Direct Renin Inhibitors and Combinations

The DUR Board recommended *Non-Preferred* status with *Prior Authorization* for *Aliskiren-Containing Products* (*Amturnide*[®], *Tekamlo*[®], *Tekturna*[®], *Tekturna*[®] HCT and *Valturna*[®]).

Growth Hormones

The DUR Board recommended Goold Health Systems request a best and final offer from the manufacturers and to reevaluate the class at the June 21, 2012 meeting.

Hepatitis C

The DUR Board recommended *Preferred* status with *Prior Authorization* for *Victrelis*[®].

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Insulins/Insulin Pens

The DUR Board recommended *Preferred* status for *Humalog[®] vials, Humalog[®] Mix 75/25 vials and Humulin[®] 70/30 vials*.

Nasal Steroids

The DUR Board recommended *Preferred* status for *Nasacort[®] AQ*.

Ophthalmic Quinolones

The DUR Board recommended *Preferred* status for *Moxeza[®]*.

Phosphate Binders

The DUR Board recommended *Preferred* status with *Prior Authorization* for *Eliphos[®]* and *Non- Preferred* status with *Prior Authorization* for *PhosLo[®]*.

Conclusion

At the conclusion of the executive session, the open session reconvened at 2:31pm and audience participants were invited back in to hear the Board's recommendations submitted to the Department. Dr. Williams, Dr. Ashworth and Dr. Wiant presented the recommendations from the Board to the Department.

With no other business for discussion, Chairman Williams adjourned the meeting at 2:38pm.

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

Gary Williams, M.D., Chairman

Department of Community Health
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ATTACHMENT A
(part 1)

As read by Dr. Tara Cockerham at the March 15, 2012 DURB Meeting:

From: christine bruno [mailto:cjbruno2001@yahoo.com]
Sent: Wednesday, December 07, 2011 9:41 AM
To: Linda Wiant
Subject: Support for adding Telaprevir to Ga Medicaid Formulary

Dear Dr Boyce and Ms. Wiant,

As a Board Certified Hepatologist and one of the earliest physicians treating Hepatitis C infection in my role as Chief of Gastroenterology at Grady Memorial Hospital in the 90's, I would like to strongly urge you to add Telaprevir to the Georgia Medicaid Formulary.

Only by effectively treating those infected with Hepatitis C can we minimize the costly and heart wrenching toll of end stage liver disease and liver cancer. As a population, we have just begun to see the exponential rise of these consequences of Chronic HCV infection. Fortunately, we now have drug regimens that are highly effective against genotype 1 infection, the most common and difficult to treat form of Hepatitis C in the United States. Telaprevir is a critical medication in these regimens that leads to much higher cure rates and in some, shortened courses of treatment. Shortened treatment courses helps not only with cost, but also compliance. More effective treatment, shortened course, better compliance leads to better eradication HCV infection and better health for our community.

For all these reasons, I strongly urge you to approve Telaprevir's addition to the Georgia Medicaid Formulary. If you would like to talk with me further about this important decision, please call me on my cell at 404 660 1751.

Sincerely,

Christine J Bruno, MD
Transplant Hepatologist
Atlanta Gastroenterology Associates

ATTACHMENT A
(part 2)

<p>The Liver Center Atlanta Gastroenterology Associates</p>	<p>980 Johnson Ferry Rd., NE Atlanta, GA 30342 Phone: 404-253-6824 Fax: 404-252-5839 E-Mail: Christine.bruno@atlantagastro.com</p>
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March 13, 2012

Gary Williams, MD
Chairman, Drug Utilization Review Board
Georgia Department of Community Health
3 Peachtree St.
Atlanta, GA 30303

RE: HCV Treatment Options

Dear Dr. Williams and Members of the Drug Utilization Review Board:

I am disappointed that despite multiple clinic rescheduling efforts I could not present at your drug review meeting on March 15th. I hope this letter can adequately express my strong and sincere recommendations regarding HCV treatment that a personal presentation would have more naturally allowed. From my previous letter, you know that I am a board certified Transplant Hepatologist and have had almost 20 years experience treating Hepatitis C in the Atlanta area. During that time, I have established health care systems' infrastructures to facilitate HCV treatment and maximize response rates. All these systems have been very diverse and include Grady Memorial Hospital, the Emory Clinic, The South East Permanente Medical Group and Piedmont Liver Transplant. In fact, The Southeast Permanente HCV clinic was recognized by Kaiser Permanente nationally as an exemplary model of quality patient care while closely containing costs.

In my practice, based on my extensive experience and reasons outlined below, I prefer Telaprevir rather than Boceprevir. As things currently stand, I do not have access to Telaprevir for my Medicaid patients. Rather than give one protease inhibitor preferred status over another, I **strongly** recommend that you allow physicians to decide what protease inhibitor they will prescribe and place both on the preferred list. My reasoning follows from three main perspectives; those specific to the drug, those specific to the patient and those relating to the physician's clinic.

Specific Medication Issues:

- The protease inhibitors are direct antiviral agents. This is unlike ribavirin and interferons which act indirectly through the host. As in HIV infection, because they are direct antivirals, **resistance** now becomes a significant issue. Because both share similar mechanisms of action, the issue of resistance, becomes paramount. Trying one initially, failing that and then retrying with the other protease, may not be an option. In addition there is absolutely no data that this would be successful.

**ATTACHMENT A – continued
(part 2)**

- Resistance issues make **compliance**, and therefore simplicity of the treatment program, paramount. Telaprevir has very simple starting, monitoring and stopping rules that are the same across the varied clinical scenarios for Hepatitis C. These rules are the same for naïve to treatment patients, cirrhotics, non cirrhotics, and relapsers from previous HCV treatment etc.
- Telaprevir appears to be more effective in **cirrhotics** than Boceprevir. These patients have the most to gain by eradicating HCV infection and hopefully avoiding hepatic decompensation. They are also the ones with a very narrow clinical window for treatment. Waiting for a new drug treatment or treating and failing with another treatment takes a significant amount of time. During this limited time, further decompensation occurs. Not only can that mean they are no longer able to be treated due to low cell counts or poor synthetic function, but they have begun the long and costly course of our management of liver decompensation. In this decline, one or two hospitalizations can easily overshadow the cost of HCV treatment.

Specific Patient Issues:

- For many patients (especially those who have had interferon and ribavirin before), adding a third drug on after one month of interferon and ribavirin therapy is emotionally and physically exhausting.
- Telaprevir's course of treatment can be shortened in select patients from 48 to 24 weeks if their viral load is negative at week 4 and 12. This shortened course is a far more positive and frequent occurrence than aborting therapy after the lead in dual therapy month with boceprevir. This 24 week course saves not only on the monetary cost of therapy, but also the emotional cost.
- The lead in month of dual therapy with interferon and ribavirin that the use of Boceprevir entails is not well received by my patients for one major reason. If they do not obtain the log drop after the interferon and ribavirin lead in month, they are deemed null responders and **DO NOT RECEIVE THE BROCEPREVIR**. They feel that they have then been **denied the new standard of care therapy**. This makes the situation difficult to say the least.
- With the clear, uniform, standard treatment protocol that Telaprevir treatment entails, there is far less opportunity for confusion and miscommunication. HCV treatment regarding lab draws, follow up visits and treatment failure, success and time course. Any minimization of confusion and standardization of the treatment process, leads to far less consumption of ancillary services and waste of medications.

**ATTACHMENT A – continued
(part 2)**

Specific Physician Clinic Issues:

- HCV treatment, with its monitoring and side effect management is a huge burden on the clinical staff. ANY process that is streamlined, uniform and can be applied to a large number of patients in a standardized fashion yields better outcomes, better satisfaction and decreases errors and misunderstanding. The treatment protocol for Telaprevir does this and is the same for all my HCV patients. The Boceprevir treatment varies with different stopping rules for different groups of HCV patients. This is too cumbersome and, prone to continuing medications longer than is necessary while confirming data. When the treatment endpoints are all the same, it makes it much easier to manage large treatment populations without adding extra “coverage” refills. Correlating complicated and varying end points with varying clinical conditions as is required with boceprevir, can be a busy clinics nightmare.

For all these reasons, I ask for your sincere consideration to at least place both telaprevir and boceprevir on the preferred list with prior approval required.

If you have any questions, I would be happy to discuss them with you. Thank you again for your consideration.

Sincerely,

Christine J. Bruno, MD

404-660-1751

ATTACHMENT B

As read by Dr. Gary Williams at the March 15, 2012 DURB Meeting:

TMAP (Texas Medication Algorithm Project)

Before we adjourn for the closed session, the chair is compelled to present to the board the results of the legal proceeding involving the Texas Medication Algorithm Project, also known as TMAP.

For those who do not recall this program, TMAP was created as an evidence based therapeutic proposal suggesting the most effective use of antipsychotic medications. It was proposed initially to be used in government sponsored medical programs in the state of Texas. After its adoption in that state, it was exported as the "gold standard " for use of antipsychotic drugs in both government sponsored and privately administered health care programs. After close evaluation, especially by a former state government employee in the state of Pennsylvania, the validity of TMAP was found to be questionable, at best, with resulting lawsuits and rulings in favor of several states that had used the algorithm.

The attorney general of the state of Texas, the state in which the algorithm was launched and whose name it carried, then sued Janssen and it's parent Johnson and Johnson. That trial began in January of 2012, lasted ten (10) days and was settled by the pharmaceutical corporation prior to the case being adjudicated.

What that trial did demonstrate without question, was that the algorithm was primarily a marketing ploy that extended from Texas to several states and into this very state...to this very room... to this Board...to this desk. In summary, the findings of that trial were as follows:

That the results of at least three studies that demonstrated the individual and comparative toxicities of this class of drugs had been withheld from the public -That academic physicians touted as "opinion leaders" had contributed to the production of the algorithm as a science based document but that the document itself was a marketing device that was, at least in part, ghostwritten -That this class of drugs was marketed specifically to children for whom no indication by regulatory agencies had been given -That state officials in the state of Texas had received unreported and illegal funds from the manufacturers of atypical antipsychotic drugs both to promote the use of TMAP in Texas and states other than Texas and -That credentialed and competent persons who discovered and reported the apparent misuse of this document were harassed, intimidated and terminated by government officials.

The results of this trial bring into doubt the data and process on which some compounds are marketed to governmental health plans. Most concerning to this chair, is that the targeted population could have involved the most defenseless citizens of this and other states and those who have the softest political voices. That group is our nation's children.

It is the function of this and similar Boards, as physicians, pharmacologist, pharmacists, consumer advocates and all others to assure that the medications purchased by and distributed to

ATTACHMENT B – continued

its dependent citizens are safe, effective and cost effective. This is a joint responsibility shared with official representatives of this the great state of Georgia and all other individual states.

This Board's responsibilities extend far beyond it's capricious composition both as individuals and collectively.

We must not abrogate our responsibilities to those who depend upon or vigilance, knowledge, and awareness.

The chair asks that this statement be included in the minutes of this session of the DURB.

Gary M. Williams, M.D.

DRAFT

Manufacturers' Forum Manufacturer Presentations

Dates: May 3, 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
Nekia Austin, PharmD, JD, Director, Program Compliance
Amy Baker, PharmD, Pharmacist

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. Dyax

Michael Snider, PharmD, Associate Director, Medical Science Liaison
Jeff Cameron, Corporate Account Director
Coy Pitts, Regional Business Manager

Kalbitor® (ecallantide)

- Hereditary angioedema (HAE) is a rare, potentially life-threatening, genetic disease characterized by recurrent sudden attacks of non-pruritic and painful localized edema. Acute attacks of HAE most commonly involve the skin (extremities, face, and/or genitalia), gastrointestinal tract, and upper airway.
- Kalbitor is a plasma kallikrein inhibitor indicated for the treatment of acute attacks of HAE in patients 16 years of age and older.

Clinical Efficacy

- In the Phase 3, clinical development program, patients treated with Kalbitor demonstrated a greater decrease in symptom severity and a greater response to therapy than patients who received placebo.

Clinical Safety

- In clinical studies, potentially serious hypersensitivity reactions, including **anaphylaxis (black box warning)**, have occurred in patients treated with Kalbitor.
- For further information regarding the product and Important Safety Information, including the **Boxed Warning for Anaphylaxis**, please refer to the Full Prescribing Information for Kalbitor, enclosed with this letter.

Home Infusion

- In 2011, Dyax introduced a formal Home Infusion Services program that stream-lines the continuity of care and ensures specialty- trained, registered nurses are equipped to administer Kalbitor. Patients experiencing a laryngeal attack are instructed to seek immediate medical attention at the emergency department.

Recommendations

- Lastly, the Hereditary Angioedema International Working Group (HAWK) recently published a report titled "Evidenced-Based Recommendations for the Therapeutic Management of Angioedema Owing to Hereditary C1 Inhibitor Deficiency: Consensus Report of an International Working Group." This report states that "on-demand therapy for acute attacks should be the initial goal for all patients"; the consensus further states that "acute

treatment aims to resolve angioedema symptoms as quickly as possible” and that “all patients with HAE owing to C1-INH deficiency, even if still asymptomatic should have access to at least one of the specific medicines” to treat acute HAE attacks.

Questions and Answers

Q: How many patients require a 2nd dose?

A: In clinical trials, approximately 10%.

Q: On average, how many attacks does a patient usually have per month?

A: The Hereditary Angioedema Association notes 12-26 attacks/year.

Q: Does the trained nurse monitor the patient after the infusion at home?

A: Yes, the nurse remains with the patient for at least 1 hour to monitor for potential anaphylaxis to the drug and worsening signs of HAE.

Q: Will there be a new formulation that does not require 3 separate injections?

A: Yes, a new reformulation that requires only 1 injection is being evaluated to decrease injection site reactions.

Q: Typically, how many doses does a patient keep at the home?

A: Two doses and the nurse brings two doses for replacement.

Q: Is Kalbitor being studied in other types of angioedema?

A: The drug is being studied in angiotensin-converting enzyme inhibitor angioedema.

II. Teva

Lisa Stevenson, RN, BSN, CMR, MS, Specialist, Teva Biologics & Specialty Products

Lisa M. Libera, MALS, National Account Manager, Public Sector

Tev-Tropin® (somatropin [rDNA origin])

- Tev-Tropin [somatropin (rDNA origin) for injection] is a genetically engineered human growth hormone (rhGH) indicated only for the long-term treatment of children who have growth hormone (GH) failure due to an inadequate secretion of normal endogenous GH.
- Teva continues to demonstrate its commitment level to the Growth Hormone class with a recent Food and Drug Administration (FDA) approval for a line extension to the product, Tjet.
- Clinical studies: Abridged Monograph study objective was to determine efficacy and safety of human growth hormone (HGH) in children with short stature due to growth hormone deficiencies.
- Clinical studies: The bioequivalency study outlines Tjet’s bioequivalence to the traditional needle and syringe in terms of changes in GH and insulin-like growth factor (IGF-1) levels.
- Available as a sterile, white, lyophilized powder intended for subcutaneous administration after reconstitution. Currently supplied in a 5 mg vial with diluent.
- Tjet (provided free of charge) offers needle-free delivery.
- Growth Solutions is a comprehensive service concept developed to facilitate & support HGH therapy.
- Growth Solutions is a single point of contact for all constituents in HGH therapy [patient & caregiver, insurance payor, healthcare provider (MD, Nurse, Pharmacy)].
- Growth Solutions facilitates initiation of therapy with the following: patient support materials (English and Spanish), free home based injection training, provides ongoing services (including Registered Nurses on staff).
- Tjet demonstration.
- Please review attached PI for further product and safety information.

Questions and Answers

Q: What are considered the advantages of Tev-Tropin?

A: Needle-free option, 3 formulations (vials, Inject Ease, Tjet needle-free) to meet patient needs, a 10mg formulation should be available later this year, 30% less expensive than others, Growth Solutions program and providers are requesting coverage under Fee-for-Service (FFS) for continuity of care since the care management organizations (CMOs) cover Tev-Tropin as the exclusive growth hormone.

Q: Do any other growth hormone products have a needle-free delivery system?

A: Saizen has a needle-free.

Q: Is the Tjet device at price parity with other formulations?

A: Devices are provided to patients for free by Teva.

III. Merck

Kerry I. Edwards, MD, FACP, Executive Medical Director

Lisa Bishop, Account Executive

Victrelis® (boceprevir)

- Victrelis is indicated for the treatment of chronic hepatitis C virus (HCV) genotype I infection in combination with peginterferon alfa and ribavirin in adult patients with compensated liver disease who are previously untreated or who have failed previous interferon and ribavirin therapy.
- The PROVIDE study is an open label, single-arm, multi-center, rollover study that assessed the efficacy and safety of boceprevir (BOC) in combination with peginterferon alfa and ribavirin (PR) in patients with chronic hepatitis C genotype 1 infection who had a prior null response to peginterferon alfa and ribavirin (PR) treatment. In this study, patients from the PR control arm of the phase 2/3 boceprevir studies who received ≥ 12 weeks of PR treatment and failed to achieve sustained virologic response (SVR) were enrolled. Patients received boceprevir 800 mg orally three times a day in combination with peginterferon alfa-2b 1.5 $\mu\text{g}/\text{kg}/\text{week}$ subcutaneously and ribavirin 600 to 1400 mg/day, based on weight, orally in 2 divided doses for up to 44 weeks. Patients received 4 weeks of PR lead-in treatment, if >2 weeks had passed since the completion of their previous study.
- Of the 168 subjects enrolled in the study, 52 were identified as null responders (>2 log decrease in HCV RNA at treatment week (TW) 12) to PR, 86 were partial responders (≤ 2 log decrease in HCV RNA by TW12 and detectable HCV RNA at the end treatment) to PR and 26 had prior relapse (undetectable HCV RNA at the end of prior treatment and detectable HCV RNA at the end of follow-up). Other baseline characteristics of patients included 67% male, 84% white, mean age 52 years, 77% with high viral load of $>800,000$ IU/mL, 10% with cirrhosis, and 61% with HCV genotype 1a.
- The primary endpoint of the study was SVR defined as undetectable HCV RNA 24 weeks post treatment with BOC/PR combination. Patients who received at least one dose of boceprevir were included in the prespecified analysis. Of the 164 patients who received BOC/PR, 138 were included in the SVR analysis. The following Table 1 shows the proportion of patients treated with BOC/PR combination with undetectable HCV RNA at tested time points. Results are based on the interim analysis of the study. Seventeen of the 164 patients treated with BOC/PR will continue the treatment.

Table 1: Proportion of patients with undetectable HCV RNA after treatment with BOC/PR combination

Week of BOC/PR	Prior null responders	Prior partial responders/relapsers	Total
	% (n/N)	% (n/N)	% (n/N)
6	22 (11/49)	61 (70/114)	50 (81/163)
12	50 (24/48)	81 (89/110)	72 (113/158)
24	47 (22/47)	78 (82/105)	68 (104/152)
End of Treatment	47 (22/47)	85 (85/100)	73 (107/147)

- The following table 2 provides the SVR rate by baseline characteristics and prior treatment response.

Table 2: SVR based on baseline characteristics and prior treatment response

	SVR % (n/N)		
	Prior Null responders	Prior Partial responders	Prior Relapse
VL $\leq 800,000$	67 (4/6)	76 (13/17)	67 (2/3)
VL $>800,000$	37 (15/41)	66 (40/61)	50 (3/6)
F0/1/2	41 (17/41)	66 (37/56)	50 (3/6)
F3/4	40 (2/5)	79 (15/19)	100 (1/1)
HCV Genotype 1a	45 (14/31)	72 (31/43)	50 (4/8)
HCV Genotype 1b	31 (5/16)	62 (21/34)	100 (1/1)
Platelets $<200,000$	17 (2/12)	54 (19/35)	33 (1/3)
Platelets $\geq 200,000$	50 (17/34)	79 (34/43)	67 (4/6)

- During the study, among all treated patients (n=168), treatment-emergent adverse events (AE) were reported in 96% of patients, serious AEs in 10%, discontinuation of study drug due to AE in 7%, and dose modification due to AE in 32% of patients. Most common adverse event reported included anemia (48%), neutropenia (22%), diarrhea

(22%), dysgeusia (34%), nausea (30%), fatigue (47%), flue-like illness (21%), headache (27%), and insomnia (23%). The following Table 3 provides percentage of patients who experienced anemia-related AEs during the study.

Table 3: Percentage of anemia-related events

	All Treatment Patients N=168
Hemoglobin <10 g/dL	50%
8.5 to ≤ 10	39%
<8.5	11%
WHO Grade 1 (9.5 to <11.0)	36%
Grade 2 (8.0 to <9.5)	29%
Grade 3 (6.5 to <8.0)	3%
Grade 4 (<6.5)	0
Study drug discontinuation due to AE	1%
Dose modification due to AE	26%*
Erythropoietin use	40%
RBC transfusion	2%

* Does not include patients who discontinued study drug due to AE

- The authors concluded that boceprevir in combination with PR was efficacious in all 3 types of prior non-responders: null responders, partial responders and relapsers.

Questions and Answers

Q: Are the discontinuation rates and percentage of anemia similar in the real world as in clinical trials?

A: Registration trials have shown a higher incidence of discontinuation rates and adverse events than in clinical trials.

Saphris® (asenapine)

- Saphris is an atypical antipsychotic indicated for:

Bipolar Disorder

- *Monotherapy*: Saphris is indicated for the acute treatment of manic or mixed episodes associated with bipolar I disorder. Efficacy was established in two 3-week monotherapy trials in adults.
- *Adjunctive Therapy*: Saphris is indicated as adjunctive therapy with either lithium or valproate for the acute treatment of manic or mixed episodes associated with bipolar I disorder. Efficacy was established in one 3-week adjunctive trial in adults.
- *Maintenance Treatment*: While there is no body of evidence available to answer the question of how long the bipolar patient should remain on Saphris, whether used as monotherapy or as adjunctive therapy with lithium or valproate, it is generally recommended that responding patients be continued beyond the acute response. If Saphris is used for extended periods in bipolar disorder, the physician should periodically re-evaluate the long-term risks and benefits of the drug for the individual patient.

Schizophrenia

- Saphris is indicated for the treatment of schizophrenia. The efficacy of Saphris was established in two 6-week trials and one maintenance trial in adults.
- *Maintenance Treatment*: Efficacy was demonstrated with SAPHRIS in a maintenance trial in patients with schizophrenia. The starting dose in this study was 5 mg twice daily with an increase up to 10 mg twice daily after 1 week based on tolerability. While there is no body of evidence available to answer the question of how long the schizophrenic patient should remain on Saphris, patients should be periodically reassessed to determine the need for maintenance treatment.

Clinical Efficacy

- *Schizophrenia*: The efficacy of SAPHRIS in the treatment of schizophrenia was evaluated in three fixed-dose, short-term (6 week), randomized, double-blind, placebo- and active-controlled trials in adult patients who met DSM-IV criteria for schizophrenia and were having an acute exacerbation of their schizophrenic illness. In two of the three trials, SAPHRIS (5 mg BID) demonstrated statistically superior efficacy to placebo on the Positive and Negative Symptom Scale (PANSS) total score, the primary efficacy rating scale. In a third trial, SAPHRIS could not be distinguished from placebo; however, an active control in that trial was superior to placebo. Maintenance of efficacy has been demonstrated in a placebo-controlled, double-blind, multicenter, flexible dose (5 mg or 10 mg twice daily based on tolerability) clinical trial with a randomized withdrawal design. SAPHRIS was statistically superior to placebo in time to relapse or impending relapse.

- *Bipolar Disorder-Monotherapy*: The efficacy of SAPHRIS in the treatment of acute mania was established in two similarly designed 3-week, randomized, double-blind, placebo-controlled, and active-controlled trials of adult patients who met DSM-IV criteria for Bipolar I Disorder with an acute manic or mixed episode with or without psychotic features. In both trials, all patients randomized to SAPHRIS were initially administered 10 mg BID, and the dose could be adjusted within the doses of 5 or 10 mg BID from Day 2 onward based on efficacy and tolerability. SAPHRIS was statistically superior to placebo on the Young Mania Rating Scale (YMRS) total score and the Clinical Global Impression – Bipolar Disorder (CGI BP) Severity of Illness score (mania) in both studies.
- *Bipolar Disorder-Adjunctive Therapy*: The efficacy of SAPHRIS as an adjunctive therapy in acute mania was established in a 12-week, placebo-controlled trial with a 3-week primary efficacy endpoint involving 326 patients with a manic or mixed episode of Bipolar I Disorder, with or without psychotic features, who were partially responsive to lithium or valproate monotherapy after at least 2 weeks of treatment. SAPHRIS was statistically superior to placebo in the reduction of manic symptoms (measured by the YMRS total score) as an adjunctive therapy to lithium or valproate monotherapy at week 3.

Clinical Safety

- **WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS: Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Saphris is not approved for the treatment of patients with dementia-related psychosis.**
- Saphris is contraindicated in patients with a known hypersensitivity to the product.
- The most common adverse reactions ($\geq 5\%$ and at least twice the rate of placebo) in schizophrenia were akathisia, oral hypoesthesia, and somnolence. The safety profile of Saphris in the maintenance treatment of schizophrenia was similar to that seen with acute treatment.
- The most common adverse reactions ($\geq 5\%$ and at least twice the rate of placebo) in bipolar disorder (monotherapy) were somnolence, dizziness, extrapyramidal symptoms other than akathisia, and weight increased.
- The most common adverse reactions ($\geq 5\%$ and at least twice the rate of placebo) in bipolar disorder (Adjunctive) were somnolence and oral hypoesthesia.
- In a 52-week double-blind, comparator controlled trial of patients with schizophrenia or schizoaffective disorder, the mean weight gain from baseline was 0.9 kg. The proportion of patients with a $\geq 7\%$ increase in body weight (at Endpoint) was 14.7%.
- In the same 52-week trial, the mean change from baseline for fasting glucose was +2.4 mg/dL, -6 mg/dL for total cholesterol, -9.8 mg/dL for fasting triglycerides, and +1.7 units/L for ALT.
- Atypical antipsychotics have been associated with cerebrovascular adverse events; neuroleptic malignant syndrome; tardive dyskinesia; hyperglycemia and diabetes mellitus; orthostatic hypotension and syncope; leukopenia, neutropenia, and agranulocytosis; seizures; body temperature regulation, suicide, and dysphagia.
- Please see the Saphris Prescribing Information, including boxed warning, for full Warnings and Precautions.

Administration

- Saphris is a sublingual tablet and will dissolve in saliva within seconds.
- Patients should be instructed to not eat or drink for 10 minutes after administration.
- Saphris is not recommended in patients with severe hepatic impairment (Child-Pugh C).
- Dosage adjustments are not routinely required on the basis of age, gender, race, or renal impairment status.

I would ask the committee to consider the scientific evidence presented on Saphris and the potential benefits that Saphris may provide your patients.

Questions and Answers

No questions followed.

IV. Sunovion

Lizbeth Delgado, PharmD, Senior Medical Specialist

Daniel Van Deventer, Account Director

Ronnie Thomas, Area Field Director

Latuda[®] (lurasidone)

- Latuda is an atypical antipsychotic agent approved for the treatment of adult patients with schizophrenia. Lurasidone has been shown to be effective in a dose range of 40 mg/day to 120 mg/day.
- A supplemental New Drug Application for a 160 mg/day dose of lurasidone is currently under review by the FDA. The efficacy, safety, and tolerability of the 160 mg/day dose of lurasidone is based upon data from Study D1050233 ("Study 233"), a 6-week, double-blind, placebo-controlled study of two fixed doses of lurasidone (80 mg/day or 160 mg/day) and an active control quetiapine XR (600 mg/day) in adult patients with acute

schizophrenia. Upon approval by the FDA, this change would also be reflected in an updated Prescribing Information for lurasidone.

- Responders from Study 233 enrolled in a one-year non-inferiority study of flexibly dosed lurasidone vs. flexibly dosed quetiapine XR Study D1050234 (“Study 234”). The results demonstrated non-inferiority of lurasidone vs. quetiapine XR on the primary endpoint, time to relapse.
- Information from both these studies (Study 233 and 234) were already made available to GA Medicaid in response to a previous request for clinical information.
- New clinical data from studies not previously reviewed by the GA Medicaid Drug Utilization Review Board are highlighted below and will be presented in more detail on May 3, 2012.

Summary of Clinical Information

Study Description	Results
<p>Study D1050289: 6-week, open-label study to evaluate the effectiveness of switching clinically stable, but symptomatic outpatients with schizophrenia or schizoaffective disorder to lurasidone (40-120 mg/day)</p>	<ul style="list-style-type: none"> • Effectiveness Measure: time to treatment failure at 6-weeks (pre-specified as discontinuation due to insufficient clinical response, exacerbation of underlying disease, or due to adverse event) • Efficacy Results: Cumulative probability of treatment failure for all patients switched from other antipsychotics to lurasidone was 7.9% • Improvements from baseline to LOCF endpoint were observed on both PANSS and CGI-S • Most common adverse events (incidence ≥5%) were nausea, insomnia, akathisia, headache, vomiting, somnolence, and dry mouth.
<p>Study D1050237E: a 6-month, open-label extension study with flexibly dosed lurasidone (40-120 mg/day) in clinically stable adult patients with schizophrenia who had been randomized to lurasidone (40-120 mg/day) or risperidone (2-6 mg/day) in a preceding 1-year double-blind study</p>	<ul style="list-style-type: none"> • Mean (SD) dose: 81.1 (13.8) mg/day • Lurasidone was generally well tolerated, with only headache and psychotic disorder being reported in >5% of patients overall. • Movement disorders were infrequently reported; minor changes were observed on movement disorder assessment scales. • Lurasidone was associated with minor changes in weight, lipids, and glycemic measures. There was a decrease in body weight (-0.1 kg) during the open-label extension for patients who had taken lurasidone during the preceding 1-year study. In patients who had taken risperidone during the 1-year phase, there was a decrease in body weight (-1.2 kg) after initiating lurasidone treatment. • During the OL extension phase, median prolactin decreased overall from OL baseline to study end by -16.5 ng/mL in patients who had previously taken risperidone for a year and then switched to lurasidone for the 6-month extension. Patients continuing on lurasidone in the extension phase had no median change (0.00 ng/mL) in prolactin.
<p>Study D1050229E: 22-month open-label extension study designed to evaluate the safety and tolerability of flexibly dosed lurasidone (40-120 mg/day) in the treatment of adult patients with schizophrenia who completed a 6-week, multicenter, randomized, double-blind, placebo-controlled study with lurasidone 40 mg, 80 mg, or 120 mg lurasidone or placebo</p>	<ul style="list-style-type: none"> • A recent study that will be highlighted on May 3, 2012; preliminary results are provided. • The five most frequently reported treatment-emergent adverse events were schizophrenia, akathisia, somnolence, vomiting, and nausea. • Body weight and BMI remained relatively stable during the OL extension in patients. • Over the entire course of the study (double-blind phase and OL extension), there were overall mean changes in total cholesterol (-3.8 mg/dL), HDL (-2.4 mg/dL), LDL (-2.7 mg/dL), triglycerides (-2.0 mg/dL), and glucose (+1.6 mg/dL). • During the OL extension phase, median prolactin decreased overall from OL baseline to study end by -1.20 ng/mL.

Questions and Answers

No questions followed.

V. Shire

Steven D. Woods, PharmD, Senior Medical Science Liaison
 Jeron Stokes, PharmD, Senior Medical Science Liaison
 Kay Barry, RN, MS, Director, Government Accounts

Firazyr® (icatibant)

- Firazyr is a bradykinin B2 receptor antagonist indicated for the treatment of acute attacks of hereditary angioedema (HAE) in patients 18 years and older.

Dosage and Administration

- The recommended dose of Firazyr is 30 mg administered by subcutaneous injection in the abdominal area. Additional doses may be administered at intervals of at least 6 hours if response is inadequate or if symptoms recur (no more than 3 doses in 24 hrs).
- Patients may self-administer upon recognition of symptoms of an HAE attack after training under the guidance of a healthcare professional.

Warnings and Precautions

- Given the potential for airway obstruction during acute laryngeal HAE attacks, patients should be advised to seek medical attention in an appropriate healthcare facility immediately in addition to treatment with Firazyr.

Clinical Efficacy

- The efficacy and safety of Firazyr for the treatment of acute attacks of HAE in adults were studied in three controlled clinical trials. Two were randomized, placebo-controlled, double-blind, parallel-group trials, and one was an active-controlled trial. Forty three patients Trial 1 (Fast-3), 26 patients in the second placebo-controlled trial (FAST-1) and 35 patients in the active-controlled trial (FAST-2) received Firazyr 30mg. Patients in Trial 1 who had developed moderate to severe cutaneous or abdominal, or mild to moderate laryngeal attacks of HAE were randomized to receive either Firazyr 30 mg or placebo by subcutaneous injection. FAST-1 and FAST-2 differs slightly, with patients experiencing laryngeal attacks not randomized, but received open-label Firazyr 30mg. All severe laryngeal attacks of HAE in the Phase III studies received open-label Firazyr 30 mg. All patients in the controlled trials were eligible for treatment of subsequent attacks in an open-label extension where patients were treated with Firazyr 30 mg and could receive up to 3 doses of Firazyr 30 mg administered at least 6 hours apart for each attack. The assessment of patient symptoms was based on the visual analog scale (VAS), which is an accepted method by which to capture patient reported outcomes. The symptoms of an HAE attack considered most important by patients and physicians (skin pain, skin swelling and abdominal pain) were assessed by the VAS instrument. A VAS utilizes a scorecard with a 100 mm horizontal line, with extreme values and associated verbal descriptors at the beginning and end of the line. The patient draws a vertical line at the point along the scale that represents the current intensity of the measured symptom.

Trial 1

- The primary endpoint in Trial 1 was the Time to Onset of Symptom Relief (TOSR) based on a 50% reduction from pretreatment VAS score, assessed using a 3-item composite VAS, comprised of averaged assessments of skin swelling, skin pain, and abdominal pain. The median time to 50% reduction in symptoms for patients with cutaneous or abdominal attacks treated with Firazyr (n=43) compared to placebo (n=45) was 2.0 hours [95% CI 1.5, 3.0] versus 19.8 hours [95% CI 6.1, 26.3], respectively ($p<0.001$). In FAST-1 and FAST-2, the primary endpoint was the Time to Onset of Symptom Relief, based on a pre-specified reduction from pretreatment VAS score for a single identified Primary symptom (TOSR-P).
- Across all three trials, Firazyr had a median time to 50% reduction from baseline symptoms ranging from 2.0 to 2.3 hours.
- In an assessment of the first 5 Firazyr-treated attacks (621 doses for 582 attacks) during the open-label phase, the median times to a 50% reduction from the pretreatment composite 3-itemVAS score were similar across attacks (2.0, 2.0, 2.4, 2.0, 1.5 hours), with the majority (93%) of these attacks of HAE were treated with a single dose of Firazyr.

Secondary Endpoints

- A number of additional secondary endpoints were also assessed across the controlled Phase III studies. The 4 secondary endpoints below assess the continuum of effect of icatibant on the broad spectrum of symptoms in acute attacks of HAE and demonstrate the onset of clinically relevant efficacy and resolution of attack. These include:
 - Change from baseline in composite VAS over time; time from treatment administration to subject- and investigator-assessed Initial Symptom Improvement (TISI); Time from treatment administration to Almost Complete Symptom Relief (TACSR), defined as the time of the first of 3 consecutive measures at which all VAS scores were less than 10 mm.
 - Use of rescue therapy.

Laryngeal attacks

- A total of 60 patients with laryngeal attacks were treated with Firazyr in the controlled trials. Efficacy results were similar to those observed for non-laryngeal (cutaneous and abdominal) sites of attack.

Self-administration Study

- Self-administration of Firazyr by 56 patients was assessed in an open label trial. Patients who administered Firazyr during an acute attack of HAE had a median time to 50% reduction from the pretreatment composite 3-itemVAS score of 2.6 hours.

Clinical Safety

Randomized, Double-blinded, Controlled Studies

- The safety of icanitbant was evaluated in three controlled trials that included 223 patients who received FIRAZYR 30 mg (n=113), placebo (n=75), or comparator (n=38). The mean age at study entry was 38 years (range 18 to 83 years), 64% were female, and 95% were white. The data described below represent adverse reactions observed from the two placebo-controlled trials, consisting of 77 patients who received Firazyr at a dose of 30 mg SC, and 75 who received placebo. The most frequently reported adverse reactions (occurring in greater than 1% of patients and at a higher rate with Firazyr versus placebo) in the two placebo-controlled trials are shown below. The third trial was active-controlled and was comprised of 35 patients who received Firazyr 30 mg and 38 patients who received the comparator, which had a similar adverse event profile in both nature and frequency to the table above.

Open-label Extensions

- In all three controlled trials, patients were eligible for treatment of subsequent attacks in an open-label extension. Patients were treated with Firazyr 30 mg and could receive up to 3 doses of Firazyr 30 mg administered at least 6 hours apart for each attack. A total of 225 patients were treated with 1,076 doses of 30 mg Firazyr for 987 attacks of acute HAE. Adverse reactions similar in nature and frequency were observed to those seen in the controlled phase of the trials. Other adverse reactions reported included rash, nausea, and headache in patients exposed to Firazyr.

Self-Administration Study

- The safety of self-administration was evaluated in a separate, open-label trial in 56 patients with HAE, which had a similar adverse event profile in nature and frequency to that of patients whose therapy was administered by healthcare professionals.

Questions and Answers

Q: Does Firazyr have a limited distribution?

A: It is available through specialty pharmacies.

Q: What are considered the advantages of Firazyr?

A: Firazyr does not have to be refrigerated and injections tend to hurt more when refrigerated, is a subcutaneous injection, is not a plasma product, is ready to use and puts treatment in patient's hands with little risk of serious adverse events.

Q: How many patients required a second dose?

A: No patients needed a second dose or rescue medication, and no more than 8 injections per month were needed.

Q: Are other studies being conducted?

A: Use in angiotensin-converting enzyme inhibitor angioedema is being studied.

Vpriv® (velaglucerase alfa)

- Vpriv is an intravenous enzyme replacement therapy used for the long term management of patients with type I Gaucher disease

Dosage and Administration

- VPRIV should be administered under the supervision of a healthcare professional.
- 60 U/kg administered every other week (QOW) as a 60 minute intravenous infusion.
- Patients currently being treated with imiglucerase for type 1 Gaucher disease can be switched to VPRIV. Patients previously treated on a stable dose of imiglucerase are recommended to begin treatment with VPRIV at that same dose when they switch from imiglucerase to VPRIV.
- Physicians can make dosage adjustments based on achievement and maintenance of each patient's therapeutic goals. Clinical trials have evaluated doses ranging from 15 units/kg to 60 Units/kg QOW.

Warnings and Precautions

- Hypersensitivity reactions have been reported in patients in clinical studies with VPRIV. As with any intravenous protein product, hypersensitivity reactions are possible, therefore appropriate medical support should be readily available when VPRIV is administered. If a severe reaction occurs, current medical standards for emergency treatment are to be followed. Treatment with VPRIV should be approached with caution in patients who have exhibited symptoms of hypersensitivity to the active ingredient or excipients in the drug product or to other enzyme replacement therapy. Infusion-related reactions were the most commonly observed adverse reactions in patients treated with VPRIV in clinical studies. The most commonly observed symptoms of infusion-related reactions were: headache, dizziness, hypotension, hypertension, nausea, fatigue/asthenia, and pyrexia. Generally the infusion-related reactions were mild and, in treatment-naïve patients, onset occurred mostly during the first 6 months of treatment and tended to occur less frequently with time. The management of infusion-related reactions should be

based on the severity of the reaction, e.g. slowing the infusion rate, treatment with medications such as antihistamines, antipyretics and/or corticosteroids, and/or stopping and resuming treatment with increased infusion time. Pre-treatment with antihistamines and/or corticosteroids may prevent subsequent reactions in those cases where symptomatic treatment was required. Patients were not routinely premedicated prior to infusion of VPRIV during clinical studies.

Clinical Efficacy

Study 032

- 12 month, randomized, double blind, multinational phase III clinical trial.
- 25 patients age 4 years and older with Gaucher disease related anemia and either thrombocytopenia or organomegaly completed the study.
- Patients were randomized to receive VPRIV at a dose of either 45 U/kg (N=13) or 60 U/kg (N=12) QOW.
- Primary endpoint: Efficacy of VPRIV 60 U/kg IV QOW in patients with type 1 Gaucher disease as measured by increase in mean Hgb concentration.
- VPRIV 60 U/kg IV QOW achieved the primary endpoint with a clinically and statistically significant improvement in Hgb concentration.

Study 039

- 9 month randomized, double blind, active-controlled (imiglucerase) multicenter study in 34 patients age 3 years and older with type 1 Gaucher disease.
- Patients were required to have Gaucher disease related anemia and either thrombocytopenia or organomegaly to be included.
- A total of 34 patients were randomized to receive 60 U/kg of either VPRIV or imiglucerase (17 in VPRIV group and 17 in imiglucerase group).
- Primary endpoint: Mean change in Hgb concentrations from baseline to week 41.
- Results: The mean absolute increase in Hgb from baseline to week 41 (ITT population) was 1.624 g/dL for VPRIV and 1.488 g/dL for imiglucerase group.

Study 034

- 12 month global, open-label study in 40 patients who had been receiving imiglucerase at doses ranging from 15 Units/kg to 60 Units/kg for a minimum of 30 consecutive months. 1 Patients were also required to have a stable biweekly dose of imiglucerase for at least 6 months prior to enrollment.
- Treatment with VPRIV was administered QOW at the same number of units/kg as the previous imiglucerase dose.
- Primary endpoint: Evaluate the safety of VPRIV 15-60 U/kg QOW over 12 months in patients previously treated with imiglucerase.
- Results: Hemoglobin and platelet counts remained stable through 12 months of VPRIV treatment¹. With VPRIV the median hemoglobin concentration was 13.5 g/dL (range: 10.8, 16.1) vs. the baseline value of 13.8 g/dL (range: 10.4, 16.5), and the median platelet count after 12 months was 174 x 10⁹/L (range: 24, 408) vs. the baseline value of 162 x 10⁹/L (range: 29, 399).

Clinical Safety

- Infusion-related reactions were the most commonly observed and reported adverse reactions in patients treated with VPRIV in clinical trials. The most common symptoms of infusion-related reactions were: headache, dizziness, hypotension, hypertension, nausea, fatigue, asthenia, and pyrexia.
- The most serious adverse reactions in patients treated with VPRIV were hypersensitivity reactions.
- With therapeutic protein products there is a potential for immunogenicity. In clinical trials, 1 of 54 treatment naïve patients treated with VPRIV developed IgG class antibodies to VPRIV. In this one patient, the antibodies were determined to be neutralizing in an *in vitro* assay.

Questions and Answers

Q: What are considered the advantages of Vpriv?

A: The infusion time is less (60 minutes vs. 60-120 minutes), decreased immunogenicity, decreased cost and no manufacturing issues.

Q: What locations is Vpriv administered in?

A: Infusion centers, hospitals and at home.

VI. DepoMed

John T. Mathis, PharmD, RPh, Medical Science Liaison

Chris DeSimone, Senior Director, Managed Care and Trade

Thom S. Martin, Associate Vice-President, VCG & Associates

Gralise® (gabapentin extended-release)

- Gralise is a once-a-day oral (PO) formulation of gabapentin that uses a patented polymer gastroretentive technology to provide more efficient and sustained delivery of drug to patients with postherpetic neuralgia (PHN).
- When taken with the evening meal, Gralise swells to a size that promotes gastric retention and provides steady delivery of gabapentin to the upper gastrointestinal (GI) tract over time (~8 hours). This results in sustained plasma levels of gabapentin and 24-hour pain relief. In addition, evening dosing provides peak concentration of gabapentin during the night, when pain is at its worst, and minimal side effects during waking hours, when side effects are most likely to affect patient safety and quality of life. This dosing schedule also allows patients to reach the effective therapeutic dose within 2 weeks.

Clinical Efficacy

The phase 3 clinical trial program for Gralise consisted of 2 trials:

- 81-0062: A Phase 3 Multi-Center, Randomized, Double-Blind, Placebo-Controlled Study of the Safety and Efficacy of Once-Daily Gabapentin Extended Release (G-ER) Tablets in the Treatment of Patients with Postherpetic Neuralgia
- 81-0045: A Phase 3 Multi-Center, Randomized, Double-Blind, Placebo-Controlled Study of the Safety and Efficacy of Gabapentin Extended Release (G-ER) Tablets in the Treatment of Patients with Postherpetic Neuralgia
- In the pivotal Phase 3 study 81-0062, an 11-week, randomized, double-blind, placebo-controlled study, the effectiveness of Gralise was demonstrated in patients with PHN following healing of herpes zoster rash and pain scores ≥ 4 on the 11-point Numeric Rating Scale. In this study of 452 patients with PHN of ≥ 6 months' duration, the baseline median duration of PHN was 20 months and the mean baseline average daily pain score was 6.6 on the Numeric Rating Scale. Statistically significant improvements in average daily pain scores were reported in the first week of titration and at each weekly measurement during the study (all $P < 0.05$).
 - At the end of the study, the average daily pain score was reduced by 37% for patients taking Gralise.
 - Thirty-seven percent of patients taking Gralise experienced at least a 50% reduction of their average daily pain score.
 - Fifty-five percent of patients taking Gralise experienced at least a 30% reduction of their average daily pain score.

Clinical Safety

- Most of the AEs that were reported in the clinical trials with patients taking Gralise were mild or moderate (97%) and only a fraction were serious AEs (SAEs; 1.8% for Gralise compared with 4.3% for placebo). Only 9.7% of patients taking Gralise discontinued treatment because of AEs versus 6.9% of placebo patients. The most common reason for discontinuation was dizziness (2.2%). Changes in weight and body mass index were similar to those associated with placebo over the duration of the study. Compliance with medication was very high: 96.2% in Study 81-0062 and 98.8% in Study 81-0045, with $\geq 80\%$ of study medication taken. Only 3.6% of patients withdrew during titration due to AEs.

Summary

- In Summary, Gralise is a nonscheduled, once-a-day PO formulation of gabapentin that uses a patented polymer gastroretentive technology that has been proven to be efficacious and approved for treatment of patients with PHN.

Questions and Answers

Q: Are there any head-to-head studies being conducted compared to gabapentin immediate-release?

A: No head-to-head studies are being conducted as it is difficult to get patients up to a dose of 1800 mg/day on immediate-release. Studies evaluating other indications such as diabetic peripheral neuropathy are being explored.

Q: What were the most common reasons for discontinuation in clinical trials?

A: Dizziness and somnolence.

VII. Vertex

Vik Patel, PharmD, MBA, Medical Science Liaison II

Dan Petty, PharmD, MBA, Regional Account Manager

Incivek® (telaprevir)

- Incivek, in combination with peginterferon alfa and ribavirin, is indicated for the treatment of genotype 1 chronic hepatitis C (HCV) in adult patients with compensated liver disease, including cirrhosis, who are treatment-naïve or who have previously been treated with interferon-based treatment, including prior null responders, partial responders, and relapsers.
- Incivek must not be administered as monotherapy and must only be prescribed with both peginterferon alfa and ribavirin. A high proportion of previous null responders (particularly those with cirrhosis) did not achieve a

Sustained Virologic Response (SVR) and had telaprevir resistance-associated substitutions emerge on treatment with Incivek combination treatment. Incivek efficacy has not been established for patients who have previously failed therapy with a treatment regimen that includes Incivek or other HCV NS3/4A protease inhibitors.

Contraindications

- Contraindications to peginterferon alfa and ribavirin also apply to Incivek combination treatment. Incivek combination treatment is contraindicated in women who are or may become pregnant. Ribavirin may cause fetal harm when administered to a pregnant woman. If ribavirin is used during pregnancy or in the event of a pregnancy while on treatment, inform the patient of the potential hazard to a fetus. Incivek combination treatment is also contraindicated in men whose female partners are pregnant. Incivek is contraindicated when combined with drugs that 1) are highly dependent on CYP3A for clearance and for which elevated plasma concentrations are associated with serious and/or life-threatening events and 2) strongly induce CYP3A and thus may lead to lower exposure and loss of efficacy of Incivek. See Incivek Prescribing Information Table 3 for contraindicated drugs.

Pharmacology

- Incivek is a direct-acting antiviral agent against the hepatitis C virus. Incivek is an inhibitor of the HCV NS3/4A serine protease, which is essential for viral replication.

Clinical Efficacy

- The efficacy and safety of Incivek in subjects with genotype 1 chronic hepatitis C were evaluated in 2 treatment-naïve and 1 previously treated (prior relapsers, partial responders, and null responders) subjects trials. Subjects received 750 mg of Incivek every 8 hours, 180 ug/week of peginterferon alfa-2a (Peg-IFN), and 1000 mg/day (<75 kg) or 1200 mg/day (≥75 kg) of ribavirin (RBV).
- The ADVANCE trial was a randomized, double-blind, placebo-controlled study in treatment-naïve subjects that compared Incivek combination treatment with a control arm. Incivek, in combination with Peg-IFN/RBV, was dosed for the first 12 weeks (T12PR) and followed by an additional 12 or 36 weeks of Peg-IFN/RBV alone, based on a response-guided therapy (RGT) approach. Subjects in the T12PR arm who had undetectable HCV RNA (target not detected) at weeks 4 and 12 (extended Rapid Virologic Response, eRVR) received an additional 12 weeks of Peg-IFN/RBV (24 weeks total), while those who did not, received an additional 36 weeks of Peg-IFN/RBV (48 weeks total). Subjects in the control arm received 48 weeks of Peg-IFN/RBV (PR48). Baseline characteristics (N=1088) showed a median age of 49 years [range: 18 to 69]; 59% were male; 23% had a body mass index (BMI) ≥30 kg/m², 9% were Black/African American; 11% were Hispanic or Latino; 77% had baseline HCV RNA levels ≥800,000 IU/mL; 15% had bridging fibrosis; 6% had cirrhosis. The sustained virologic response (SVR) rates were 79% in the T12PR arm compared to 46% in the PR48 group ($P<.0001$). An additional treatment arm evaluated an 8-week Incivek combination treatment (T8PR). Seventy-two percent of patients in this T8PR arm achieved SVR. Sixteen percent of patients in the T8PR arm experienced viral breakthrough after week 12 compared to 10% in the PR48 group. Fifty-eight percent of T12PR subjects had an eRVR, and were therefore eligible to shorten total treatment duration to 24 weeks following the RGT recommendation; 92% of them achieved an SVR.
- The ILLUMINATE trial was a randomized, open-label, non-inferiority study that compared SVR rates in treatment-naïve subjects with eRVR who were treated with Incivek combination treatment for either 24 weeks (T12PR24) or 48 weeks (T12PR48) total treatment. Subjects (N=540) had a median age of 51 years [range: 19 to 70]; 60% were male; 32% had a BMI ≥30 kg/m²; 14% were Black/African American; 10% were Hispanic or Latino; 82% had baseline HCV RNA levels ≥800,000 IU/mL; 16% had bridging fibrosis; 11% had cirrhosis. The SVR rate for all subjects enrolled in the trial was 74%. Sixty-five percent of subjects achieved eRVR and of those, 60% were randomized to 24 weeks (T12PR24) or 48 weeks (T12PR48) of total treatment. The SVR rates were similar at 92% (T12PR24) and 90% (T12PR48), respectively. The REALIZE trial was a randomized, double-blind, placebo-controlled study conducted in treatment-experienced subjects, including prior relapsers, partial responders, and null responders. Subjects were randomized to one of 2 Incivek combination treatment arms (with or without a 4-week Peg-IFN/RBV lead-in) or a control arm (PR48). Both Incivek combination treatment groups included Incivek in combination with Peg-IFN/RBV for 12 weeks and 36 weeks of Peg-IFN/RBV alone. Subjects (N=662) had a median age of 51 years (range: 21 to 70); 70% were male; 26% had a BMI ≥30 kg/m²; 5% were Black/African American; 11% were Hispanic or Latino; 89% had baseline HCV RNA levels ≥800,000 IU/mL; 22% had bridging fibrosis; 26% had cirrhosis. The lead-in and immediate start regimens produced comparable SVR and no SVR rates, so data from these 2 groups were pooled (T12PR48). The SVR rates of the T12PR48 vs. PR48 groups were 86% vs. 22% for prior relapsers ($P<.001$), 59% vs. 15% for prior partial responders ($P<.001$), and 32% vs. 5% for prior null responders ($P<.001$), respectively. In an ongoing 3-year follow-up study of 56 treatment-naïve and prior treatment-failure subjects who did not achieve SVR with an Incivek combination treatment in a Phase 2 study and had resistant variants to Incivek after treatment failure, variants were detected by population sequencing in 11% (6/56) of subjects (median follow-up of 25 months).

Dosage and Administration

- The recommended dose of Incivek is 750 mg (two 375 mg tablets) taken orally 3 times a day (7-9 hours apart) with food (not low fat). Incivek must be administered in combination with Peg-IFN/RBV for all patients for 12 weeks, followed by an additional 12 or 36 weeks of Peg-IFN/RBV alone, depending on viral response and prior response

status. If Incivek is discontinued for any reason (futility rule or adverse drug reaction), it should not be reinitiated. HCV RNA levels should be monitored at weeks 4 and 12 using a sensitive real-time RT-PCR assay to determine combination treatment duration and assess treatment futility. To prevent treatment failure, the dose of INCIVEK must not be reduced or interrupted. Patients with inadequate viral response are unlikely to achieve SVR and may develop treatment-emergent resistance substitutions. Discontinuation of therapy is therefore recommended in all patients with 1) HCV RNA levels >1000 IU/mL at week 4 or 12; or 2) confirmed detectable HCV RNA at week 24.

Warnings and Precautions

- Warnings and Precautions to peginterferon alfa and ribavirin also apply to Incivek combination treatment. Ribavirin may cause birth defects and/or death of the exposed fetus. A Ribavirin Pregnancy Registry has been established to monitor maternal-fetal outcomes in patients exposed to ribavirin. Extreme care must be taken to avoid pregnancy in female patients and in female partners of male patients. A negative pregnancy test prior to initiation of therapy and monthly pregnancy tests during treatment and during the 6-month period after stopping all treatment are required. Female patients of childbearing potential and their male partners as well as male patients and their female partners must use 2 effective contraceptive methods during treatment and for 6 months after all treatment has ended. Hormonal contraceptives may be continued but may not be reliable during Incivek dosing and for up to 2 weeks after stopping Incivek. During this time, female patients of childbearing potential should use 2 effective non-hormonal methods of contraception.
- Serious skin reactions, including Drug Rash with Eosinophilia and Systemic Symptoms (DRESS) and Stevens-Johnson syndrome (SJS) were reported in less than 1% of subjects receiving Incivek combination treatment compared to none with peginterferon alfa and ribavirin alone. These reactions required hospitalization and all patients recovered. Rash (all grades) developed in 56% of patients who received Incivek combination treatment compared to 34% with peginterferon alfa and ribavirin alone. Severe rash was reported in 4% of patients treated with Incivek combination treatment compared to less than 1% with peginterferon alfa and ribavirin alone. Patients with rash should be followed for progression of rash or development of systemic symptoms. If rash becomes severe or systemic symptoms develop, discontinue Incivek and/or Incivek combination treatment. Incivek must not be reduced or restarted if discontinued due to rash. Rash events led to discontinuation of Incivek alone in 6% of subjects and discontinuation of Incivek combination treatment in 1% of subjects.
- Anemia has been reported in 36% of patients receiving Incivek combination treatment compared to 17% with peginterferon alfa and ribavirin alone. Use the labeled ribavirin dose modification guidelines to manage anemia; if ribavirin dose reductions are inadequate, consider discontinuing Incivek. If ribavirin is permanently discontinued, Incivek must also be permanently discontinued. The dose of Incivek must not be reduced and must not be restarted if discontinued. Anemia adverse events led to discontinuation of Incivek alone in 4% of subjects and discontinuation of INCIVEK combination treatment in 1% of subjects.
- Certain drugs are contraindicated for use with Incivek due to potentially life-threatening adverse events or potential loss of therapeutic effect to Incivek. See Incivek Prescribing Information Table 3 for contraindicated drugs, and Table 5 for established and other potentially significant drug interactions.
- Monitor HCV RNA levels at Weeks 4 and 12 and as clinically indicated. Use a sensitive assay to monitor HCV RNA during treatment.
- Hematology and chemistry evaluations are recommended at baseline and at weeks 2, 4, 8 and 12 or as indicated.
- Incivek is not recommended for patients with moderate or severe hepatic impairment (Child-Pugh B or C, score ≥ 7) or patients with decompensated liver disease. The safety and efficacy of Incivek combination treatment has not been established in co-infected HCV/HIV and HCV/HBV patients, pediatric patients, or in solid organ transplant.

Adverse Reactions

- Adverse reactions to peginterferon alfa and ribavirin also apply to INCIVEK combination treatment. The most common adverse reactions seen with an incidence $\geq 5\%$ with INCIVEK over controls were rash (56% vs. 34%), fatigue (56% vs. 50%), pruritus (47% vs. 28%), nausea (39% vs. 28%), anemia (36% vs. 17%), diarrhea (26% vs. 17%), vomiting (13% vs. 8%), hemorrhoids (12% vs. 3%), anorectal discomfort (11% vs. 3%), dysgeusia (10% vs. 3%), and anal pruritus (6% vs. 1%).

Summary

- Incivek combination treatment demonstrated significantly higher SVR rates than Peg-IFN/RBV alone in both treatment-naïve and treatment-experienced patients with genotype 1 chronic hepatitis C. Incivek is administered with Peg-IFN/RBV in all patients for 12 weeks, followed by an additional 12 or 36 weeks of Peg-IFN/RBV alone, depending on viral response and prior response status. In clinical trials, the majority of treatment-naïve patients were eligible for the shorter 24 week treatment duration. Rash, anemia, fatigue, pruritus, nausea, and vomiting were the most frequent adverse drug reactions leading to discontinuation of Incivek.

Questions and Answers

Q: Are any other studies being conducted?

A: Studies evaluating shorter treatment duration are being conducted.

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 SXC Health Solutions, announces the Manufacturers' Forum occurring on Thursday, August 9, 2012.

Date: Thursday, August 9, 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:

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

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Georgia Department of Community Health (GDCH)

Opportunities for Pharmaceutical Manufacturer Input on Clinical Recommendations and Clinical Management Strategies by the Drug Utilization Review Board

Clinical Information and Clinical Management Strategies relevant to the GDCH Medicaid Fee-For-Service program will be presented to the Drug Utilization Review Board (DURB) at each meeting through SXC Health Solutions 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.

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**

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/SXC 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/SXC.

Please see the Manufacturers’ Forum Announcement at <http://dch.georgia.gov> under Providers – Pharmacy – Drug Utilization Review Board – Meeting Information.

Questions not addressed in this document may be sent to NorthStar HealthCare Consulting by e-mail: GAMedicaid@nhc-llc.com

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2012

Upcoming Meetings

Drug Utilization Review Board Meeting

2 Peachtree Street, N.W.

5th Floor Board Room

Atlanta, Georgia 30303

Thursday, September 20, 2012: 10:00am – 2:00pm

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

Manufacturers' Forum

NorthStar HealthCare Consulting

1121 Alderman Drive

Suite 112

Alpharetta, Georgia 30005

Thursday, August 9, 2012: 9:00am – 5:00pm

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