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 4, 2015

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GEORGIA DEPARTMENT OF COMMUNITY HEALTH

DRUG UTILIZATION REVIEW BOARD MEETING
AGENDA

2 Peachtree Street - 5th Floor DCH Board Room
Atlanta, Georgia 30303
Thursday, June 4, 2015
9:30 a.m. to 2:30 p.m.

CALL TO ORDER	*Drew Miller, RPh, Chair*
COMMENTS FROM THE DEPARTMENT	*Turkesia Robertson-Jones, PharmD, Interim Pharmacy Director* *Linda Wiant, PharmD, Medicaid Chief*
MINUTES FROM PREVIOUS MEETING	*Chair*
EXTERNAL COMMENTS SESSION	*Chair*
ADJOURNMENT OF OPEN SESSION	*Chair*
EXECUTIVE SESSION	*Steve Liles, PharmD, Senior Director, Goold*
LUNCH	
RECONVENING OF OPEN SESSION	*Chair*
CLINICAL REVIEWS AND DURB VOTES ➢ **Manufacturers' Forum**	*Tara R. Cockerham, PharmD, NorthStar* *Afzal Mistry, PharmD, NorthStar* *Emily Baker, PharmD, BCPS, NorthStar*

➢ **New Drugs**

- Akynzeo
- Auryxia
- Cerdelga
- Dalvance, Sivextro
- Esbriet, Ofev
- Jublia, Kerydin
- Northera
- Zydelig

➢ **Supplemental Rebate Classes**

➢ **Utilization Trends**

➢ **Drug Information**

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

FUTURE AGENDA ITEMS	*Chair*
ADJOURNMENT	*Chair*

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Department of Community Health
Drug Utilization Review Board (DURB)
MINUTES
Thursday, March 26, 2015

MEMBERS PRESENT

Osgood (Drew) A. Miller, R.Ph., Chair
Gurinder J.S. Doad, M.D., Vice-Chair
Mia Avery, Pharm.D.
Ann R. Damon, Pharm.D.
Deborah W. Fincher, M.S., R.Ph.
Thomas B. Gore, M.D.
J. Russell May, Pharm.D.
Brent L. Rollins, R.Ph., Ph.D.
Robert E. Shervette III, M.D.

MEMBERS ABSENT

M. Celeste Fowler, Pharm.D.
Robyn Lorys, Pharm.D.

Staff

Linda Wiant, Pharm.D., Chief, Medical Assistance Plans
Turkesia Robertson-Jones, Pharm.D., Interim Pharmacy Director, Pharmacy Services
Gilletta Gray, R.Ph., Clinical Manager, Pharmacy Services
Lori Garner, MHS, MBA, R.Ph., Pharmacist, Pharmacy Services
Patricia Z. Jeter, MPA, R.Ph., Pharmacist, Pharmacy Services

NorthStar HealthCare Consulting

Emily Baker, Pharm.D., BCPS, MHA, MBA, President
Tara R. Cockerham, Pharm.D., Clinical Programs Director
Afzal "Fez" Mistry, Pharm.D., Clinical Pharmacist

Catamaran

Susan McCreight, Sr. Director, Public Sector Account Management
Mark Hall, MBA, PMP, Account Manager
Talmahjia "Tami" Sweat, Pharm.D., Clinical Systems Product Manager

Goold Health Services

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

Call to Order

The Drug Utilization Review Board (DURB/DUR Board/Board) held its first meeting for the calendar year on March 26, 2015. The Chair, Osgood (Drew) A. Miller, R.Ph., called the meeting to order at 9:06am.

Comments from the Department

Linda Wiant, Pharm.D., Chief, Medical Assistance Plans, commented on the following items:

1. DUR Board – There is no further managed care representation on the Board. The Common PDL initiative has been tabled. DCH is actively recruiting for positions. Joseph R. Bona, M.D., MBA, has resigned (received promotion to CEO).
2. Continuing Education (CE) – CE (4 hours) is offered for all four DURB meetings (requested by Dr. Shervette). It is offered through the University of Georgia.
3. Controlled Substance Project – Quantity limits are being reviewed for appropriateness. A committee is being established to work with NorthStar and DCH to establish high level appropriate use guidelines. Volunteers are being solicited. Fez Mistry, Pharm.D. and Gilletta Gray, R.Ph. will be heading up the committee. A pain specialist has also agreed to be on the committee. Patient profiles will also be reviewed.
4. Turkesia Robertson-Jones, Pharm.D. – She is currently serving as the Interim Pharmacy Director.
5. Medicaid Snapshot: Year in Review – A presentation was given to provide an overview of Medicaid expenditures/growth, Medicaid initiatives, Georgia Families 360 update, and Fee For Service pharmacy expenditures (See Attachment A). Comments and questions were made on the following: Anticonvulsants-stratify data by age and diagnosis, inclusion of Medicare and Medicaid data for pharmacy expenditures (excludes crossover claims), Foster Care data, and generic price inflation.
6. New Chair and Vice-Chair – A welcome was extended to the new Chair and Vice-Chair, Osgood (Drew) A. Miller, R.Ph., Chair and Gurinder J.S. Doad, M.D., Vice-Chair.

Minutes from the Previous Meeting

Chair Miller asked for corrections or changes to the minutes from the December 4, 2014 meeting. There were no corrections. A motion was made (Thomas B. Gore, M.D.), seconded (Brent L. Rollins, R.Ph., Ph.D.), and carried to approve the minutes as written.

External Comments Session

External comments were presented to the Board from the following:

- Tara Cockerham, Pharm.D., provided an overview of written comments received by the following:
  - William Stuart, MD, Chairman, MS Center of Georgia and Medical Director, MS Center of Atlanta – Multiple Sclerosis treatment (Attachment B)
  - Dorothy Leone-Glasser, RN, HHC, Executive Director, Advocates for Responsible Care and Chair, Advocacy and Disparities Leadership Council, Arthritis Foundation, SE Region – Rheumatoid Arthritis treatment (Attachment C)
  - John A. Goldman, MD, Chief of Rheumatology, St Joseph's Hospital – Xeljanz, Rheumatoid Arthritis treatment (Attachment D)
  - David Cheatham, MD, Beacon Pediatrics – non-stimulant/non-controlled ADHD therapy, Strattera (Attachment E)

Disclosure forms were completed by Dr. William Stuart, Dorothy Leone-Glasser (RN), Dr. John A. Goldman, and Dr. David Cheatham and were reviewed by the Department.

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 with the Board members were from the Department of Community Health, Goold Health Services, NorthStar HealthCare Consulting, and Catamaran. A motion was

made by Thomas B. Gore, M.D., and seconded by Robert E. Shervette III, M.D., to adjourn the open session and approve the closed session. There was a unanimous vote approving the closed session. The Chairman, Drew Miller, R.Ph., adjourned the open session at approximately 10:06 am, at which time members took a break then reconvened for the executive (closed) session.

Executive Session
The Executive Session was held from 10:19am to 11:35am.

Reconvening of Open Session
The DUR Board reconvened for the open session at 12:38pm.

External Comments Session (continued)
External comments were presented to the Board from the following:

- Ryan Ford, MD, Emory University and Clinic – Hepatitis C treatment

Comments and questions were made on the following:

- Use of guidelines
- Sovaldi monotherapy
- Viekira Pak vs. Harvoni
- Drug interaction between amiodarone and Harvoni
- HIV Co-infection

Disclosure form was completed by Dr. Ryan Ford and reviewed by the Department.

Manufacturers' Forum
Tara Cockerham, Pharm.D., reviewed information regarding the Manufacturers' Forum that was provided in the Manufacturer Information section in the DUR Board binder. A total of twenty-eight (28) manufacturers participated or provided information regarding the following drugs discussed at the March 2015 DURB meeting:

Manufacturers	Drugs
Otsuka	Abilify Maintena
AbbVie	Viekira Pak
Sunovion	Aptiom
GlaxoSmithKline	Anoro Ellipta, Incruse Ellipta, Tanzeum
Pfizer	Chantix, Lyrica, Quillivant XR, Toviaz, Xeljanz
Indivior	Suboxone
AstraZeneca	Brilinta, Bydureon, Byetta, Farxiga
Actavis	Fetzima, Viibryd
Novartis	Gilenya,
Novo Nordisk	Norditropin, Victoza
Amgen	Enbrel
Astellas	Myrbetriq, Vesicare
Gilead	Harvoni
Zylera	Millipred, Veripred 20
Biogen	Plegridy, Tecfidera
Celgene	Otezla
Merck	Zontivity

Supernus	Oxtellar XR, Trokendi XR
Johnson & Johnson	Invega Sustenna, Stelara, Xarelto
Salix	Apriso, Uceris
Teva	Copaxone, Qnasl
Purdue	Hysingla ER
Biodelivery Sciences	Bunavail
Sanofi/Genzyme	Afrezza, Aubagio, Sklice
Bristol-Myers Squibb	Eliquis
Lilly	Trulicity
Boehringer Ingelheim	Striverdi Respimat, Spiriva Respimat, Jardiance, Tradjenta, Jentadueto, Pradaxa
Orexo	Zubsolv

Questions and comments were received on the following:

- Comparison data on Byetta and Victoza
- Afrezza – reports of hypoglycemia

The next forum will be held on Thursday, April 30, 2015 from 9am-5pm at the NorthStar Healthcare Consulting office: 1121 Alderman Drive, Suite 112, Alpharetta, GA 30005.

Therapeutic Class Review

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

Therapeutic Class Name
Anticonvulsants

Following the therapeutic class review, Eric Zurbrugg, M.D., Pediatric Neurologist in private practice and an affiliate of Children's Healthcare of Atlanta, presented an overview of Epilepsy and anti-epileptic drugs (see Attachment F). A disclosure form was completed by Dr. Eric Zurbrugg and reviewed by the Department. Questions and comments were made from the Board on the following:

- Use of Cannabis Oil – helps with certain group of children
- Sleep deprivation – lifestyle

The Board voted and made recommendations on the Anticonvulsants noted in the Board's Recommendations to the Department.

New Drug Reviews

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

Therapeutic Class	Drugs	Presenter
Antidiabetics	*Cycloset, Jardiance, Tanzeum, Trulicity*	Afzal Mistry, Pharm.D.

Bronchodilators	*Anoro Ellipta, Incruse Ellipta, Striverdi Respimat*	Afzal Mistry, Pharm.D.
Immunomodulators	*Otezla, Stelara*	Afzal Mistry, Pharm.D.
Platelet Aggregation Inhibitor	*Zontivity*	Afzal Mistry, Pharm.D.
Antivirals, Hepatitis C	*Harvoni, Viekira Pak*	Afzal Mistry, Pharm.D.
Multiple Sclerosis Agent	*Plegridy*	Afzal Mistry, Pharm.D.
Inflammatory Bowel Agent	*Uceris*	Afzal Mistry, Pharm.D.

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

- Antidiabetics
  - Risk of hypoglycemia with inhaled vs. SC (about the same)
  - Converting Byetta to Bydureon (or other GLP-1 inhibitors) - no issues with converting, wait 3 days, start with initial dose, formulary changes-communication with members through clinical team outreach/communication letters (Comments were provided by Kendra Manigault, PharmD, CDE, BCPS, BCACP, Clinical Assistant Professor at Mercer University and clinical site at Kaiser)

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

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 and presented to the Board by Dr. Emily Baker. The following therapeutic categories had updates:

Drug Class/Name
Anticoagulants
Antihyperlipidemics
Angiotensin Receptor blocker (ARB) and Calcium Channel Blocker Combinations
Drug Class/Name
Antihypertensives, Angiotensin Receptor blockers (ARBs)
Antihypertensives, Beta Blockers (BB)
Antipsychotics
Dermatologic, Scabicides and Pediculocides
Digestive Enzymes
Gastrointestinal, Proton Pump Inhibitors
Nasal Steroids
Opioid Agonist, Partial Agonists
Analgesics, Opioid-Long-Acting

Analgesics, Opioid-Short-Acting
Androgens-Anabolics
Antidepressants
Antiinflammatory, Nonsteroidal Antiinflammatory Drugs (NSAIDs)
Attention Deficit Hyperactivity Disorder (ADHD) Agents
Calcium Regulators, Osteoporosis
Dermatologic, Antiinflammatory Agents
Estrogens
Otic Antiinfectives
Pulmonary Hypertension Drugs
Smoking Deterrents
Urinary Antispasmodics

There were no comments or questions from the Board.

DCH Decisions

DCH Decisions from the December 2014 DUR Board meeting were provided in the DCH Decision section of the DUR Board binder.

Utilization Trend Review

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

Drug Information

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

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

Future Agenda Items

The following future agenda items were noted:

- Give consideration to exempting meds approved for children from PA
- Transition care for children from Fee For Service to Amerigroup/WellCare/Peachcare (approval of 1-2 months of medication)

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, June 4, 2015
  Thursday, September 24, 2015

Thursday, December 15, 2015

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

  Thursday, April 30, 2015
  Thursday, August 6, 2015
  Thursday, November 5, 2015

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

Board's Recommendations to the Department
After all clinical and financial evaluations and discussions, the DUR Board voted and presented the Department with the following recommendations for changes to the Preferred Drug List (PDL). All motions and votes are noted in Attachment G.

New Drugs and Supplemental Rebate Classes

Anticonvulsants

The DUR Board recommended ***Preferred*** status for ***Gabapentin (Oral) Solution***, ***Preferred*** status with ***Prior Authorization*** for ***Oxtellar® XR (Oral) Tablet and Qudexy® XR (Oral) Capsule***, ***Non-Preferred*** status for ***Felbatol (Oral) Suspension and Tablet*** and ***Non-Preferred*** status with ***Prior Authorization*** for ***Aptiom® (Oral) Tablet***.

Antidiabetics, Non-Insulin

The DUR Board recommended ***Preferred*** status with ***Prior Authorization*** for ***Tradjenta® (Oral) Tablet, Jentadueto® (Oral) Tablet, Bydureon® (Subcutaneous) Vial*** and ***Tanzeum™ Subcutaneous) Pen*** and ***Non-Preferred*** status with ***Prior Authorization for Cycloset® (Oral) Tablet, Jardiance® (Oral) Tablet, Byetta® (Subcutaneous) Pen, Trulicity™ (Subcutaneous) Pen*** and ***Victoza® (Subcutaneous) Pen with grandfathering for Victoza®***.

Bronchodilators, Anticholinergics

The DUR Board recommended ***Preferred*** status for ***Ipratropium/Albuterol (Inhalation) Ampule*** and ***Non-Preferred*** status with ***Prior Authorization*** for ***Anoro® Ellipta® (Inhalation) Blister with Device*** and ***Incruse® Ellipta® (Inhalation) Blister with Device***.

Bronchodilators, Steroid Inhalants

The DUR Board recommended ***Preferred*** status for ***Aerospan® (Inhalation) HFA***

Aerosol and ***Non-Preferred*** status with ***Prior Authorization*** for ***Asmanex® HFA (Inhalation) Aerosol***.

Bronchodilators, Sympathomimetics

The DUR Board recommended ***Preferred*** status with ***Prior Authorization*** for ***Brovana® (Inhalation) Vial*** and ***Non-Preferred*** status with ***Prior Authorization*** for ***Albuterol Sulfate (Oral) Tablet, Serevent® Diskus® (Inhalation) Blister with Device*** and ***Striverdi® Respimat® (Inhalation) Inhaler***.

Biologic Immunomodulators

The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Otezla® (Oral) Tablet*** and ***Stelara® (Subcutaneous) Syringe***.

Platelet Aggregation Inhibitors

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

Antivirals, Hepatitis C Agents

The DUR Board recommended ***Preferred*** status with ***Prior Authorization*** for ***Harvoni® (Oral) Tablet*** and ***Non-Preferred*** status with ***Prior Authorization*** for ***Viekira™ Pak (Oral) Tablet Dose Pack***.

Multiple Sclerosis (MS) Agents

The DUR Board recommended ***Preferred*** status for ***Tecfidera®*** (***Oral***) ***Capsule,*** ***Preferred*** status with ***Prior Authorization*** for ***Ampyra® (Oral) Tablet*** and ***Non-Preferred*** status with ***Prior Authorization*** for ***Plegridy™ (Subcutaneous)***.

Inflammatory Bowel Agents

The DUR Board recommended ***Preferred*** status for ***Pentasa® (Oral) Capsule 500 MG*** and ***Non-Preferred*** status with ***Prior Authorization*** for ***Uceris® (Oral) Tablet and (Rectal) Foam and SFRowasa® (Rectal) Enema***.

Antihyperlipidemics

The DUR Board recommended ***Preferred*** status for ***Fenofibrate (Oral) Capsules*** and ***Vytorin® (Oral) Tablet*** and ***Non-Preferred*** status with ***Prior Authorization*** for ***Colestipol (Oral) Granules/Packets, Prevalite® (Oral) Packets*** and ***Trilipix® (Oral) Capsule***.

Antihypertensives, Angiotensin Receptor Blocker-Calcium Channel Blocker Combinations

The DUR Board recommended ***Preferred*** status with ***Prior Authorization*** for ***Azor® (Oral) Tablet*** and ***Tribenzor® (Oral) Tablet***.

Antihypertensives, Angiotensin Receptor Blockers

The DUR Board recommended ***Preferred*** status for ***Atacand® (Oral) Tablet, Benicar®/Benicar® HCT (Oral) Tablets***, ***Diovan® (Oral) Tablet, Irbesartan/Irbesartan HCTZ (Oral) Tablets, Micardis®/Micardis® HCT (Oral) Tablets*** and ***Valsartan HCTZ (Oral) Tablet***.

Corticosteroids, Oral

The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Veripred® 20 (Oral) Solution***.

Dermatologics, Scabicides-Pediculocides

The DUR Board recommended ***Preferred*** status with ***Prior Authorization*** for ***Natroba® (Topical) Suspension*** and ***Non-Preferred*** status with ***Prior Authorization*** for ***Ulesfia® (Topical) Lotion***.

Digestive Enzymes

The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Zenpep® (Oral) Capsule with grandfathering***.

Migraine Products

The DUR Board recommended ***Preferred*** status for ***Relpax® (Oral) Tablet***.

Multivitamins, Prenatal

The DUR Board recommended ***Prenate® DHA Products*** as the ***Sole Preferred Prenatal Vitamins with DHA.***

Nasal Steroids

The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Beconase® AQ (Nasal) Spray*** and ***Qnasl® (Nasal) Aerosol***.

Ophthalmics, Antiinfectives

The DUR Board recommended ***Preferred*** status for ***Zymaxid® (Ophthalmic) Drops***.

Ophthalmics, Antiinflammatories

The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Nevanac® (Ophthalmic) Drops Suspension***.

Opioid Agonists, Partial Agonist

The DUR Board recommended ***Preferred*** status with ***Prior Authorization*** for ***Bunavail® (Buccal) Film with step of Suboxone® (Sublingual) Film*** and ***Non-Preferred*** status with ***Prior***

Authorization for ***Zubsolv® (Sublingual) Tablet***.

Urinary Prostatic Hypertrophy

The DUR Board recommended ***Preferred*** status for ***Alfuzosin (Oral) Tablet***.

Attention Deficit Hyperactivity Disorder Agents

The DUR Board recommended ***Preferred*** status with ***Prior Authorization*** for ***Quillivant® XR (Oral) Suspension*** and ***Strattera® (Oral) Capsule***.

Conclusion

At the conclusion of the reconvened open session and no other business for discussion, there was a unanimous decision to adjourn the meeting. Chair Miller adjourned the meeting at 3:50pm.

THESE MINUTES ARE HEREBY APPROVED AND ADOPTED, THIS THE _____ DAY OF _____, 2015.

_____

Osgood (Drew) A. Miller, R.Ph., Chair

Georgia Department of Community Health

Medicaid Snapshot: The Year in Review

Presentation to: Medicaid Drug Utilization Review Board

Presented by: Linda Wiant, Chief, Medical Assistance Plans

March 26, 2015

Georgia Department of Community Health

Mission

The Georgia Department of Community Health

We will provide Georgians with access to affordable, quality health care through effective planning, purchasing and oversight.

We are dedicated to A Healthy Georgia.

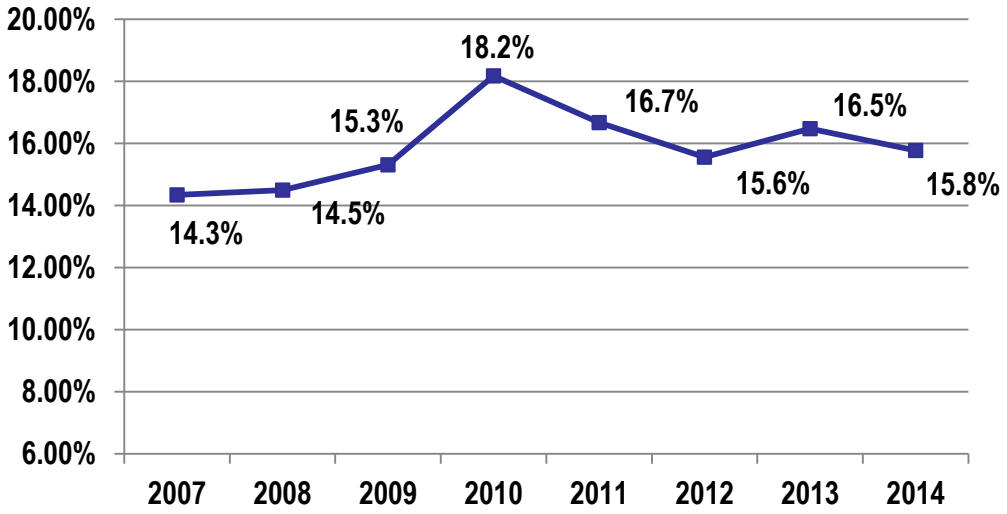
Medicaid Expenditures and Growth

GA Medicaid and PeachCare for Kids

Total FY2014 Expenditures (includes State, Federal and other Fund Sources):

- Medicaid: $ 8,930,730,330
- PeachCare for Kids: $ 412,353,797
- Average Spend per Day - **$37.7 million per work day**
- Claims Paid per Day – 215,500 per work day

Medicaid and PeachCare represents 16% of the state funds budget (excluding motor fuel and lottery) (2014)



Georgia Medicaid and PeachCare for Kids

Percentage of Georgia Population On Medicaid or PeachCare for Kids

Average Monthly Membership (FY14):

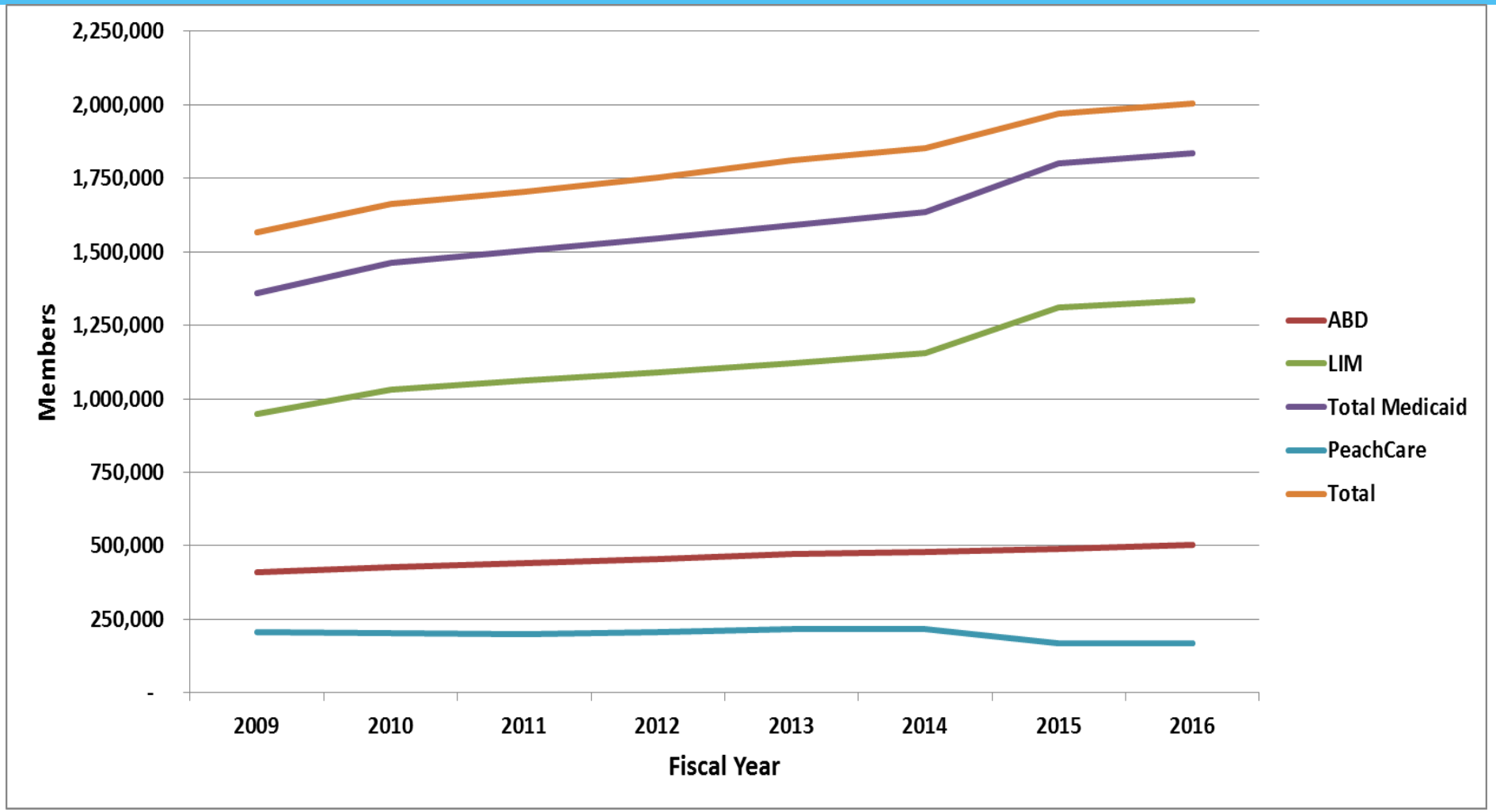
- **Medicaid: 1,633,977**
- **PeachCare for Kids: 215,438**
- **Total: 1,849,415**

Age Categories	GA Population*	Medicaid/PCK	%
All Ages	9,992,167	1,849,415	18.51%
Children (0-19)	2,772,897	1,228,760	44.31%

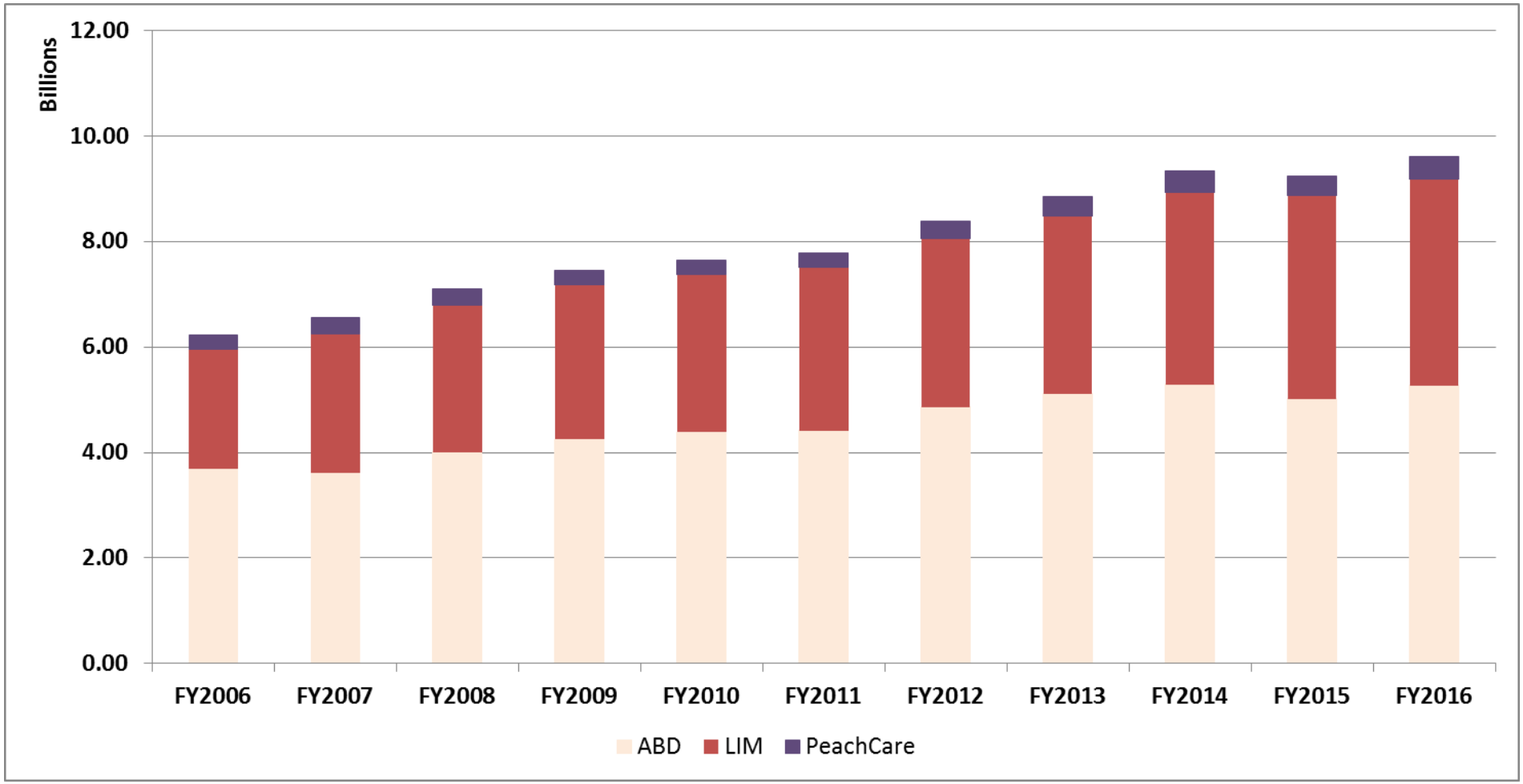
54% of total Georgia Births are paid for by Medicaid

* GA. Population based on estimated 2013 population figures from www.census.gov

GA Medicaid and CHIP Enrollment Trend



Medicaid and PeachCare Total Funds Cost Trends



Medicaid Initiatives – 2014/2015

Medicaid Initiatives

- Integrated Eligibility System (IES)
  - Multi-agency (DCH, DHS, DPH, DECAL, GTA, OPB, DOAS)
  - Replace Eligibility System for Public Assistance Programs
- ABD Care Coordination Update

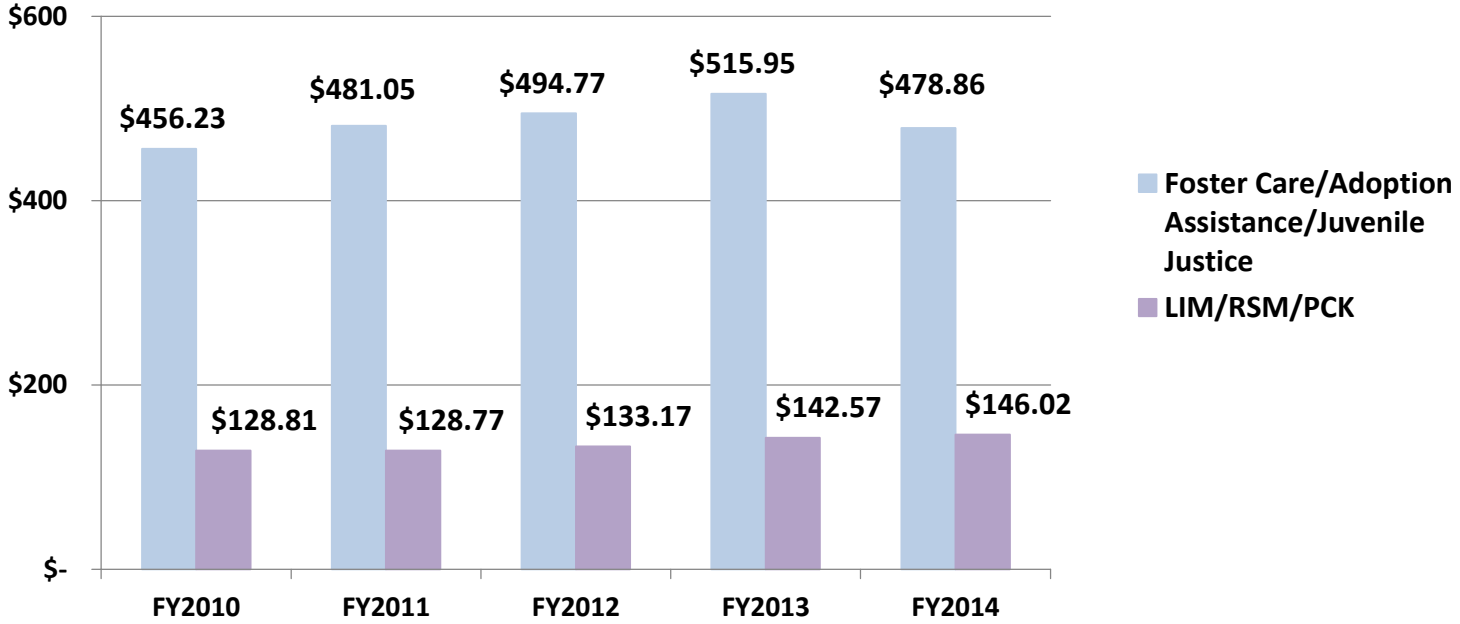
New Medicaid Initiatives

- Centralized Credentialing Verification Organization (CVO)
  - Centralized provider credentialing and re-credentialing function
  - Credentialing for both FFS and CMO populations
  - Single enrollment portal
  - Reduce administrative burden

- 4 Major Procurements Underway

Georgia Families 360® Update

- Transitioned approximately 24,000 children and youth to managed care
- Children in foster care, adoption assistance and DJJ cost the state significantly more per month when compared to other Medicaid/CHIP children*



*Cost comparison based on net payment for FFS and CMO plan paid amounts for CMO encounter claims

Georgia Families 360° Update

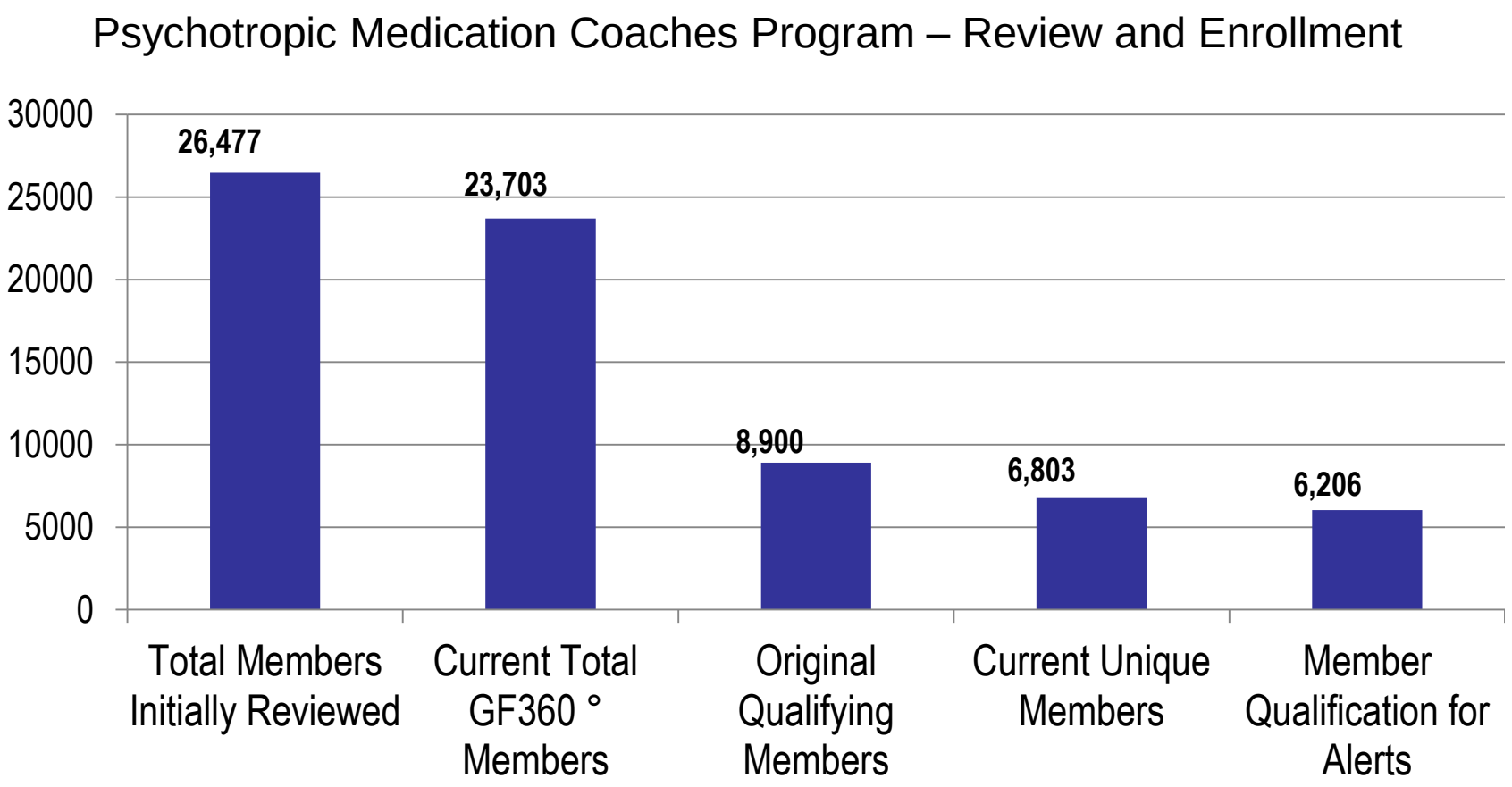
Psychotropic Medication Coaches Program Goals

- Improving medication compliance
- Detecting and reducing adverse drug events
- Monitoring and reducing patterns of overuse
- Providing frequent and routine outreach for high risk members

Process for Improving Treatment Outcomes

- Qualify members and identify potential drug therapy problems through claims analysis.
- Target population: members taking 1 or more psychotropic medications were enrolled in the program.
- Monitor prescription claims weekly to identify opportunities for patient outreach and therapeutic intervention.

Georgia Families 360° Update



Georgia Department of Community Health

Fee For Service Pharmacy Expenditures

Fee For Service Drivers

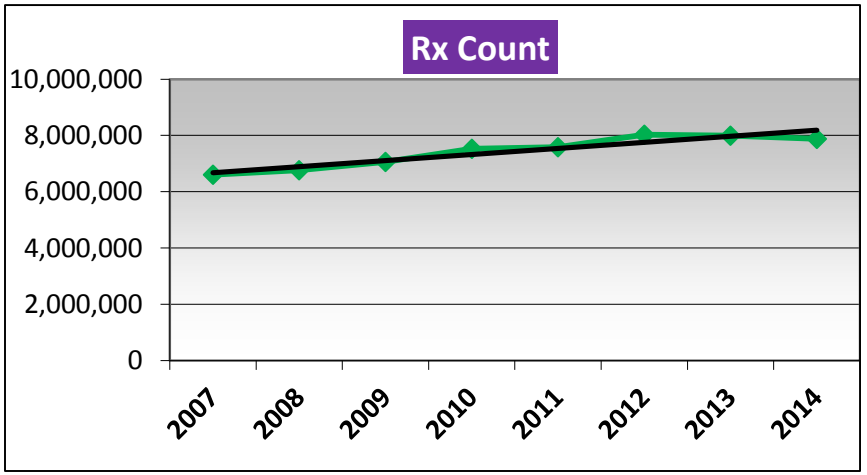
"Last year, the US regulator approved eight products painted as future blockbusters, and the crop of new molecules that reached the market are forecast to become the most valuable cohort in at least a decade. This year also promises to yield strong stories about the industry's capabilities. The launch of Gilead's oral hepatitis C therapy Sovaldi, which is expected to smash drug launch records, could well set the tone."

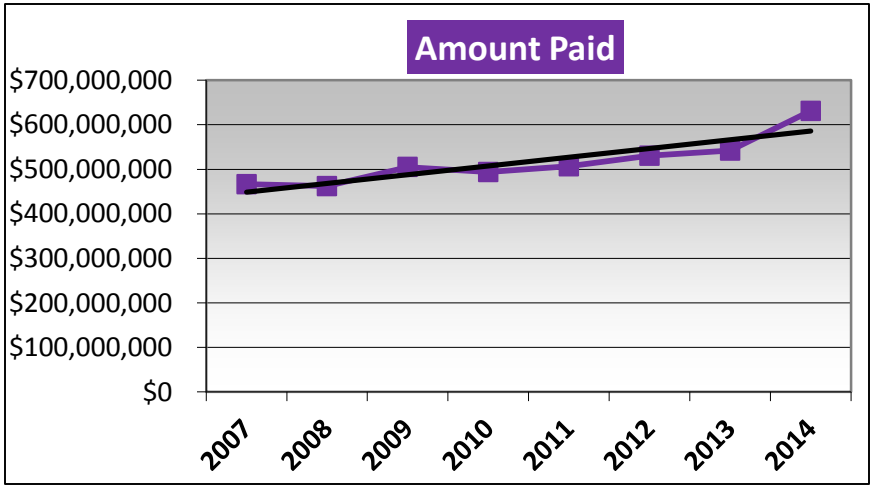
EPVantage Market Analysis. *PHARMA and Biotech 2013 Year in Review.* Accessed online 3/13/14. http://info.evaluategroup.com/epv-phr13-lp_lp.html?mkt_tok=3RkMMJWWfF9wsRoluqrJZKXonjHpfsX64%2BssXLHr08Yy0EZ5VunJEUWy2oQHSdQ%2FcOedCQkZHblFnVoITa2sW7MNqaMJ

GA Medicaid FFS Prescription Spending

2007-2014

- Change in enrollment
- Increase in expenditures (35.23%)
  (cost at pharmacy, not net of rebate)
- Increase in Rxs paid (19.4%)
- 2007: $ 466,554,372.54
- 2014: $ **$630,926,045.21**





	PMPM (Rx)	PMPM ($)	PUPM (Rx)	PUPM ($)
2007	1.3	$92.24	4.06	$286.83
2014	1.51	$102.50	4.59	$311.14

Fee For Service Drivers

2008					
Rank	Drug Grouping Description	Rx Count	Amount Paid	Avg Cost per Rx	Count of Members
1	ANALGESICS - OPIOID*	498,582	$12,526,412	$25.12	102,429
2	ANTICONVULSANTS*	432,456	$52,446,941	$121.28	51,456
3	ANTIHYPERTENSIVES*	376,999	$11,980,642	$31.78	54,159
4	ANTIDEPRESSANTS*	372,617	$14,221,955	$38.17	57,071
5	ANTIASTHMATIC AND BRONCHODILATOR AGENTS*	353,980	$31,928,892	$90.20	68,348
6	ANTIPSYCHOTICS/ANTIMANIC AGENTS*	321,096	$83,952,701	$261.46	35,947
7	ANTIANXIETY AGENTS*	295,218	$2,648,610	$8.97	56,472
8	ANTIDIABETICS*	267,035	$19,662,297	$73.63	26,010
9	ULCER DRUGS*	242,806	$12,094,734	$49.81	47,409
10	ANTIHISTAMINES*	208,746	$2,170,148	$10.40	80,778

2014					
Rank	Drug Grouping Description	Rx Count	Amount Paid	Avg Cost per Rx	Count of Members
1	ANALGESICS - OPIOID*	587,104	$18,310,433	$31.19	107,094
2	ANTICONVULSANTS*	564,315	$47,030,194	$83.34	64,009
3	ANTIDEPRESSANTS*	487,975	$8,354,049	$17.12	68,391
4	ANTIHYPERTENSIVES*	476,687	$7,209,043	$15.12	68,125
5	ANTIASTHMATIC AND BRONCHODILATOR AGENTS*	459,280	$59,851,242	$130.32	77,261
6	ANTIPSYCHOTICS/ANTIMANIC AGENTS*	338,209	$52,766,724	$156.02	37,989
7	ANTIHISTAMINES*	305,125	$2,805,907	$9.20	99,680
8	ULCER DRUGS*	303,260	$7,037,298	$23.21	55,768
9	ANTIDIABETICS*	299,226	$37,756,460	$126.18	29,361
10	ANTIHYPERLIPIDEMICS*	281,749	$10,079,945	$35.78	38,937

2008					
Rank	Drug Group Description	Amount Paid	Rx Count	Avg Cost per Rx	Count of Members
1	ANTIPSYCHOTICS/ANTIMANIC AGENTS*	$83,952,701	321,096	$261.46	35,947
2	ANTICONVULSANTS*	$52,446,941	432,456	$121.28	51,456
3	ANTIVIRALS*	$34,488,452	66,820	$516.14	12,631
4	ANTIASTHMATIC AND BRONCHODILATOR AGENTS*	$31,928,892	353,980	$90.20	68,348
5	HEMATOLOGICAL AGENTS - MISC.*	$23,686,734	46,051	$514.36	7,182
6	ADHD/ANTI-NARCOLEPSY/ANTI-OBESITY/ANOREX	$20,459,591	183,188	$111.69	32,656
7	ANTIDIABETICS*	$19,662,297	267,035	$73.63	26,010
8	ANTIDEPRESSANTS*	$14,221,955	372,617	$38.17	57,071
9	ANALGESICS - OPIOID*	$12,526,412	498,582	$25.12	102,429
10	ULCER DRUGS*	$12,094,734	242,806	$49.81	47,409

2014					
Rank	Drug Group Description	Amount Paid	Rx Count	Avg Cost per Rx	Count of Members
1	ANTIVIRALS*	$114,053,382	96,275	$1,184.66	18,549
2	ANTIASTHMATIC AND BRONCHODILATOR AGENTS*	$59,851,242	459,280	$130.32	77,261
3	ANTIPSYCHOTICS/ANTIMANIC AGENTS*	$52,766,724	338,209	$156.02	37,989
4	ANTICONVULSANTS*	$47,030,194	564,315	$83.34	64,009
5	ANTIDIABETICS*	$37,756,460	299,226	$126.18	29,361
6	HEMATOLOGICAL AGENTS - MISC.*	$30,556,852	50,486	$605.25	7,406
7	ADHD/ANTI-NARCOLEPSY/ANTI-OBESITY/ANOREX	$29,578,429	181,388	$163.07	34,838
8	ANALGESICS - OPIOID*	$18,310,433	587,104	$31.19	107,094
9	ENDOCRINE AND METABOLIC AGENTS - MISC.*	$17,802,658	34,666	$513.55	5,726
10	ANTINEOPLASTICS AND ADJUNCTIVE THERAPIES	$17,378,559	24,254	$716.52	5,296

Fee For Service Drivers

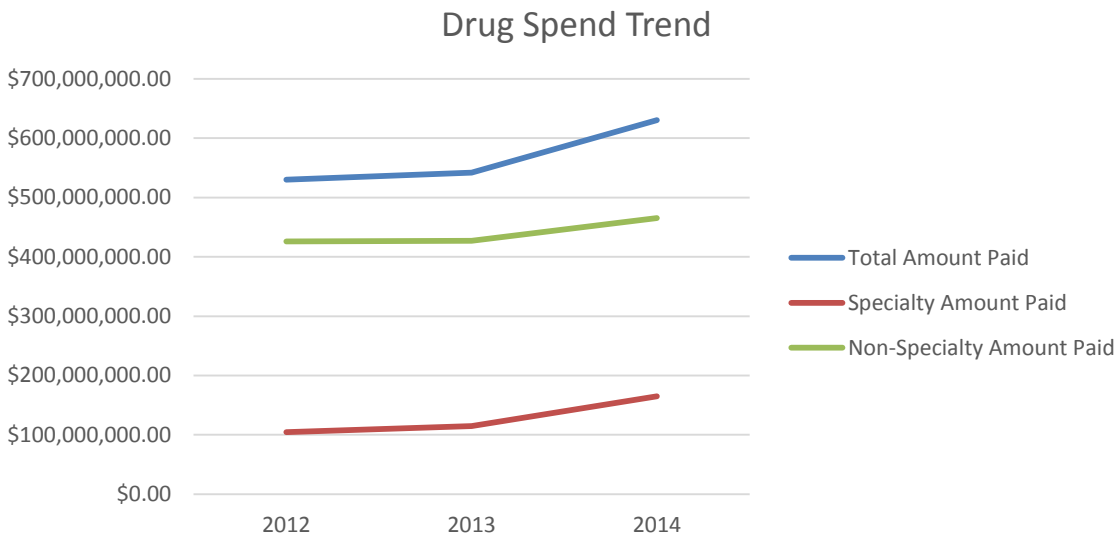
Top 10 Drugs by Prescription Count and Amount Paid

	2014				
Rank	Drug Name	Rx Count	Amount Paid	Avg Cost per Rx	Count of Members
1	HYDROCODONE/ACETAMINOPHEN	269,190	$4,117,914	$15.30	66,452
2	LISINOPRIL	167,112	$672,282	$4.02	27,888
3	PROVENTIL HFA	149,564	$9,214,733	$61.61	52,138
4	RANITIDINE HCL	144,461	$1,508,131	$10.44	31,632
5	GABAPENTIN	133,803	$2,055,714	$15.36	25,251
6	AMLODIPINE BESYLATE	133,511	$482,970	$3.62	22,228
7	TRAMADOL HCL	101,845	$695,082	$6.82	33,661
8	SIMVASTATIN	97,244	$778,938	$8.01	14,455
9	ALPRAZOLAM	96,688	$754,614	$7.80	15,382
10	RISPERIDONE	95,749	$1,971,063	$20.59	14,852

	2014				
Rank	Drug Group	Amount Paid	Rx Count	Avg Cost per Rx	Count of Members
1	SOVALDI	$30,447,333	1,075	$28,323.10	329
2	ABILIFY	$17,667,919	20,297	$870.47	3,021
3	LANTUS	$14,026,916	44,693	$313.85	7,632
4	TRUVADA	$13,251,910	11,532	$1,149.14	1,749
5	ADVAIR DISKUS	$12,669,797	42,186	$300.33	9,624
6	ATRIPLA	$11,609,428	6,011	$1,931.36	822
7	INVEGA SUSTENNA	$10,295,360	7,287	$1,412.84	1,018
8	VYVANSE	$9,957,599	50,674	$196.50	12,425
9	PROVENTIL HFA	$9,214,733	149,564	$61.61	52,138
10	EXJADE	$9,094,015	1,847	$4,923.67	233

Fee For Service Drivers: Specialty Drug Spending

- Specialty Spending
  - 19.7% (2012)
  - 21.2% (2013)
  - 26.2% (2014)
- Trends
  - 16.3 % (overall)
  - 9 % (non-specialty)
  - 43.5% (specialty)
- Drug Cost (Avg Cost/Rx)
  - $4,042.09 (2012)
  - $4,536.56 (2013)
  - $6,094.20 (2014)



YEAR	Total Amount Paid	Specialty Amount Paid	Non-Specialty Amount Paid
2012	$530,384,160.01	$104,294,462.51	$426,089,697.50
2013	$541,851,901.84	$114,870,626.32	$426,981,275.52
2014	$630,202,488.99	$164,808,629.85	$465,393,859.14

2015 Fee-For-Service Drivers

For those seeking proof of the pharma sector's ability to innovate, 2015 promises much evidence.

A dozen products due to be launched next year are forecast to reach blockbuster sales by 2020, including new drug classes in huge disease areas such as cardiovascular and respiratory diseases. Cancer will also have a big year as the promise of immuno-oncology therapies like the checkpoint inhibitors are further tested in both the market and in the clinic.

At the other end of the market, the lack of any really substantial patent expiries will be another boost to the industry's top line – the potential loss of exclusivity of Teva's Copaxone and the confirmed departure of Otsuka's Abilify notwithstanding. *EvaluatePharma* data show that, overall, the pharma industry is set to replace sales lost to patent expiries more than three times over next year. This is a far cry from the desperate year of 2011, when generics bit hard and big drug approvals were hard to find.

EPVantage Market Analysis. *PHARMA and Biotech 2015 Preview.* Accessed 3/23/2015
http://info.evaluategroup.com/epv-pb2015-lp-lp.html

Questions?

MSCA

THE MULTIPLE SCLEROSIS CENTER OF ATLANTA

A Center for MS Research and Patient Care

March 24, 2015

Chairman, Drug Utilization Review Board
Georgia Department of Community Health
Att: Giletta Gray
Fax: 404-657-5461

Dear Mr. Chairman and Board Members:

I am writing to you to discuss the pending decision by the Drug Utilization Board to limit access to the new oral disease modifying drugs (DMD) that are available for the treatment of multiple sclerosis. It is my understanding that the point under discussion is whether or not a patient should first fail the effectiveness of other drugs and that these drugs would be Copaxone and one of the injectable interferon drugs.

Currently I am the Medical Director and Chairman of the Board of the Multiple Sclerosis Center of Atlanta. The MSCA is a large comprehensive multiple sclerosis treatment center that covers the lives of 4,000 MS patients. We have 3,000 of those patients on immunomodulators at the present time. It is the largest comprehensive MS treatment care center in the Southeastern United States. Prior to that, I was the Director of the MS Center at Shepherd Spinal Center. The MS Center of Atlanta is a 501c3 Foundation with a Board of Directors and we treat all patients, whether they are insured or not, Medicare and Medicaid patients as well.

I am a neurologist and I have been in the practice of neurology since 1970. I currently limit and have limited my practice to MS since 1990.

I mention this only to support the fact that I have an extensive experience in treating MS patients and in using the new DMD's that have become available for the treatment of MS. The first of these drugs became available in 1994, and since then there has been a steady stream with increasing effectiveness. The drugs are given by injection, by infusion, and now we have 3 very effective drugs that can be given orally. All of these drugs have come through Phase III trials that were vigorously controlled and approved through the FDA process. They have varying degrees of effectiveness and varying degrees of complication. The selection of a drug for any given patient is not easy and requires a good bit of time and discussion with the patients. It is not a decision that can be appropriately made by formulary rules.

The evolution of these drugs began with the injectables, Copaxone and the three interferons. It was followed by the emergence of a very effective monoclonal antibody, Tysabri and since then there has been the appearance of 3 oral agents, Gilenya, Aubagio and Tecfidera. More recently another monoclonal antibody has been approved by the FDA for use, called Lemtrada. Lemtrada is Campath which was invented in 1980 and was the first monoclonal antibody used in health care, mainly for treating marrow tumor

It has recently been studied in MS and found to be an effective drug.

If you look at these drugs in terms of general levels of effectiveness in modifying MS, one would say that the original four drugs, Copaxone and the injectable interferons are at the bottom, followed by the 3 oral agents being roughly the same effectiveness with varying degrees of complication and Lemtrada then being the next most effective drug and finally if the patient can and is able and qualifies for the use of Tysabri, it is by far, in my opinion, our most superior drug approaching 90% effectiveness.

By the careful selection of these drugs, we have been able to definitely modify the clinical course of multiple sclerosis. Unfortunately, this has been a very difficult effort.

At the present time in the State of Georgia, based on data which is accurately accumulated and at a time in our medical history when we are 20 years after the availability of these effective drugs coming to market, we only have 39% of our 14,600 MS patients in the State of Georgia on a disease modifying drug. Eighty percent (80%) or more of these patients are insured in an effective enough way so that these medicines could be obtained and often by financial support from a variety of sources including the pharmaceutical companies, they are made available to all patients. In my own experience, it is rare that we are not able to find the financing for an MS patient that wants to be on a disease modifying drug.

The literature in the MS community regarding the percentage of MS patients who should be on a disease modifying drug generally is supportive of 90% of patients being on treatment. The treatment is not short term, it is generally a long term treatment and it requires constant clinical monitoring.

Having 39 percent of any chronic disease in our State under treatment is a medical failure. There are many reasons why this is happening and I can discuss them at other times. The passage of a rule implementing the use of Copaxone and/or an interferon prior to using the oral agents would increase the difficulty in getting MS patients on treatment. It would further reduce the percentage of patients that we have on treatment and furthermore, it would place the Medicaid patient in a lower tier of care.

I don't think this is the type of decisions that we want to make for our State.

I know that it is likely some of these older medicines being made available to the Medicaid pharmacy and formulary are considerably reduced rates. This is an attempt on their part to continue having a share of the DMD market while they are being superceded by more effective drugs in the MS community.

I appreciate your consideration of this lengthy letter and I am more than willing to continue this discussion with any or all of you and could do this either by phone, email, or I am more than willing to attend your meetings and present this material to your satisfaction.

I am hoping that you make a decision to leave your formulary open to all of these drugs for the care of our patients.

Sincerely,

Wm H. Stuart, MD

William H. Stuart, M.D.
Medical Director
MS Center of Atlanta

Chairman of the Board
MS Center of Atlanta

WHS: rb

Advocates for Responsible Care
Dorothy Leone-Glasser, RN, HHC.
President
1434 Brook Valley Lane
Atlanta, Georgia 30324

Linda Wiant, Pharm.D
Director of Pharmacy Services
Georgia Department of Community Health
2 Peachtree Street NW.
37th Floor
Atlanta, Georgia 30303

Dear Dr. Wiant,

ARxC and the Arthritis Foundation, Georgia knows too well the devastating effects of rheumatoid arthritis (RA). For those suffering from RA, medication treatments can greatly reduce pain and restore mobility for countless patients helping them to postpone disability. RA is a systemic illness which can affect multiple organ systems as it causes destruction of joints. Without the full range of treatment options available to patients from early onset of disease, RA can be a risk factor for developing cancer, cardiovascular illness and premature death.

As devoted patient advocates we ask that there be complete access to all rheumatoid arthritis therapies, including oral administered medications like Tofacitinib, that are FDA approved. We ask that these drugs are placed on Georgia's Medicaid formulary. Full access to these medications on the formulary will give doctors an early and viable choice to treat severe arthritis patients. At the same time, we will be giving diagnosed arthritis patients on Medicaid hope, taking steps to prevent complications, keeping them mobile and engaged citizens in their communities.

Thank you for your support of the care of this vulnerable patient population.

Dorothy Leone-Glasser

Dorothy Leone-Glasser, RN, HHC.
Executive Director, Advocates for Responsible Care, (ARxC)
Chair, Advocacy and Disparities Leadership Council, Arthritis Foundation, SE Region

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Facebook: Keeping Treatment In Reach Movement
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ATLANTA, GA 30342

Linda Wiant, Pharm D

Director of Pharmacy Services Medical Assistance Plans

2 Peachtree Street, NW

37th Floor

Atlanta, GA 30303

Georgia Medicaid Task Force February 13, 2015

Re: Xeljanz (tofacitinib)

I see that you and your committee will be discussing the position of Tofacitinib (Xeljanz®) in the step edit of the Medicaid formulary. In my letter of June 2013 I discussed that Tofacitinib is used to treat people with Rheumatoid Arthritis who have failed or are intolerant to methotrexate. Methotrexate is the cornerstone of our therapy for rheumatoid arthritis. That means as a rheumatologist I will initiate methotrexate (either orally or by injection if the patient can tolerate it) first when I start a medication that is actually a DMARD (Disease Modifying Anti Rheumatic Disease – the rheumatology code word for needing something more than an NSAID to treat rheumatoid arthritis). DMARDs are actually medications that can help modify the inflammation and retard the damage from Rheumatoid Arthritis. Other DMARDS include Plaquenil (hydroxychloroquine) and Azulfidine (sulfasalazine). If the patient does not respond I will consider a biologic medication which are given parentally such as injectable like Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab pegol), injectable Orencia (abatacept), Simponi (golimumab), Actemra (Tolcilizumab) or an infusible like Remicade (Infliximab), Orencia (abatacept), Rituxan (rituximab), Actemra (Tolcilizumab) and Simponi Aria (Golimumab) .

Tofacitinib is now a choice that is taken by mouth, is not a biological medication but rather a small molecule that is taken orally but still has biological effects on the immune and inflammatory processes that drive the damage of rheumatoid arthritis. It can be taken alone or in combination with methotrexate (or actually other DMARDS that are not biologics such as hydroxychloroquine or sulfasalazine).

I am asking your committee to add Tofacitinib as preferred or Step1 to the Medicaid formulary for the treatment of rheumatoid arthritis. This will give rheumatologists an earlier choice, this time an oral treatment) in the approach to the therapy of a person with rheumatoid arthritis on the Medicaid program.

John A. Goldman, MD

Beacon Pediatrics

To Whom it may concern:

It would be great to have a non-stimulent + non-controlled agent for treatment of AdHd, as well as, one that works 24 Hours like Straterra on the Medicaid Drug Formulary.

Thank you for your ~~conside~~ consideration,

David H. Cheatham

David H. Cheatham, M.D.

Beacon Pediatrics • 801 Beacon Street • Waycross, Georgia 31501 • Tel.

DRUG UTILIZATION REVIEW BOARD

March 26th 2015

EPILEPSY AND DRUGS (AEDs)

Eric B. Zurbrugg, MD Alliant Georgia Medical Care Foundation (child neurology)

Definitions:

“Seizure”: sudden, involuntary time-limited, alteration in behavior (motor activity, autonomic function,sensation, consciousness accompanied by an abnormal electrical discharge in the brain.

“*Epilepsy*”: recurrent seizures.

Incidence: number of ***new*** cases, typically per year.

Prevalence: number of people with the condition at a ***point*** in time, or a ***period*** of time(like a year) or a ***lifetime***.

So, in USA:

Incidence:

300,000 new “seizure” patients per year.

125,500 new “epilepsy” patients per year.

Prevalence:

6-10 per 1000 population

2.5 Million in USA with epilepsy

50 Million worldwide

Georgia? No evidence of much difference between states.

The epilepsy evaluation

History: single seizure or recurrent; semiology=signs and symptoms; family history.

Physical exam: focal signs; markers

Suspect structural lesion: imaging.

EEG pattern

Concurrent meds, drugs, alcohol?

Sleep deprivation?

Formulation: partial or generalized; recognizable syndrome?

Epilepsy Foundation of America web site is very educational.

Pick a medication (AED) to start based upon above.

The Epileptologist's goal:

Derive an optimal treatment plan.

Accurate diagnosis of the patient's seizure type(s).

Objective measurement of the intensity and frequency of the seizures.

Awareness of medication side effects.

Evaluation of epilepsy-related psychosocial problems.

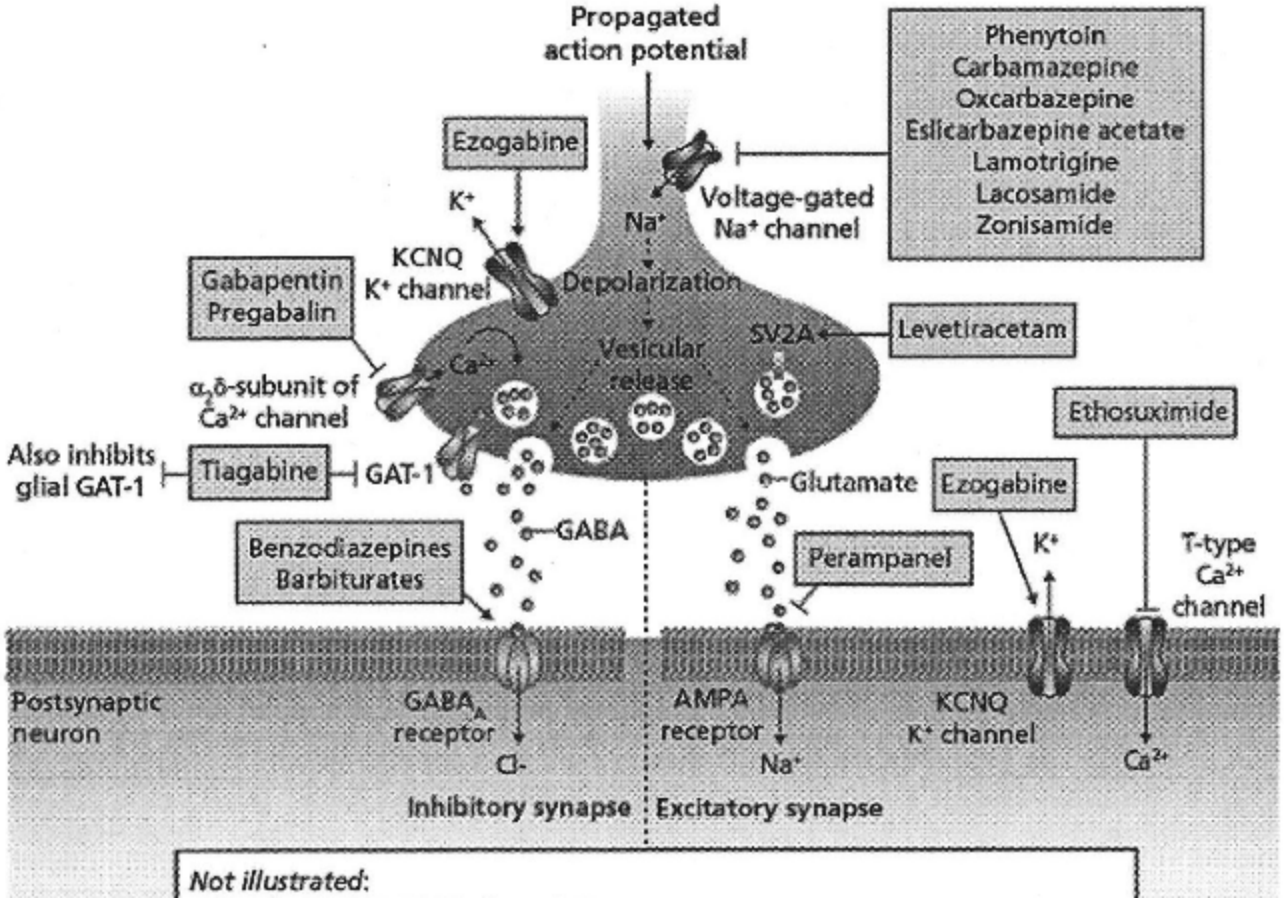
A working knowledge of available AEDs, their mechanism of action, pharmacokinetics, drug-drug interaction, and adverse side effects is required.

Unknown: the individual genetics of the patient and how that influences the AED metabolism.

FDA-Approved Treatment Options for Epilepsy

Approved Before 1992	Approved 1992 to 2007	Approved 2008 or After
• Benzodiazepines (diazepam, lorazepam, clonazepam) • Carbamazepine • Ethosuximide • Mysoline • Phenobarbital • Phenytoin • Valproic acid	• Felbamate • Gabapentin • Lamotrigine • Levetiracetam • Pregabalin • Oxcarbazepine • Rectal diazepam • Tiagabine • Topiramate • Vagus nerve stimulator • Zonisamide	• Clobazam • Eslicarbazepine • Ezogabine • Lacosamide • Perampanel • Responsive neurostimulation • Rufinamide • Vigabatrin

Selecting AEDs: Mechanism of Action[1]



Selecting AEDs: Broad vs Narrow Spectrum[1]

Seizure Type	AED(s)
Broad spectrum • *All* seizure types (generalized from onset *and* focal-onset seizures)	• Clobazam • Felbamate • Lamotrigine • Levetiracetam • Phenobarbital • Rufinamide • Topiramate • Valproate • Zonisamide
Narrow spectrum • Focal with or without alteration in consciousness or awareness *and* focal evolving to bilateral convulsive seizure	• Carbamazepine • Eslicarbazepine • Ezogabine • Gabapentin • Lacosamide • Oxcarbazepine • Perampanel • Phenytoin • Pregabalin • Primidone • Tiagabine • Vigabatrin
Absence seizure • A type of generalized seizure	• Ethosuximide

Three Goals of Epilepsy Management

Control seizures

Avoiding treatment-related side effects

Maintaining or restoring quality of life.

and

AEDs are the mainstay of epilepsy treatment.

Vagal nerve stimulation

Surgery

CBD trial

Selecting AEDs: Adverse Effects[1]

Adverse Effect	More Favorable	Less Favorable
Rash	• Levetiracetam • Pregabalin • Gabapentin • Topiramate • Valproate • Lacosamide	• Lamotrigine • Carbamazepine • Oxcarbazepine • Phenytoin • Phenobarbital
Life-threatening blood dyscrasias		• Felbamate • Carbamazepine • Valproate • Phenytoin
Hepatic disease	• Levetiracetam • Pregabalin • Gabapentin	• Valproate • Carbamazepine • Phenytoin • Felbamate • Lamotrigine
Sedation	• Lamotrigine	• Carbamazepine • Phenytoin • Phenobarbital • Primidone • Benzodiazepines
Concentration/ cognition	• Lamotrigine • Lacosamide	• Topiramate? • Phenytoin • Zonisamide
Weight gain	• Topiramate • Zonisamide • Felbamate • Rufinamide	• Valproate • Pregabalin • Gabapentin • Vigabatrin • Ezogabine • Carbamazepine (lesser extent)
Coordination disturbances	• Levetiracetam • Gabapentin	• Carbamazepine • Phenytoin • Primidone • Topiramate • Pregabalin • Eslicarbazepine

MMWR August 2008: Surveillance Summary for 2005

Telephone Population Study of 19 states 2005:

Prevalence will increase because of the aging of the population.

1.65% of adults self identified as having had seizures or epilepsy.

0.84% reported “active” : history of epilepsy and taking AEDs or 1+ Szs in the last 3 months.

0.75% “inactive” : a history of epilepsy but no AEDs or Szs in last 3 months.

No sex or racial differences.

“Actives” more likely to report poor health, unemployed, low income, co-morbid disorders (stroke, arthritis) be obese, physically inactive, and smokers**.**

16.1% reported not taking their AEDs and 65.1% reported >1 seizure in last 30 days.

24% said cost was a barrier; 35% of “actives” had not seen a neurologist in 1yr.

Questions for Georgia DCH going forward:

March 2000 ***Epilepsia:***

Uncontrolled seizures 25% of the total, 86% of the costs: $10,000 per year

Controlled: $2000 per year

Direct Cost of Epilepsy Care:

Evaluations: imaging scans, EEG's, video, ambulatory

Vagus nerve stimulators

Epilepsy surgery

AEDs

Blood work

Visits to epileptologist

Is it Time for Big Data?:

Epilepsia March 2000 Cost of care.

US: 2.3 Million cases: $12.5 Billion (4th leading neurological disease)

AEDs 30% of direct costs.

Indirect costs of lost earnings/productivity 85%.

Case for Georgia DCH: what are the questions: who is getting care? where? adherence? outcome? Model: care of the complex patient.

Your questions??

Drug Utilization Review Board

Motions - Votes - **New Drugs**

March 26, 2015

ANTICONVULSANTS, NEW GENERATION

Drug	PDL Status	Motion - Recommendations	Additional Comments
GABAPENTIN (ORAL) SOLUTION	NPPA	P	
OXTELLAR XR (ORAL) TABLET	NPPA	PPA	
QUDEXY XR (ORAL) CAP SPR 24	NPPA	PPA	
FELBATOL (ORAL) ORAL SUSP	P	NP	
FELBATOL (ORAL) TABLET	P	NP	
*APTIOM (ORAL) TABLET	NPPA	NPPA	
***NEW DRUG**			

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Damon, Ann R., Pharm.D.		√	√		
3	Doad, Gurinder J.S., M.D.- **Vice**	√		√		
4	Fincher, Deborah W., M.S., R.Ph.			√		
5	Gore, Thomas B., M.D.			√		
6	May, J. Russell (Rusty)			√		
7	Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
8	Rollins, Brent L., R.Ph., Ph.D.			√		
9	Shervette III, Robert E., M.D.			√		
			TOTAL	9	0	0

	Board Members - Absent
1	Fowler, M. Celeste, Pharm.D.
2	Lorys, Robyn Pharm.D.

Drug Utilization Review Board

Motions - Votes - **New Drugs**

March 26, 2015

ANTIDIABETICS, NON-INSULIN DPP41

	Drug	PDL Status	Motion - Recommendations	Additional Comments
	TRADJENTA (ORAL) TABLET	NPPA	PPA	
	JENTADUETO (ORAL) TABLET	NPPA	PPA	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Damon, Ann R., Pharm.D.		√	√		
3	Doad, Gurinder J.S., M.D.- **Vice**			√		
4	Fincher, Deborah W., M.S., R.Ph.			√		
5	Gore, Thomas B., M.D.			√		
6	May, J. Russell (Rusty)	√		√		
7	Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
8	Rollins, Brent L., R.Ph., Ph.D.			√		
9	Shervette III, Robert E., M.D.			√		
			TOTAL	9	0	0

	Board Members - Absent
1	Fowler, M. Celeste, Pharm.D.
2	Lorys, Robyn Pharm.D.

Drug Utilization Review Board

Motions - Votes - **New Drugs**

March 26, 2015

	ANTIDIABETICS, NON-INSULIN DOPAMINE AGONISTS	Drug (New)	PDL Status	Motion - Recommendations	Additional Comments	
		CYCLOSET (ORAL) TABLET	NPPA	NPPA		
	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Damon, Ann R., Pharm.D.			√		
3	Doad, Gurinder J.S., M.D.- **Vice**			√		
4	Fincher, Deborah W., M.S., R.Ph.			√		
5	Gore, Thomas B., M.D.			√		
6	May, J. Russell (Rusty)	√		√		
7	Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
8	Rollins, Brent L., R.Ph., Ph.D.		√	√		
9	Shervette III, Robert E., M.D.			√		
			TOTAL	9	0	0

	Board Members - Absent
1	Fowler, M. Celeste, Pharm.D.
2	Lorys, Robyn Pharm.D.

Drug Utilization Review Board

Motions - Votes - **New Drugs**

March 26, 2015

	ANTIDIABETICS, NON-INSULIN SGLT21	Drug (New)	PDL Status	Motion - Recommendations	Additional Comments	
		JARDIANCE (ORAL) TABLET	NPPA	NPPA		
	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Damon, Ann R., Pharm.D.			√		
3	Doad, Gurinder J.S., M.D.- **Vice**			√		
4	Fincher, Deborah W., M.S., R.Ph.			√		
5	Gore, Thomas B., M.D.		√	√		
6	May, J. Russell (Rusty)	√		√		
7	Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
8	Rollins, Brent L., R.Ph., Ph.D.			√		
9	Shervette III, Robert E., M.D.			√		
			TOTAL	9	0	0

	Board Members - Absent
1	Fowler, M. Celeste, Pharm.D.
2	Lorys, Robyn Pharm.D.

Drug Utilization Review Board

Motions - Votes - **New Drugs**

March 26, 2015

ANTIDIABETICS, NON-INSULIN GLP-1RA

Drug	PDL Status	Motion - Recommendations	Additional Comments
BYDUREON (SUB-Q) VIAL	NPPA	PPA	GRANDFATHERING FOR MEMBERS CURRENTLY ON VICTOZA
BYETTA (SUB-Q) PEN INJCTR	PPA	NPPA	
*TANZEUM (SUB-Q) PEN INJCTR	NPPA	PPA	
*TRULICITY (SUB-Q) PEN INJCTR	NPPA	NPPA	
VICTOZA (SUB-Q) PEN INJCTR	PPA	NPPA	
*** NEW DRUGS**			

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Damon, Ann R., Pharm.D.			√		
3	Doad, Gurinder J.S., M.D.- **Vice**			√		
4	Fincher, Deborah W., M.S., R.Ph.			√		
5	Gore, Thomas B., M.D.		√	√		
6	May, J. Russell (Rusty)	√		√		
7	Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
8	Rollins, Brent L., R.Ph., Ph.D.			√		
9	Shervette III, Robert E., M.D.			√		
			TOTAL	9	0	0

	Board Members - Absent
1	Fowler, M. Celeste, Pharm.D.
2	Lorys, Robyn Pharm.D.

Bronchodilators, Anticholinergics

Drug	PDL Status	Motion - Recommendations	Additional Comments
*ANORO ELLIPTA (INHALATION) BLISTER W/DEVICE	NPPA	NPPA	
*INCRUSE ELLIPTA (INHALATION) BLISTER W/DEVICE	NPPA	NPPA	
IPRATROPIUM-ALBUTEROL (INHALATION) AMPULE-NEB	NPPA	P	
***NEW DRUGS**			

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Damon, Ann R., Pharm.D.			√		
3	Doad, Gurinder J.S., M.D.- **Vice**		√	√		
4	Fincher, Deborah W., M.S., R.Ph.	√		√		
5	Gore, Thomas B., M.D.			√		
6	May, J. Russell (Rusty)			√		
7	Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
8	Rollins, Brent L., R.Ph., Ph.D.			√		
9	Shervette III, Robert E., M.D.			√		
			TOTAL	9	0	0

	Board Members - Absent
1	Fowler, M. Celeste, Pharm.D.
2	Lorys, Robyn Pharm.D.

Drug Utilization Review Board

Motions - Votes - **New Drugs**

March 26, 2015

Bronchodilators, Steroid Inhalants

	Drug	PDL Status	Motion - Recommendations	Additional Comments
	AEROSPAN (INHALATION) HFA AER AD	NPPA	P	
	ASMANEX HFA (INHALATION) HFA AER AD	P	NPPA	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Damon, Ann R., Pharm.D.			√		
3	Doad, Gurinder J.S., M.D.- **Vice**			√		
4	Fincher, Deborah W., M.S., R.Ph.	√		√		
5	Gore, Thomas B., M.D.			√		
6	May, J. Russell (Rusty)		√	√		
7	Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
8	Rollins, Brent L., R.Ph., Ph.D.			√		
9	Shervette III, Robert E., M.D.			√		
			TOTAL	9	0	0

	Board Members - Absent
1	Fowler, M. Celeste, Pharm.D.
2	Lorys, Robyn Pharm.D.

Drug Utilization Review Board

Motions - Votes - **New Drugs**

March 26, 2015

Bronchodilators, Sympathomimetics

Drug	PDL Status	Motion - Recommendations	Additional Comments
ALBUTEROL SULFATE (ORAL) TABLET	P	NPPA	
BROVANA (INHALATION) VIAL-NEB	NPPA	PPA	
SEREVENT DISKUS (INHALATION) BLISTER W/DEVICE	P	NPPA	
*STRIVERDI RESPIMAT (INHALATION) MIST INHAL	NPPA	NPPA	

*** NEW DRUG**

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Damon, Ann R., Pharm.D.			√		
3	Doad, Gurinder J.S., M.D.- **Vice**			√		
4	Fincher, Deborah W., M.S., R.Ph.	√		√		
5	Gore, Thomas B., M.D.		√	√		
6	May, J. Russell (Rusty)			√		
7	Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
8	Rollins, Brent L., R.Ph., Ph.D.			√		
9	Shervette III, Robert E., M.D.			√		
			TOTAL	9	0	0

	Board Members - Absent
1	Fowler, M. Celeste, Pharm.D.
2	Lorys, Robyn Pharm.D.

Drug Utilization Review Board

Motions - Votes - **New Drugs**

March 26, 2015

Biologic Immunomodulators

Drug	PDL Status	Motion - Recommendations	Additional Comments
*OTEZLA (ORAL) TABLET	NPPA	NPPA	
*STELARA (SUB-Q) SYRINGE	NPPA	NPPA	

*** NEW DRUGS**

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Damon, Ann R., Pharm.D.			√		
3	Doad, Gurinder J.S., M.D.- **Vice**	√		√		
4	Fincher, Deborah W., M.S., R.Ph.			√		
5	Gore, Thomas B., M.D.		√	√		
6	May, J. Russell (Rusty)			√		
7	Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
8	Rollins, Brent L., R.Ph., Ph.D.			√		
9	Shervette III, Robert E., M.D.			√		
			TOTAL	9	0	0

	Board Members - Absent
1	Fowler, M. Celeste, Pharm.D.
2	Lorys, Robyn Pharm.D.

Drug Utilization Review Board

Motions - Votes - **New Drugs**

March 26, 2015

Platelet Aggregation Inhibitors

Drug	PDL Status	Motion - Recommendations	Additional Comments
*ZONTIVITY (ORAL) TABLET	NPPA	NPPA	
***NEW DRUG**			

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Damon, Ann R., Pharm.D.			√		
3	Doad, Gurinder J.S., M.D.- **Vice**			√		
4	Fincher, Deborah W., M.S., R.Ph.			√		
5	Gore, Thomas B., M.D.	√		√		
6	May, J. Russell (Rusty)			√		
7	Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
8	Rollins, Brent L., R.Ph., Ph.D.		√	√		
9	Shervette III, Robert E., M.D.			√		
			TOTAL	9	0	0

	Board Members - Absent
1	Fowler, M. Celeste, Pharm.D.
2	Lorys, Robyn Pharm.D.

Antivirals, Hepatitis C Agents

	Drug	PDL Status	Motion - Recommendations	Additional Comments
	*HARVONI (ORAL) TABLET 90MG-400MG	PPA	PPA	
	*VIEKIRA PAK (ORAL) TAB DS PK 12.5-75-50	PPA W/STEP	NPPA	
	* NEW DRUGS			

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Damon, Ann R., Pharm.D.			√		
3	Doad, Gurinder J.S., M.D.- **Vice**			√		
4	Fincher, Deborah W., M.S., R.Ph.		√	√		
5	Gore, Thomas B., M.D.			√		
6	May, J. Russell (Rusty)			√		
7	Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
8	Rollins, Brent L., R.Ph., Ph.D.	√		√		
9	Shervette III, Robert E., M.D.			√		
			TOTAL	9	0	0

	Board Members - Absent
1	Fowler, M. Celeste, Pharm.D.
2	Lorys, Robyn Pharm.D.

Multiple Sclerosis (MS) Agents

Drug	PDL Status	Motion - Recommendations	Additional Comments
AMPYRA (ORAL) TAB ER 12H	NPPA	PPA	
*PLEGRIDY (SUB-Q) SYRINGE	NPPA	NPPA	
*PLEGRIDY PEN (SUB-Q) PEN INJCTR	NPPA	NPPA	
TECFIDERA (ORAL) CAPSULE DR	NPPA	P	
* NEW DRUGS			

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.		√	√		
2	Damon, Ann R., Pharm.D.	√		√		
3	Doad, Gurinder J.S., M.D.- **Vice**			√		
4	Fincher, Deborah W., M.S., R.Ph.			√		
5	Gore, Thomas B., M.D.			√		
6	May, J. Russell (Rusty)			√		
7	Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
8	Rollins, Brent L., R.Ph., Ph.D.			√		
9	Shervette III, Robert E., M.D.			√		
			TOTAL	9	0	0

	Board Members - Absent
1	Fowler, M. Celeste, Pharm.D.
2	Lorys, Robyn Pharm.D.

Inflammatory Bowel Agents

Drug	PDL Status	Motion - Recommendations	Additional Comments
PENTASA (ORAL) CAPSULE ER 500 MG	NPPA	P	
SFROWASA (RECTAL) ENEMA	P	NPPA	
*UCERIS (ORAL) TAB DR & ER	NPPA	NPPA	
*UCERIS (RECTAL) FOAM/APPL	NPPA	NPPA	
***NEW DRUGS**			

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.	√		√		
2	Damon, Ann R., Pharm.D.		√	√		
3	Doad, Gurinder J.S., M.D.- **Vice**			√		
4	Fincher, Deborah W., M.S., R.Ph.			√		
5	Gore, Thomas B., M.D.			√		
6	May, J. Russell (Rusty)			√		
7	Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
8	Rollins, Brent L., R.Ph., Ph.D.			√		
9	Shervette III, Robert E., M.D.			√		
			TOTAL	9	0	0

	Board Members - Absent
1	Fowler, M. Celeste, Pharm.D.
2	Lorys, Robyn Pharm.D.

Antihyperlipidemics

Drug	PDL Status	Motion - Recommendations	Additional Comments
COLESTIPOL HCL (ORAL) GRANULES	P	NPPA	
COLESTIPOL HCL (ORAL) PACKET	P	NPPA	
FENOFIBRATE (ORAL) CAPSULE	NPPA	P	
PREVALITE (ORAL) POWD PACK	P	NPPA	
TRILIPIX (ORAL) CAPSULE DR	P	NPPA	
VYTORIN (ORAL) TABLET	NPPA	P	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Damon, Ann R., Pharm.D.			√		
3	Doad, Gurinder J.S., M.D.- **Vice**			√		
4	Fincher, Deborah W., M.S., R.Ph.			√		
5	Gore, Thomas B., M.D.			√		
6	May, J. Russell (Rusty)	√		√		
7	Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
8	Rollins, Brent L., R.Ph., Ph.D.		√	√		
9	Shervette III, Robert E., M.D.			√		
			TOTAL	9	0	0

	Board Members - Absent
1	Fowler, M. Celeste, Pharm.D.
2	Lorys, Robyn Pharm.D.

Antihypertensive, Angiotensin Receptor Blockers

Drug	PDL Status	Motion - Recommendations	Additional Comments
ATACAND (ORAL) TABLET	NPPA	P	
BENICAR (ORAL) TABLET	PPA	P	
BENICAR HCT (ORAL) TABLET	PPA	P	
DIOVAN (ORAL) TABLET	PPA	P	
IRBESARTAN (ORAL) TABLET	PPA	P	
IRBESARTAN-HYDROCHLOROTHIAZIDE (ORAL) TABLET	PPA	P	
MICARDIS (ORAL) TABLET	PPA	P	
MICARDIS HCT (ORAL) TABLET	PPA	P	
VALSARTAN-HYDROCHLOROTHIAZIDE (ORAL) TABLET	PPA	P	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.		√	√		
2	Damon, Ann R., Pharm.D.			√		
3	Doad, Gurinder J.S., M.D.- **Vice**			√		
4	Fincher, Deborah W., M.S., R.Ph.			√		
5	Gore, Thomas B., M.D.	√		√		
6	May, J. Russell (Rusty)			√		
7	Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
8	Rollins, Brent L., R.Ph., Ph.D.			√		
9	Shervette III, Robert E., M.D.			√		
			TOTAL	9	0	0

	Board Members - Absent
1	Fowler, M. Celeste, Pharm.D.
2	Lorys, Robyn Pharm.D.

Antihypertensive, Angiotensin Receptor Blocker - Calcium Channel Blocker Combinations

Drug	PDL Status	Motion - Recommendations	Additional Comments
AZOR (ORAL) TABLET	NPPA	PPA	
TRIBENZOR (ORAL) TABLET	NPPA	PPA	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Damon, Ann R., Pharm.D.			√		
3	Doad, Gurinder J.S., M.D.- **Vice**			√		
4	Fincher, Deborah W., M.S., R.Ph.			√		
5	Gore, Thomas B., M.D.	√		√		
6	May, J. Russell (Rusty)		√	√		
7	Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
8	Rollins, Brent L., R.Ph., Ph.D.			√		
9	Shervette III, Robert E., M.D.			√		
			TOTAL	9	0	0

	Board Members - Absent
1	Fowler, M. Celeste, Pharm.D.
2	Lorys, Robyn Pharm.D.

Attention Deficit Hyperactivity Disorder (ADHD) Agents

Drug	PDL Status	Motion - Recommendations	Additional Comments
QUILLIVANT XR (ORAL) SU ER RC24	NPPA	PPA	
STRATTERA (ORAL) CAPSULE	NPPA	PPA	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.		√	√		

2	Damon, Ann R., Pharm.D.			√		
3	Doad, Gurinder J.S., M.D.- **Vice**			√		
4	Fincher, Deborah W., M.S., R.Ph.			√		
5	Gore, Thomas B., M.D.			√		
6	May, J. Russell (Rusty)			√		
7	Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
8	Rollins, Brent L., R.Ph., Ph.D.			√		
9	Shervette III, Robert E., M.D.	√		√		
			TOTAL	**9**	**0**	**0**

	Board Members - Absent
1	Fowler, M. Celeste, Pharm.D.
2	Lorys, Robyn Pharm.D.

Drug Utilization Review Board

Motions - Votes - **New Drugs**

March 26, 2015

Corticosteroids, Oral	Drug	PDL Status	Motion - Recommendations	Additional Comments
	VERIPRED 20 (ORAL) SOLUTION	P	NPPA	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.	√		√		
2	Damon, Ann R., Pharm.D.		√	√		
3	Doad, Gurinder J.S., M.D.- **Vice**			√		
4	Fincher, Deborah W., M.S., R.Ph.			√		
5	Gore, Thomas B., M.D.			√		
6	May, J. Russell (Rusty)			√		
7	Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
8	Rollins, Brent L., R.Ph., Ph.D.			√		
9	Shervette III, Robert E., M.D.			√		
			TOTAL	9	0	0

	Board Members - Absent
1	Fowler, M. Celeste, Pharm.D.
2	Lorys, Robyn Pharm.D.

Drug Utilization Review Board

Motions - Votes - **New Drugs**

March 26, 2015

Dermatolgoics, Scabicides- Pediculocides

	Drug	PDL Status	Motion - Recommendations	Additional Comments
	NATROBA (TOPICAL) SUSPENSION	NPPA	PPA	
	ULESFIA (TOPICAL) LOTION	PPA	NPPA	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.		√	√		
2	Damon, Ann R., Pharm.D.			√		
3	Doad, Gurinder J.S., M.D.- **Vice**	√		√		
4	Fincher, Deborah W., M.S., R.Ph.			√		
5	Gore, Thomas B., M.D.			√		
6	May, J. Russell (Rusty)			√		
7	Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
8	Rollins, Brent L., R.Ph., Ph.D.			√		
9	Shervette III, Robert E., M.D.			√		
			TOTAL	9	0	0

	Board Members - Absent
1	Fowler, M. Celeste, Pharm.D.
2	Lorys, Robyn Pharm.D.

Drug Utilization Review Board

Motions - Votes - **New Drugs**

March 26, 2015

Digestive Enzymes

	Drug	PDL Status	Motion - Recommendations	Additional Comments
	ZENPEP (ORAL) CAPSULE DR	P	NPPA	
Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1 Avery, Mia, Pharm.D.			√		
2 Damon, Ann R., Pharm.D.			√		
3 Doad, Gurinder J.S., M.D.- **Vice**			√		
4 Fincher, Deborah W., M.S., R.Ph.			√		
5 Gore, Thomas B., M.D.		√	√		
6 May, J. Russell (Rusty)	√		√		
7 Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
8 Rollins, Brent L., R.Ph., Ph.D.			√		
9 Shervette III, Robert E., M.D.			√		
		TOTAL	9	0	0

Board Members - Absent
1 Fowler, M. Celeste, Pharm.D.
2 Lorys, Robyn Pharm.D.

Drug Utilization Review Board

Motions - Votes - **New Drugs**

March 26, 2015

Migraine Products

	Drug	PDL Status	Motion - Recommendations	Additional Comments	
	RELPAX (ORAL) TABLET	NPPA	P		
Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1 Avery, Mia, Pharm.D.			√		
2 Damon, Ann R., Pharm.D.			√		
3 Doad, Gurinder J.S., M.D.- **Vice**	√		√		
4 Fincher, Deborah W., M.S., R.Ph.		√	√		
5 Gore, Thomas B., M.D.			√		
6 May, J. Russell (Rusty)			√		
7 Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
8 Rollins, Brent L., R.Ph., Ph.D.			√		
9 Shervette III, Robert E., M.D.			√		
		TOTAL	9	0	0

Board Members - Absent
1 Fowler, M. Celeste, Pharm.D.
2 Lorys, Robyn Pharm.D.

Multivitamins, Prenatal

	Drug	PDL Status	Motion - Recommendations	Additional Comments
	PRENATE DHA PRODUCTS	NPPA	P	PRENATE DHA PRODUCTS ARE THE SOLE PREFERRED VITAMINS WITH DHA
	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES: YES (√) / NO (√) / ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Damon, Ann R., Pharm.D.			√		
3	Doad, Gurinder J.S., M.D.- **Vice**	√		√		
4	Fincher, Deborah W., M.S., R.Ph.			√		
5	Gore, Thomas B., M.D.			√		
6	May, J. Russell (Rusty)			√		
7	Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
8	Rollins, Brent L., R.Ph., Ph.D.		√	√		
9	Shervette III, Robert E., M.D.			√		
			TOTAL	9	0	0

	Board Members - Absent
1	Fowler, M. Celeste, Pharm.D.
2	Lorys, Robyn Pharm.D.

Drug Utilization Review Board

Motions - Votes - **New Drugs**

March 26, 2015

Nasal Steroids

	Drug	PDL Status	Motion - Recommendations	Additional Comments
	BECONASE AQ (NASAL) SPRAY	P	NPPA	
	QNASL (NASAL) HFA AER AD	P	NPPA	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Damon, Ann R., Pharm.D.			√		
3	Doad, Gurinder J.S., M.D.- **Vice**			√		
4	Fincher, Deborah W., M.S., R.Ph.	√		√		
5	Gore, Thomas B., M.D.		√	√		
6	May, J. Russell (Rusty)			√		
7	Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
8	Rollins, Brent L., R.Ph., Ph.D.			√		
9	Shervette III, Robert E., M.D.			√		
			TOTAL	9	0	0

	Board Members - Absent
1	Fowler, M. Celeste, Pharm.D.
2	Lorys, Robyn Pharm.D.

Drug Utilization Review Board

Motions - Votes - **New Drugs**

March 26, 2015

Ophthalmics, Antiinfectives

	Drug	PDL Status	Motion - Recommendations	Additional Comments
	ZYMAXID (OPHTHALMIC) DROPS	NPPA	P	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Damon, Ann R., Pharm.D.			√		
3	Doad, Gurinder J.S., M.D.- **Vice**			√		
4	Fincher, Deborah W., M.S., R.Ph.		√	√		
5	Gore, Thomas B., M.D.			√		
6	May, J. Russell (Rusty)	√		√		
7	Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
8	Rollins, Brent L., R.Ph., Ph.D.			√		
9	Shervette III, Robert E., M.D.			√		
			TOTAL	9	0	0

	Board Members - Absent
1	Fowler, M. Celeste, Pharm.D.
2	Lorys, Robyn Pharm.D.

Drug Utilization Review Board

Motions - Votes - **New Drugs**

March 26, 2015

Ophthalmics
Antiinflammatories

	Drug	PDL Status	Motion - Recommendations	Additional Comments
	NEVANAC (OPHTHALMIC) DROPS SUSP	P	NPPA	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.		√	√		
2	Damon, Ann R., Pharm.D.			√		
3	Doad, Gurinder J.S., M.D.- **Vice**			√		
4	Fincher, Deborah W., M.S., R.Ph.			√		
5	Gore, Thomas B., M.D.			√		
6	May, J. Russell (Rusty)	√		√		
7	Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
8	Rollins, Brent L., R.Ph., Ph.D.			√		
9	Shervette III, Robert E., M.D.			√		
			TOTAL	9	0	0

	Board Members - Absent
1	Fowler, M. Celeste, Pharm.D.
2	Lorys, Robyn Pharm.D.

Drug Utilization Review Board

Motions - Votes - **New Drugs**

March 26, 2015

Opioid Agonist, Partial Agonists

	Drug	PDL Status	Motion - Recommendations	Additional Comments
	BUNAVAIL (BUCCAL) FILM	NPPA	PPA	BUNAVAIL PREFERRED STATUS IS A STEP OF SUBOXONE (SUBLINGUAL) FILM.
	ZUBSOLV (SUBLINGUAL) TAB SUB	PPA	NPPA	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Damon, Ann R., Pharm.D.			√		
3	Doad, Gurinder J.S., M.D.- **Vice**	√		√		
4	Fincher, Deborah W., M.S., R.Ph.			√		
5	Gore, Thomas B., M.D.		√	√		
6	May, J. Russell (Rusty)			√		
7	Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
8	Rollins, Brent L., R.Ph., Ph.D.			√		
9	Shervette III, Robert E., M.D.			√		
			TOTAL	9	0	0

	Board Members - Absent
1	Fowler, M. Celeste, Pharm.D.
2	Lorys, Robyn Pharm.D.

Drug Utilization Review Board

Motions - Votes - **New Drugs**

March 26, 2015

Urinary Prostatic Hypertrophy

	Drug	PDL Status	Motion - Recommendations	Additional Comments
	ALFUZOSIN HCL ER (ORAL) TAB ER	NPPA	P	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.	√		√		
2	Damon, Ann R., Pharm.D.		√	√		
3	Doad, Gurinder J.S., M.D.- **Vice**			√		
4	Fincher, Deborah W., M.S., R.Ph.			√		
5	Gore, Thomas B., M.D.			√		
6	May, J. Russell (Rusty)			√		
7	Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
8	Rollins, Brent L., R.Ph., Ph.D.			√		
9	Shervette III, Robert E., M.D.			√		
			TOTAL	9	0	0

	Board Members - Absent
1	Fowler, M. Celeste, Pharm.D.
2	Lorys, Robyn Pharm.D.

The board voted unanimously to make no changes to these classes

	Classes	Motion Made By	Motion Seconded By
1	Analgesics - Opioid, Long Acting	Fincher, Deborah W., M.S., R.Ph.	Gore, Thomas B., M.D.
2	Analgesics - Opioid, Short Acting	Fincher, Deborah W., M.S., R.Ph.	Rollins, Brent L., R.Ph., Ph.D.
3	Androgens, Anabolic	Avery, Mia, Pharm.D.	Gore, Thomas B., M.D.
4	Anticoagulants	Gore, Thomas B., M.D.	May, J. Russell (Rusty)
5	Antidepressants	Fincher, Deborah W., M.S., R.Ph.	Avery, Mia, Pharm.D.
6	Antidiabetics - Insulin	May, J. Russell (Rusty)	Rollins, Brent L., R.Ph., Ph.D.
7	Antihemophilic Products - Vwf	Damon, Ann R., Pharm.D.	Avery, Mia, Pharm.D.
8	Antihistamines	May, J. Russell (Rusty)	Damon, Ann R., Pharm.D.
9	Antihypertensive, ACE Inhibitors	May, J. Russell (Rusty)	Gore, Thomas B., M.D.
10	Antihypertensives, Beta Blockers	Gore, Thomas B., M.D.	Rollins, Brent L., R.Ph., Ph.D.
11	Antiinfectives, Miscellaneous	Damon, Ann R., Pharm.D.	Avery, Mia, Pharm.D.
12	Anti-Inflammatory, NSAIDS	Avery, Mia, Pharm.D.	Rollins, Brent L., R.Ph., Ph.D.
13	Antipsychotics	Shervette III, Robert E., M.D.	Avery, Mia, Pharm.D.
14	Biologics, Miscellaneous (Allergen Immunotherapy)	Avery, Mia, Pharm.D.	May, J. Russell (Rusty)
15	Bronchodilators, PDE4	Fincher, Deborah W., M.S., R.Ph.	May, J. Russell (Rusty)
16	Calcium Channel Blockers	Damon, Ann R., Pharm.D.	Gore, Thomas B., M.D.
17	Calcium Regulators - Osteoporosis	May, J. Russell (Rusty)	Fincher, Deborah W., M.S., R.Ph.
18	Dermatologics, Acne Product (Sulfones)	Avery, Mia, Pharm.D.	Shervette III, Robert E., M.D.
19	Dermatolgoics, Anti-Inflammatory Agents	Fincher, Deborah W., M.S., R.Ph.	Rollins, Brent L., R.Ph., Ph.D.
20	Dermatolgoics, Antipsoriatics	Damon, Ann R., Pharm.D.	Avery, Mia, Pharm.D.
21	Epinephrine Pens	Avery, Mia, Pharm.D.	Damon, Ann R., Pharm.D.
22	Estrogens	Doad, Gurinder J.S., M.D.- **Vice**	Avery, Mia, Pharm.D.
23	Fibromyalgia Agents	Rollins, Brent L., R.Ph., Ph.D.	Shervette III, Robert E., M.D.
24	Growth Hormones	Rollins, Brent L., R.Ph., Ph.D.	Shervette III, Robert E., M.D.
25	Hematopoietic, Growth Factor	Rollins, Brent L., R.Ph., Ph.D.	Shervette III, Robert E., M.D.
26	Irritable Bowel Syndrome Agents	Rollins, Brent L., R.Ph., Ph.D.	Gore, Thomas B., M.D.
27	Ophthalmics, Adrenergic Agents	Rollins, Brent L., R.Ph., Ph.D.	Shervette III, Robert E., M.D.
28	Ophthalmic, Antiallergic	Rollins, Brent L., R.Ph., Ph.D.	Shervette III, Robert E., M.D.

29	Ophthalmic - Antibiotic Steroid Combinations	Rollins, Brent L., R.Ph., Ph.D.	Shervette III, Robert E., M.D.
30	Ophthalmic, Beta Blockers	Rollins, Brent L., R.Ph., Ph.D.	Shervette III, Robert E., M.D.
31	Ophthalmics, Prostaglandins	Rollins, Brent L., R.Ph., Ph.D.	Shervette III, Robert E., M.D.
32	Otic Anti-Infectives	Gore, Thomas B., M.D.	Rollins, Brent L., R.Ph., Ph.D.
33	Pulmonary Hypertension Drugs	Gore, Thomas B., M.D.	Avery, Mia, Pharm.D.
34	Smoking Deterrents	Damon, Ann R., Pharm.D.	Fincher, Deborah W., M.S., R.Ph.
35	Ulcer Drugs, PPIs	Fincher, Deborah W., M.S., R.Ph.	Avery, Mia, Pharm.D.
36	Urinary Antispasmodics	Avery, Mia, Pharm.D.	May, J. Russell (Rusty)
37	Vaginal Anti-Infectives	Avery, Mia, Pharm.D.	Rollins, Brent L., R.Ph., Ph.D.

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Georgia Department of Community Health

Goold Health Systems

Important Update
DCH Decision Document

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

EFFECTIVE July 1, 2015 (see chart below)

DCH rebate vendor Goold Health Systems (GHS) has reviewed SFY2016 supplemental rebate offers with DCH and reviewed the below drug categories at the March 2015 DURB meeting. The PDL decisions or PDL changes for new drugs or categories reviewed during the March DURB meeting are outlined below. Those drugs highlighted in red indicate a change from current PDL status. For a full listing of our PDL, go to www.dch.georgia.gov/pharmacy and select the "preferred product list" option.

ONLY DRUGS with Supplemental Rebate Offer or reviewed during the March DURB as either new to market or a change in PDL status are listed	PREFERRED AGENTS	NON-PREFERRED AGENTS
ADHD AGENTS – Strattera PDL status still under review		
	ADDERALL XR	PROCENTRA (ORAL) SOLUTION
	FOCALIN TAB, XR	
	INTUNIV TAB ER 24H	
	QUILLIVANT XR	
	VYVANSE	
ANALGESIC OPIOID ABUSE - Bunavail and Suboxone PDL status still under review		
		ZUBSOLV
ANALGESICS, OPIOID - LONG ACTING		
	BUTRANS PATCH TDWK	DURAGESIC PATCH TD72
		HYSINGLA ER TAB 24H
		OXYCONTIN TAB ER 12H
ANALGESICS, OPIOID- SHORT		
	IBUDONE	
	LORTAB SOLN 10-300/15	
ANDROGENS, ANABOLIC		
	ANDROGEL	
ANTICOAGULANTS		
	LOVENOX	ELIQUIS
		PRADAXA
		XARELTO
ANTICONVULSANTS		
	GABAPENTIN SOLN	APTIOM
	LYRICA CAPS	FELBATOL
	OXTELLAR XR	TROKENDI XR
	QUDEXY XR	
	TOPIRAMATE ER	
	VIMPAT	
ANTIDEPRESSANTS		
	BRINTELLIX	FETZIMA

ONLY DRUGS with Supplemental Rebate Offer or reviewed during the March DURB as either new to market or a change in PDL status are listed	PREFERRED AGENTS	NON-PREFERRED AGENTS
		PRISTIQ ER
		VIIBRYD
ANTIDIABETICS - INSULIN		
	HUMULIN 70-30 INSULN PEN	
	HUMULIN 70/30 KWIKPEN INSULN PEN	
	HUMULIN N KWIKPEN INSULN PEN	
	HUMULIN N INSULN PEN	
	HUMULIN R VIAL	
	HUMALOG CARTRIDGE	
	HUMALOG INSULN PEN	
	HUMALOG MIX 50-50 INSULN PEN	
	HUMALOG MIX 75-25 INSULN PEN	
	LANTUS	
	LANTUS SOLOSTAR	
ANTIDIABETICS - NON-INSULIN		
	BYDUREON (SUB-Q) VIAL	BYETTA (SUB-Q) PEN INJCTR
	JENTADUETO	CYCLOSET
	KOMBIGLYZE XR	FARXIGA
	ONGLYZA	INVOKAMET
	TANZEUM (SUB-Q) PEN INJCTR	INVOKANA
	TRADJENTA	JANUMET, XR TBMP 24HR
		JANUVIA
		JARDIANCE
		PRANDIMET
		TRULICITY (SUB-Q) PEN INJCTR
		VICTOZA (SUB-Q) PEN INJCTR
		XIGDUO XR
ANTIHEMOPHILIC PRODUCTS-vWF		
	WILATE KIT	
ANTIHYPERLIPIDEMICS		
	FENOFIBRATE CAP	COLESTIPOL GRAN, PKT
	VYTORIN	LIPTRUZET
		PREVALITE POWD PACK
		TRILIPIX
		ZETIA
ANTIHYPERTENSIVE, ANGIOTENSIN RECEPTOR BLOCKER-CCB COMBINATIONS INHIBITORS		
	AZOR	
	EXFORGE HCT	
	EXFORGE	
	TRIBENZOR	
ANTIHYPERTENSIVE, ANGIOTENSIN RECPTOR BLOCKERS		
	BENICAR	ATACAND
	BENICAR HCT	
	DIOVAN	
	IRBESARTAN	

ONLY DRUGS with Supplemental Rebate Offer or reviewed during the March DURB as either new to market or a change in PDL status are listed	PREFERRED AGENTS	NON-PREFERRED AGENTS
	IRBESARTAN-HYDROCHLOROTHIAZIDE	
	MICARDIS	
	MICARDIS HCT	
	VALSARTAN-HYDROCHLOROTHIAZIDE	
ANTIHYPERTENSIVES, BETA BLOCKERS		
		BYSTOLIC
ANTIINFECTIVES, MISCELLANEOUS		
		TINDAMAX
ANTI-INFLAM, NSAIDS		
	NAPROXEN ORAL SUSP	
ANTIPSYCHOTICS		
	LATUDA	ABILIFY MAINTENA
		INVEGA SUSTENNA
		SAPHRIS
ANTIVIRAL, HEPATITIS C AGENTS		
	HARVONI	OLYSIO
	SOVALDI	RIBAPAK
		VIEKIRA PAK
BIOLOGIC IMMUNOMODULATORS		
	ENBREL	OTEZLA
	HUMIRA	SIMPONI
		STELARA
		XELJANZ
BIOLOGICALS, MISC BIOLOGICS, MISCELLANEOUS (ALLERGEN IMMUNOTHERAPY)		
		GRASTEK
		RAGWITEK
BRONCHODILATOR, ANTICHOLINERGICS		
	COMBIVENT RESPIMAT	ANORO ELLIPTA
	IPRATROPIUM-ALBUTEROL (INH) AMPUL-NEB	INCRUSE ELLIPTA
	SPIRIVA RESPIMAT	TUDORZA PRESSAIR
BRONCHODILATOR, PDE4		
		DALIRESP
BRONCHODILATOR, STEROID INHALANTS		
	AEROSPAN HFA	ASMANEX HFA
	FLOVENT - DISKUS, HFA	
	PULMICORT FLEXHALER	
BRONCHODILATOR,SYMPATHOMIMETICS		
	BROVANA (INH) VIAL-NEB	ALBUTEROL SULFATE TABLET
		SEREVENT DISKUS
		STRIVERDI RESPIMAT
		VENTOLIN HFA
CALCIUM REGULATORS-OSTEOPOROSIS		
		BINOSTO
CORTICOSTEROIDS, ORAL		
	DEXPAK	
	PREDNISOLONE SOL 25MG/5ML	VERIPRED 20 (ORAL) SOLUTION

ONLY DRUGS with Supplemental Rebate Offer or reviewed during the March DURB as either new to market or a change in PDL status are listed	PREFERRED AGENTS	NON-PREFERRED AGENTS
DERM, ACNE PRODUCT (SULFONES)		
		ACZONE GEL
DERM, ANTI-INFLAMMATORY AGENTS		
		FLECTOR PATCH
DERM, ANTIPSORIATICS		
	TAZORAC CREAM, GEL	
DERMATOLOGICAL SCABICIDES AND PEDICULICIDES		
	NATROBA	ULESFIA
	SKLICE	
DIGESTIVE ENZYMES		
	CREON	PERTZYE
		ZENPEP
EPINEPHRINE PENS		
	EPIPEN	
ESTROGENS		
		EVAMIST SPR
FIBROMYALGIA AGENTS		
		SAVELLA
GROWTH HORMONE		
	GENOTROPIN	
	NORDITROPIN FLEXPRO, NORDIFLEX	
	NUTROPIN, -AQ, -PEN	
HEMATAPOIETIC,GROWTH FACTOR		
	PROCRIT	ARANESP
INFLAMMATORY BOWEL AGENTS		
	APRISO	LIALDA
	PENTASA 250MG	SFROWASA
	PENTASA 500MG	UCERIS
IRRITABLE BOWEL SYNDROME AGENTS		
		LINZESS
MIGRAINE PRODUCTS		
	RELPAX	
MULTIPLE SCLEROSIS AGENTS		
	AMPYRA	BETASERON
	AVONEX	COPAXONE
	EXTAVIA	PLEGRIDY
	TECFIDERA	
MULTIVITAMINS, PRENATAL		
	CONCEPT OB CAPSULE	CALCIUM PNV
	PRENATE AM	CITRANATAL 90 DHA COMBO. PKG 90-1-300MG
	PRENATE CHEWABLE	CITRANATAL ASSURE COMBO. PKG
	PRENATE DHA CAPSULE 18-1-300MG	CITRANATAL DHA COMBO. PKG
	PRENATE DHA 28-1-300MG	CITRANATAL HARMONY CAPSULE
	PRENATE ELITE	CONCEPT DHA CAPSULE
	PRENATE ENHANCE	NATELLE ONE CAPSULE

ONLY DRUGS with Supplemental Rebate Offer or reviewed during the March DURB as either new to market or a change in PDL status are listed	PREFERRED AGENTS	NON-PREFERRED AGENTS
	PRENATE ESSENTIAL 18-1-300MG	NESTABS ABC COMBO. PKG
	PRENATE MINI	OB COMPLETE 400 CAPSULE
	PRENATE PIXIE	OB COMPLETE ONE CAPSULE
	PRENATE RESTORE CAPSULE	OB COMPLETE PETITE CAPSULE
	PRENATE STAR TABLET	OB COMPLETE WITH DHA CAPSULE
	PROVIDA OB CAPSULE	TRICARE PRENATAL COMPLEAT CMB TAB CP
	VITAFOL	VIRT-PN PLUS CAPSULE
		VITAFOL ULTRA CAPSULE
		VITAFOL-ONE CAPSULE
		ZATEAN-PN PLUS CAPSULE
NASAL STEROIDS		
		BECONASE AQ (NASAL) SPRAY
		QNASL (NASAL) HFA AER AD
OPHTHALMICS, ADRENERGIC AGENTS		
	SIMBRINZA	ALPHAGAN P
OPHTHALMICS ANTIALLERGICS		
	PATADAY	LASTACAFT DROPS
OPHTHALMICS ANTIBIOTIC STEROID COMBINATIONS		
	TOBRADEX	
OPHTHALMICS, ANTIINFLAMMATORY DRUGS		
	DUREZOL	LOTEMAX GEL, OINT
	ILEVRO	NEVANAC
		PROLENSA
OPHTHALMICS ANTIINFECTIVES		
	BACITRACIN OINT.	BESIVANCE
	MOXEZA	
	VIGAMOX	
	ZYMAXID	
OPHTHALMICS BETA BLOCKERS		
	COMBIGAN 5ML	COMBIGAN 10ML
OPHTHALMICS PROSTAGLANDINS		
	TRAVATAN Z	LUMIGAN
		TRAVOPROST
OTIC ANTIINFECTIVES		
		CIPRODEX
PLATELET AGGREGATION INHIBITORS		
	BRILINTA	ZONTIVITY
PULMONARY HYPERTENSION DRUGS		
	ADCIRCA	OPSUMIT
	LETAIRIS	ORENITRAM ER
	TRACLEER	
SMOKING DETERRENTS		
		CHANTIX
URINARY ANTISPASMODICS		
	TOVIAZ	MYRBETRIQ
	VESICARE	

ONLY DRUGS with Supplemental Rebate Offer or reviewed during the March DURB as either new to market or a change in PDL status are listed	PREFERRED AGENTS	NON-PREFERRED AGENTS
URINARY PROSTATIC HYPERTROPHY		
	ALFUZOSIN HCL ER	AVODART
VAGINAL ANTI-INFECTIVES		
	GYNAZOLE-1 CRE	CLINDESSE CRE

Manufacturers' Forum
Manufacturer Presentations

Dates: April 30, 2015

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

Attendees
Department of Community Health
Turkesia Robertson-Jones, PharmD, Interim Director, Pharmacy Services

NorthStar HealthCare Consulting
Tara R. Cockerham, PharmD, Clinical Programs Director
Emily Baker, PharmD, BCPS, MBA, MHA, President

Catamaran
Talmahjia "Tami" Sweat, PharmD, Director, Clinical Management-Public Sector

Drug Summary Documents
Please note that relevant, electronic materials that were provided by manufacturers were forwarded to the Drug Utilization Review Board (DURB). 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. Genzyme
Judy Hull, MS, CGC, Senior Medical Science Liaison
Vince Lawler, Government Market Director

Cerdelga® (eliglustat)
Gaucher disease is a rare autosomal recessive lysosomal glycolipid storage disorder affecting 1 in 57,000 live births in the general population, and 1 in 850 among those of Ashkenazi Jewish descent. It is caused by a deficiency of acid beta glucosidase and results in accumulation of the substrate, glucosylceramide, in the lysosomes of cells in the liver, spleen, bones, lungs and other vital tissues. Clinical hallmarks of Type 1 Gaucher disease include enlargement of the liver and spleen, hematologic abnormalities, displacement of normal bone marrow by lipid-engorged cells and bone damage leading to bone infarctions and fractures. Patients with Gaucher disease type 1 may have diminished life span as well as diminished quality of life. Note that improvement of bone and lung manifestations and quality of life are outside of the approved labeling for Cerdelga.

There are currently two approved therapeutic approaches to treating Gaucher disease type 1. Enzyme replacement therapy (ERT) has been commercially available since 1991. Cerdelga (eliglustat), a substrate reduction therapy, was approved in August of 2014. Cerdelga can be used as a first-line treatment as the FDA labeled indication is for the long-term treatment of adult patients with Gaucher disease type 1 who are CYP2D6 extensive metabolizers (EMs), intermediate metabolizers (IMs), or poor metabolizers (PMs) as detected by an FDA-cleared test. Limitations of use are as follows: Patients who are CYP2D6 ultra-rapid metabolizers (URMs) may not achieve adequate concentrations of Cerdelga to achieve a therapeutic effect, and a specific dosage cannot be recommended for those patients whose CYP2D6 genotype cannot be determined (indeterminate metabolizers). The FDA-approved product labeling is available online at www.cerdelga.com.

In Genzyme's phase III, randomized placebo-controlled trial of Cerdelga in untreated adult patients with Gaucher disease type 1, Cerdelga was shown to reduce mean spleen volume (primary endpoint) by 27.77% (95% CI, −32.57% to −22.97%). In the placebo group, mean spleen volume increased by 2.26% (95% CI, −2.54% to 7.06%). The absolute treatment difference between the Cerdelga and placebo group was −30.03% (95% CI, −36.82% to −23.24%;

P <0.001). Liver volume decreased in the Cerdelga group (−5.2%) and increased in the placebo group (+1.4%) for an absolute treatment difference of −6.64% (95% CI, −11.37% to −1.91%; P = 0.007). Mean hemoglobin level increased in the Cerdelga group (+0.69 g/dL) and decreased in the placebo group (−0.54 g/dL) resulting in an absolute treatment difference of 1.22 g/dL (95% CI, 0.57 to 1.88 g/dL; P < 0.001). Mean platelet count increased in the Cerdelga group (+32.0%) and decreased in the placebo group (−9.1%), resulting in an absolute treatment difference of 41.06% (95% CI, 23.95% to 58.17%; P < 0.001).

A phase III randomized, controlled open-label non-inferiority study was also conducted to compare Cerdelga to Cerezyme® (imiglucerase for injection) in patients who had received ERT for at least three years and who had attained therapeutic goals. The primary composite endpoint required stability in all four component domains (hemoglobin level, platelet count, liver volume, and spleen volume). Stability was based on pre-defined thresholds for change between baseline and 12 months. One hundred and forty six patients completed the one year primary analysis period. Eight-five percent (84/99) of patients from the Cerdelga arm and 94% (44/47) of patients from the Cerezyme arm met the primary composite endpoint. The between group difference was –8.8% (95% CI –17.6 to 4.2%). The lower bound of the 95% confidence interval was within the pre-specified non-inferiority margin of –25%; therefore, Cerdelga met the criteria to be declared non-inferior to Cerezyme in maintaining patient stability.

Metabolic phenotype is important for both patient selection for Cerdelga and for the management of drug-drug interactions. Cerdelga is available in 84 mg capsules. The dose for extensive and intermediate CYP2D6 metabolizers is one capsule two times daily. For poor metabolizers, the dose is one capsule once per day. Co-administration of Cerdelga with drugs that inhibit CYP2D6 and CYP3A may significantly increase the exposure to the drug and may result in prolongation of the PR, QTc, and/or QRS cardiac interval, which could result in cardiac arrhythmias. Therefore, Cerdelga is contraindicated in CYP2D6 EMs and IMs taking a strong or moderate CYP2D6 inhibitor with a strong or moderate CYP3A inhibitor, and in CYP2D6 IMs and PMs taking a strong CYP3A inhibitor. Cerdelga is not recommended in patients with pre-existing cardiac disease, long QT syndrome, and in combination with Class IA and Class III anti-arrhythmics. For individuals taking concomitant medications that are also metabolized by CYP2D6 or CYP3A4, a dosage adjustment may be necessary.

The most common adverse reactions to Cerdelga (occurring in ≥10% of the 126 GD1 patients treated with Cerdelga across the two registration trials mentioned) were fatigue, headache, nausea, diarrhea, back pain, pain in extremities, and upper abdominal pain.

In summary, treatment of naïve adult Gaucher type 1 patients with Cerdelga significantly improves thrombocytopenia and anemia, reduces spleen volume, and reduces liver volume. Cerdelga was also shown to be non-inferior to imiglucerase in maintaining stability in patients who have reached therapeutic goals with enzyme replacement therapy.

Questions and Answers
Q: How many patients did not achieve the primary endpoint in the study of eliglustat vs. imiglucerase?
A: 12 in the eliglustat arm and 3 in the imiglucerase arm.

Q: Have physicians been comfortable with 2D6 interactions?
A: Hematologists are comfortable prescribing with the 2D6 interactions and Cerdelga provides a non-intravenous administration option.

Cerezyme® (imiglucerase)
Gaucher disease is an autosomal recessive lysosomal glycolipid storage disorder affecting about 1 in 57,000 live births in the general population, and 1 in 850 among those of Ashkenazi Jewish descent. It is caused by a deficiency of glucocerebrosidase and results in accumulation of the substrate, glucoslyceramide. Clinical hallmarks of Type 1 Gaucher disease include enlargement of the liver and spleen, hematologic abnormalities, displacement of normal bone marrow by lipid-engorged cells and bone damage leading to bone infarctions and fractures. At diagnosis, 42% of children are below the 5th percentile for height.

Enzyme replacement therapy with Cerezyme® (imiglucerase for injection) has been the standard of care for patients with Type 1 Gaucher disease since its approval in 1994. Cerezyme and other commercially available enzyme replacement products are considered similar, but they are not identical. Genzyme uses the industry standard, CHO cells, to produce Cerezyme. CHO cell-based therapeutics have been in use globally over the last 24 years and are currently used in the production of nearly 70% of all recombinant therapeutic proteins. Cerezyme's genetic sequence for glucocerebrosidase differs from the wild-type sequence by one amino acid at position 495, where histidine is

substituted for arginine. Cerezyme uses a unique method of altering glycosylation to facilitate uptake into Gaucher cells.

In Genzyme's pivotal trial of Cerezyme, at 9 months Cerezyme treatment was shown to reduce hepatomegaly by a mean of 21.4% (95% CI, -9.8% to -44.3%) and splenomegaly by 47.1% (95% CI, -22.5% to -69.6%).9 Hemoglobin increased by a mean of 2.5 g/dL (95% CI 0.4 to 5.8 g/dL), and platelets increased by a mean of 43.5 x 109/L (95% CI -6.3 to 95 x 109/L). In this double-blind, randomized parallel trial, in a 1:1 ratio, 30 naïve patients received either Cerezyme or Ceredase® (alglucerase), a placentally-derived enzyme replacement therapy and Genzyme's first approved product for the treatment of Gaucher disease Type 1. Ceredase's genetic sequence does not differ from the wild-type sequence. In this study, there were no statistically significant differences seen between Ceredase and Cerezyme in the rate or extent of improvement in Gaucher symptoms.

The ICGG Gaucher Registry, initiated in 1991 and supported by Genzyme, is a voluntary observational database of clinical, biochemical, and therapeutic characteristics of patients with GD, regardless of disease severity and treatment status. It is supervised by a collaborative group of international physician experts in Gaucher Disease. Outcomes data discussed from the Gaucher Registry are specific to Cerezyme. A study of 1028 Gaucher patients enrolled in the Gaucher Registry demonstrated statistically significant improvements in mean values for hematologic and visceral parameters as well as decreases in bone pain and bone crisis for patients receiving Cerezyme for 2-5 years. A study evaluating 757 patients (including 200 who were splenectomized) participating in the Gaucher Registry long-term showed that after 10 years, significant ($p<0.05$) improvements were seen in mean hemoglobin levels, platelet count, liver and spleen (non-splenectomized) volumes, and bone crises. A study of 884 children enrolled in the Gaucher Registry and treated with Cerezyme for 8 years also demonstrated improvements in Gaucher symptoms. The median height z-score for the study population was -1.4 at baseline and improved to -0.3 after 8 years of Cerezyme, which approaches the median for the general pediatric population. Median spleen size at baseline was 23 multiples of normal (MN) and improved to 4.3 MN. The median liver volume was 2.0 MN at baseline and 1.1 MN after 8 years of Cerezyme.

Cerezyme impacts bone disease in type 1 Gaucher disease. It has been shown to improve bone pain as early as 3 months after starting therapy, decrease bone crisis within 12 months and significantly improve bone mineral density in the lumbar spine after 24 months. Long-term studies of Cerezyme use in the Gaucher registry show a decrease in the incidence of osteonecrosis.

The adverse event profile for Cerezyme is based on greater than 20 years of clinical experience. Approximately 13.8% of patients experienced adverse events related to Cerezyme. Symptoms suggestive of hypersensitivity have been reported in approximately 6.6% of all patients treated with Cerezyme. Onset of such symptoms has occurred during or shortly after infusions; these symptoms include pruritus, flushing, urticaria, angioedema, chest discomfort, dyspnea, coughing, cyanosis, and hypotension. Anaphylactoid reaction has been reported in less than 1 % of the total patient population.

In summary, in adults and children with Gaucher disease type 1, treatment with Cerezyme significantly improves hematologic abnormalities, reduces spleen volume, reduces liver volume, increases lumbar spine BMD to near-normal levels, reduces frequency of bone crises and bone pain and accelerates growth velocity in children with growth retardation due to Gaucher disease type 1.

Questions and Answers
There were no additional questions and answers.

II. Shire
Laura T. Smith, PhD, Senior Medical Science Liaison
Candace N. Brown, PharmD, Medical Science Liaison
Darlene Bitel, Director, Government Affairs

Vyvanse® (lisdexamfetamine)
Vyvanse [*Vī' - vănse*], lisdexamfetamine (lis-dex-am-FET-a-meen) dimesylate, is a schedule II medication with a black box warning stating that CNS stimulants have a high potential for abuse and dependence, and that the risk of abuse should be assessed prior to prescribing. Signs of abuse and dependence should be monitored while on therapy.

Vyvanse is indicated for the treatment of ADHD in patients six years and older. In January, Vyvanse received FDA-approval for the treatment of moderate to severe binge eating disorder in adults. It is important to note that Vyvanse has a limitation of use: Vyvanse is not indicated or recommended for weight loss. Use of other sympathomimetic drugs for weight loss has been associated with serious cardiovascular adverse events. The safety and effectiveness of Vyvanse for the treatment of obesity have not been established.

Vyvanse is contraindicated in patients with a known hypersensitivity to amphetamine products or other ingredients in Vyvanse, and with concurrent administration of monoamine oxidase inhibitors (MAOI) or administration of Vyvanse within 14 day of the last MAOI dose; hypertensive crisis can occur.

In May of 2013, BED was recognized as a distinct eating disorder in the newly released DSM-5. A diagnosis for BED can be made when an individual fulfills criterion A – E:

- Criterion A: Recurrent episodes of binge eating characterized by both of the following: consuming an abnormally large amount of food in a short period of time compared with what others might eat in the same amount of time under the same or similar circumstances and experiencing a loss of control over eating during the episode.
- Criterion B: Binge eating episodes are associated with > 3 of the following: consuming food faster than normal, consuming food until uncomfortably full, consuming large amounts of food when not hungry, consuming food along due to embarrassed over how much one is eating.
- Criterion C: Overall, there is significant distress about the binge eating.
- Criterion D: The binge eating occurs, on average, at least once a week for 3 months.
- Criterion E: The binge eating is not associated with the regular inappropriate compensatory behavior associated with bulimia nervosa and does not occur solely during an episode of bulimia nervosa or anorexia nervosa.

The estimated 12-month prevalence of adults with BED in the U.S. is 1.2%. BED can occur in normal weight, overweight, and obese adults. Epidemiological data show that 55% of BED patients are not obese (BMI <30) and in fact, 19% are normal weight (BMI 18.5-24.9). It is important to note that drug treatment is not indicated for all adult patients with BED.

The efficacy and safety of Vyvanse for BED were evaluated in 2 identically designed phase 3, 12-week, placebo-controlled studies enrolling over 700 adults aged 18-55 with moderate to severe BED based on DSM-IV criteria. Subjects had at least 3 binge days per week for 2 weeks prior to baseline, and a Clinical Global Impression-Severity score of 4 or more. The primary efficacy outcome was change in the number of binge days per week from baseline to week 12.

Vyvanse demonstrated a statistically significant greater reduction in least squares mean number of binge days per week compared to placebo. Subjects on Vyvanse went from approximately 5 binge days per week at baseline to less than 1 binge day per week at week 12.

The most common adverse reactions reported in the Vyvanse arm were dry mouth, insomnia, decreased appetite, increased heart rate, constipation, feeling jittery, and anxiety.

The recommended starting dose of Vyvanse for moderate to severe BED in adults is 30mg/d with target doses of 50-70 mg/d.

Questions and Answers

Q: What is the usual treatment duration?
A: Varies depending on patient but mean is 8 years.

Q: Any inclination of when the treatment guidelines will be updated?
A: Not yet.

Q: What are criteria for other states so far?
A: Indication, DSM-5 criteria met and 18 years of age and older but not requiring trial of other medication since Vyvanse is the only FDA-approved medication.

Q: Any safety that differed in BED patients vs. ADHD patients?
A: Constipation was $\geq$5% in BED studies but not in ADHD studies.

VPRIV® [Vee-PRIV] (velaglucerase alfa for injection) [VEL-a-GLOO-ser-ase Al-fa]

Indication: VPRIV (velaglucerase alfa for injection) is a hydrolytic lysosomal glucocerebroside-specific enzyme indicated for long-term enzyme replacement therapy (ERT) in pediatric and adult patients with type 1 Gaucher disease.

Dosage and administration: (1) VPRIV should be administered under the supervision of a healthcare professional. **(2)** Therapy-naïve patients 4 years and older: 60 U/kg administered every other week (QOW) as a 60 minute intravenous infusion. **(3)** 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. **(4)** Physicians can make dosage adjustments based on achievement and maintenance of each patient's therapeutic goals.

Warnings and Precautions: **(1)** Hypersensitivity reactions, including anaphylaxis, were the most commonly observed adverse reactions in clinical studies with VPRIV. The most commonly observed symptoms of hypersensitivity reactions were: headache, dizziness, hypotension, hypertension, nausea, fatigue/asthenia, and pyrexia. Generally the 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. **(2)** As with any intravenous protein product, hypersensitivity reactions are possible, therefore appropriate medical support should be readily available when VPRIV is administered. If anaphylactic or other acute reactions occur, immediately discontinue the infusion of VPRIV and initiate appropriate medical treatment. **(3)** The management of hypersensitivity 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 patients exhibited symptoms of hypersensitivity. Patients were not routinely pre-medicated prior to infusion of VPRIV during clinical studies.

Clinical Studies

Study 032 (Study 1 in package insert): (1) 12-month, randomized, double-blind, parallel-dose-group, multinational, phase III clinical trial in patients with Type 1 Gaucher disease. **(2)** 25 treatment-naïve patients age 4 years and older with Gaucher disease-related anemia and either thrombocytopenia or organomegaly. **(3)** Patients were randomized to receive VPRIV at a dose of either 45 U/kg (N=13) or 60 U/kg (N=12) QOW. **(4)** Primary endpoint: Efficacy of VPRIV 60 U/kg IV QOW as measured by mean change from baseline in hemoglobin (Hgb) concentration. **(5)** VPRIV 60 U/kg IV QOW achieved the primary endpoint with a clinically and statistically significant improvement in mean Hgb concentration (+2.43 g/dL; $P<0.001$).

Study 039 (Study 2 in package insert): (1) 9-month, randomized, double-blind, active-controlled (imiglucerase), multinational, phase III clinical trial in patients with Type 1 Gaucher disease. **(2)** 34 treatment-naïve patients age 4 years and older with Gaucher disease-related anemia and either thrombocytopenia or organomegaly. **(3)** Patients were randomized to receive 60 U/kg of either VPRIV (N=17) or imiglucerase (N=17). **(4)** Primary endpoint: Mean change in Hgb concentration from baseline to 9 months. **(5)** Results: The mean increase in Hgb after 9 months (ITT population) was +1.624 g/dL for VPRIV and +1.488 g/dL for imiglucerase group.

Study 034 (Study 3 in package insert): (1) 12-month, open-label, single-arm, multinational, phase II/III clinical trial in patients with Type 1 Gaucher disease. **(2)** 40 patients age 9 years and older who had been receiving imiglucerase at doses ranging from 15 Units/kg to 60 Units/kg for a minimum of 30 consecutive months; patients were also required to have a stable biweekly dose of imiglucerase for at least 6 months prior to enrollment. **(3)** Treatment with VPRIV was administered QOW at the same number of units/kg as the previous imiglucerase dose. **(4)** Primary endpoint: Evaluate the safety of VPRIV 15-60 U/kg QOW over 12 months in patients previously treated with imiglucerase. **(5)** Results: The most frequently reported adverse events (AEs) were headache (12/40); arthralgia (9/40); and nasopharyngitis (8/40). Most AEs were mild to moderate in severity. Seven severe AEs were reported in five patients, none of which were deemed related to VPRIV. **(6)** Hemoglobin and platelet counts remained stable through 12 months of VPRIV treatment. 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).

Study 044 (Study 4 in package insert): (1) Treatment-naïve patients and patients who had previously received imiglucerase treatment from studies 032 and 034 were administered VPRIV. **(2)** Treatment-naïve patients continued to show improvements in clinical parameters (hemoglobin concentration, platelet count, liver volume, and spleen volume) compared with baseline for up to 60 months. **(3)** Patients who had previously been receiving imiglucerase treatment maintained stability in clinical parameters (hemoglobin concentration, platelet count, liver volume, and spleen volume) compared with baseline for up to 60 months.

Safety: (1) The most commonly reported adverse reactions that were considered related to VPRIV in clinical trials and occurring in ≥10% of patients were: hypersensitivity reaction, headache, dizziness, pyrexia, abdominal pain, back pain, joint pain (knee), asthenia/fatigue, activated partial thromboplastin time (aPTT) prolonged, and nausea**. (2)** 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).

Special Populations: (1) Pregnancy: Category B **(2) Nursing Mothers:** It is not known whether VPRIV is excreted in human milk. **(3) Pediatric Use:** The safety and effectiveness of VPRIV have been established in patients between 4 and 17 years of age. Use of VPRIV in this age group is supported by evidence from adequate and well-controlled studies of VPRIV in adults and pediatric [20 of 94 (21%)] patients. Adverse reactions more commonly seen in pediatric patients compared to adult patients (>10% difference) include rash, aPTT prolonged, and pyrexia. **(4) Geriatric Use:** During clinical studies, 56 patients aged 65 or older were treated with VPRIV. The adverse reaction profile in elderly patients was consistent with that of pediatric and adult patients. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be approached cautiously, considering potential comorbid conditions.

Questions and Answers
Q: Does ERT require some enzyme activity?
A: Enzyme replacement therapy (ERT) does not require some enzyme activity as substrate replacement therapy (SRT) does.

III. Bristol-Myers Squibb

Barbara Jacob-Mungin, PhD, Medical Science Liaison
Mohammed A. Omar, PhD, RPh, Director, Health Economics & Outcomes Research
Greg A. Martin, MBA, State Access Manager

Atripla (uh-TRIP-luh)® (efavirenz[eff-ah-VYE-renz]/emtricitabine[em tri SIT uh bean] /tenofovir disoproxil fumarate[teh-NOE-foh-veer DYE-soe-PROX-il FUE-ma-rate]; EFV/FTC/TDF)
Updated data from phase 3 clinical data that compared ATRIPLA (or its components) to other ARV agents and regimens:
Study 102: Elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate (EVG/cobi/FTC/TDF) was non-inferior to efavirenz/emtricitabine/tenofovir (EFV/FTC/TDF) in treatment naive patients in Study 102: 75% on EFV/FTC/TDF vs. 80% on EVG/cobi/FTC/TDF at week 144 (by Snapshot analysis). At week 144:

- Protocol-Defined Virologic Failure Rates: EFV/FTC/TDF 10%, EVG/cobi/FTC/TDF 7.0%
- Resistance mutations were found in 14 of 28 EFV/FTC/TDF-treated and in 10 of 21 EVG/cobi/FTC/TDF-treated patients. A total of 13 EFV/FTC/TDF-treated patients had the resistance mutation K103N, and 4 had nucleoside reverse transcriptase inhibitor (NRTI) resistance mutations. A total of 9 EVG/cobi/FTC/TDF-treated patients had integrase resistance mutations, and all 10 had NRTI resistance mutations.
- Discontinuation of treatment due to adverse events (AEs): EFV/FTC/TDF 7.4%, EVG/cobi/FTC/TDF 6.0%
- The frequencies of AEs occurring in ≥ 1 subject in either treatment arm cumulatively through week 144 and leading to study drug discontinuation in the EVG/cobi/FTC/TDF and EFV/FTC/TDF arms respectively included renal abnormalities (2.2%[with proximal renal tubulopathy (1.1%)], and 0%), depression (0.3% and 1.4%), fatigue (0.3% and 0.6%), abnormal dreams (0% and 0.6%), anxiety (0% and 0.6%), insomnia (0% and 0.6%), and rash events and hypersensitivity (0% and 1.4%).

SINGLE: Dolutegravir + abacavir sulfate/lamivudine (DTG + ABC/3TC) was shown to be statistically superior to EFV/FTC/TDF on virologic response rate by Snapshot analysis in treatment naive patients in the SINGLE Study. This was driven primarily by an increased rate in discontinuations due to adverse events in the EFV/FTC/TDF arm. After week 96, the study was extended to week 144 in an open label fashion. At week 144:

- Virologic response rates were 63% and 71% for EFV/FTC/TDF and DTG + ABC/3TC, respectively.
- Protocol-defined virologic failure rates: 8% in the EFV/FTC/TDF arm, and 9% in the DTG + ABC/3TC arm.
- Resistance Data: In the EFV/FTC/TDF arm, a total of 1 patient developed an NRTI resistance mutation, and 6 patients developed NNRTI resistance mutations. In the DTG + ABC/3TC arm, no resistance mutations were detected.
- Discontinuation of treatment due to AEs through week 144: 14% for EFV/FTC/TDF and 4% for DTG + ABC/3TC.

- Adverse Events (all grades) reported in > 5% of patients in either arm for DTG + ABC/3TC and EFV/FTC/TDF respectively: dizziness (7% and 33.2%), abnormal dreams (7%, 16.2%), nausea (11.2%, 12%), insomnia (10%, 6.7%), diarrhea (6%, 8%), fatigue (7%, 7%), headache (6%, 7%), rash (<1%, 8%).

Data on the association of suicidality with efavirenz is available from 4 analyses:

- A cross-study analysis of 4 AIDS Clinical Trials Group studies showed that EFV-containing regimens were associated with a 2-fold higher hazard of suicidality compared to EFV-free regimens (hazard ratio [HR] 2.28, P = .006)
- A study utilizing the U.S. FDA Adverse Event Reporting System database to assess the potential association of 6 antiretroviral (ARV) drugs, including EFV, with suicidality was conducted. The data showed that the predefined thresholds for signals of suicidality were not exceeded for EFV, using a drug-event pair disproportionality analysis. 5
- A retrospective cohort study examining data from a commercial insurance and Medicaid database for patients ≥ 12 years of age with at least one medical claim with an ICD-9-CM diagnosis code for HIV infection showed no observed evidence for an increased risk of suicidality (suicidal ideation and attempted suicide) among patients taking an EFV-containing regimen vs. those taking an EFV-free regimen [adjusted HR: 1.03 (commercial database), 0.90 (Medicaid database)].
- An observational cohort study analyzing data collected from the Data Collection on Adverse Events of Anti-HIV Drugs (D:A:D) cohort showed that rates of death from suicide were similar in patients receiving EFV-based ART compared to other regimens.

Cost-Effectiveness analysis: An individual discrete-event simulation model, using 2014 WAC pricing was developed based on the SINGLE trial to evaluate the long-term cost-effectiveness of DTG+ABC/3TC versus EFV/TDF/FTC regimens from a US payer perspective. Base-case results indicated that over a lifetime, DTG+ABC/3TC increases costs by $19,153 and provides an incremental benefit of 0.12 quality-adjusted life years (QALYs) compared to EFV/TDF/FTC, resulting in an ICER of $158,890, well above the standard willingness-to-pay threshold of $50,000. ICERs comparing DTG+ABC/3TC to EFV/TDF/FTC across multiple scenarios exceed standard cost-effectiveness thresholds, indicating that the incremental benefit in efficacy associated with DTG+ABC/3TC may not be worth the incremental increase in costs. In the scenario looking at the newly available DTG/ABC/3TC single tablet regimen, the ICER drops to $70,945 due to lower pricing of the STR. However, based on a $50,000/QALY threshold, which remains the default willingness-to-pay threshold in the US, DTG/ABC/3TC is not sufficiently cost-effective.

Questions and Answers
There were no additional questions and answers.

Evotaz™ (EV-oh-taz) (atazanavir [A-ta-ZAN-a-vir] 300 mg and cobicistat [koe-bik'-i-stat] 150 mg)
INDICATIONS AND USAGE
EVOTAZ is a fixed-dose combination tablet containing atazanavir (ATV), a protease inhibitor (PI) and a pharmacoenhancer, cobicistat (COBI), indicated in combination with other antiretroviral agents for the treatment of human immunodeficiency virus (HIV-1) infection in adults. Use of EVOTAZ in treatment-experienced patients should be guided by the number of baseline primary protease inhibitor resistance substitutions.

CLINICAL EVIDENCE
EVOTAZ is the only PI pharmacoenhanced by cobicistat that is supported by comparative Phase III clinical trial data, with safety and efficacy shown up to 144 weeks.
Study 114, GS-US-216-0114, is a randomized, double-blind, active-controlled study of EVOTAZ in combination with emtricitabine/tenofovir disoproxil fumarate (FTC/TDF), in HIV-1 infected treatment-naive patients through 144 weeks.
Efficacy Data: ATV pharmacoenhanced with COBI (ATV/c) demonstrated high rates of virologic suppression through 144 weeks. ATV/c was noninferior to ATV pharmacoenhanced with ritonavir (ATV/r) for both the primary efficacy endpoint (HIV-1 RNA <50 copies/mL at Week 48) (85.2% vs 87.4%, [95% CI, -7.4 to 3.0], respectively) and for the secondary endpoint (HIV-1 RNA <50 copies/mL at Week 144) (72% vs 74% [95% CI, -8.7 to 4.5]).

- At Week 48, virologic failure occurred in 6% of patients in the ATV/c groups and 4% of the patients in the ATV/r group. No patient in either arm developed a primary PI resistance mutation. Two patients developed a nucleoside reverse transcriptase inhibitor (NRTI) resistance mutation (M184V/I) in the ATV/c group and no NRTI resistance mutations were reported in the ATV/r group.
- At Week 144, virologic failure occurred in 8% of patients in the ATV/c group and 5% in the ATV/r group. In total through Week 144, 4 patients developed NRTI resistance mutations in the ATV/c arm (V1181, n=1; M184V/I, n=3)

and 1 patient developed an NRTI resistance mutation in the ATV/r arm (M184V/I, n = 1). No patient in either arm developed any primary PI mutations.

Safety Data: At Week 48 in a pooled analysis of Phase 2 and 3 trials, Study 105 and 114, adverse reactions (AEs) (Grades 2−4) occurring, in at least 2% of the patients in the ATV/c group, were jaundice 5%, ocular icterus 3%, nausea 2%, rash 5% and in the ATV/r group were jaundice 3%, ocular icterus 1%, nausea 2% and rash 4%.

- ATV/c had a comparable safety profile versus ATV/r, demonstrating similar rates of discontinuations due to AEs (7.3% vs 7.2%, respectively).
- Hyperbilirubinemia (Grades 3-4) was the most common laboratory abnormality observed at Week 48 in both the ATV/c and ATV/r groups (65.3% vs 56.5%, respectively). The rates of discontinuation due to elevated bilirubin-related adverse events were low and similar between groups (3.5% and 3.2% in the ATV/c and ATV/r groups, respectively).
- At Week 144, AEs (all grades) occurring in ≥10% of patients in either treatment group, ATV/c versus ATV/r, were jaundice (22% vs 17% , respectively), ocular icterus (19% vs 21%), hyperbilirubinemia (13% vs 11%), nausea (19% vs 19%), diarrhea (22% vs 28%), headache (15% vs 20%), nasopharyngitis (15% vs 21%), and upper respiratory tract infection (16% vs 18%).
- At Week 144, 6 patients (1.7%) in the ATV/c arm and 5 patients (1.4%) in the ATV/r arm discontinued study drug due to renal abnormalities (5 patients in the ATV/c arm and 2 patients in the ATV/r arm discontinued due to proximal tubulopathy). Of those with follow-up data available, all 4 patients in the ATV/c arm and 2 in the ATV/r arm experienced improvement in their renal laboratory values after discontinuing treatment.

Study 118, GS-US-236-0118, NCT01363011, was a single arm, open-label Phase 3 trial assessing the renal safety of COBI in HIV patients with mild to moderate renal impairment at baseline, (CrCl 50-89 ml/min) (N = 73) following a switch from ritonavir (RTV). Patients continued on their ATV or darunavir + 2 NRTI regimen. Eligible patients were virologically suppressed on the RTV regimen (HIV-1 RNA < 50 c/mL > 6 months).

- A switch from RTV to COBI was well tolerated through Week 48 in HIV patients with mild to moderate renal impairment (Creatinine Clearance (CrCl) 50-89 mL/min), who were suppressed on a PI containing regimen.10 Small changes in CrCl were observed. The decreases were smaller in patients with CrCl <70 mL/min at baseline (-1.1 mL/min) compared to patients with baseline CrCl >70 mL/min (-6.6 mL/min). There was no change in Cystatin C-based eGFR and actual GFR using iohexol clearance at Weeks 24 and 48, respectively.
- After switching, a viral load of <50 copies/mL at Week 48 (secondary endpoint) was maintained by 82% of patients (ITT). Two patients had virologic failure, of which 1 discontinued due to lack of efficacy with HIV-1 RNA ≥ 50 c/mL at Week 48 and 1 was resuppressed by Week 60. Resistance did not develop to any components of the PI plus COBI containing regimen.

Pharmacokinetic Data:

- In an intensive pharmacokinetic (PK) sub-study of Study 114, ATV PK parameters, AUC, Cmax, and Cmin, were comparable when given with COBI compared to RTV in HIV-1 infected patients with a FTC/TDF backbone.
- An FDC of ATV/COBI demonstrated bioequivalent ATV levels compared with ATV and COBI coadministered as individual agents under fed conditions in an open label, single dose crossover study in healthy subjects.

Questions and Answers

Q: What are thoughts on recent guideline update?

A: BMS Virology has put together response on totality of data on atazanavir (Reyataz) and stands behind product. The guidelines noted hyperbilirubinemia only from one study but all data and other studies show a decrease in bilirubin.

IV. Eisai

Keith W. Kerstann, PhD, Medical Science Liaison

Akynzeo® (netupitant/palonosetron)

AKYNZEO (netupitant/palonosetron) is an oral fixed combination of two antiemetic agents—netupitant, a substance P/neurokinin 1 receptor antagonist (NK1 RA), and palonosetron, a serotonin 3 receptor antagonist (5HT3 RA). Both netupitant and palonosetron are anti-nausea and anti-emetic agents. AKYNZEO is the first fixed combination antiemetic approved by the FDA.

AKYNZEO is indicated for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy.

Each AKYNZEO capsule contains three tablets each containing 100 mg netupitant and one gelatin capsule containing 0.50 mg palonosetron. One AKYNZEO capsule should be administered approximately 1 hour prior to the start of chemotherapy.

CINV remains one of the most distressing symptoms associated with cancer therapy and patients consider CINV as one of the most troubling side effects of such treatment. Prevention of CINV is an important component of supportive care for patients receiving cytotoxic chemotherapy. Inadequately controlled CINV can significantly impair a patient's quality of life (QOL), increase medical costs and the use of health care resources, and lead to poor compliance with further chemotherapy.

Despite considerable progress in recent years, prevention of delayed CINV, specifically delayed nausea, remains a challenge. The incidence and severity of CINV are frequently underestimated by health care providers, particularly delayed CINV and adherence to evidence-based antiemetic guidelines is suboptimal in clinical practice. Compliance with guideline recommendations for the use of NK_1 RA is particularly poor. Guideline-adherent therapy is associated with significantly decreased risk for CINV. The requirement for administration of multiple medications significantly increases the probability of poor adherence by patients and suboptimal therapy outcomes.

The efficacy and safety of AKYZNEO was established in three multicenter, randomized, double-blind pivotal trials. In a Phase II study, AKYNZEO plus dexamethasone significantly improved prevention of CINV in the acute, delayed and overall phases compared with oral palonosetron plus dexamethasone in patients receiving cisplatin-based HEC. In a Phase III study, AKYNZEO plus a single dose of dexamethasone was superior to palonosetron plus dexamethasone in preventing CINV in the acute, delayed and overall phases in patients receiving AC-based regimen. AKYNZEO was also superior to oral palonosetron for no significant nausea in the 2 pivotal efficacy trials. An additional Phase III study found AKYNZEO to be generally well tolerated over multiple cycles in patients receiving HEC or MEC regimens; efficacy was maintained throughout all cycles. Most common AEs (≥3% and greater than palonosetron) included headache, asthenia, dyspepsia, fatigue, constipation and erythema. Co-administration of single dose netupitant 600 mg and palonosetron 1.5 mg had no significant effects on the QTc interval.

In summary, AKYNZEO provides patients, providers and payors with a new FDA-approved option for prevention of CINV in the indicated population. AKYNZEO is a single-dose oral antiemetic combination targeting two critical antiemetic pathways, consistent with antiemetic guidelines. AKYNZEO may provide convenience for both patients and prescribers and therefore has a potential to improve CINV control for patients. Based on the clinical information above, Eisai seeks unrestricted access for AKYNZEO in patients receiving cancer chemotherapy, including but not limited to HEC.

Questions and Answers
Q: Are you seeing any PRN use?
A: No, not so far.

Q: Any barriers to size of capsule?
A: There have been some complaints and Eisai is working on.

Q: Any other formulations being sought?
A: Not pursuing an oral formulation of palonosetron alone but pursuing an IV formulation of netupitant/palonosetron.

Q: What location is medication dispensed in?
A: May be dispensed by outpatient pharmacies for patient to bring to facility or by facility itself.

V. Gilead

Sunil Majethia, PharmD, Associate Director, Medical Sciences

Stribild® (STRY-bild) (elvitegravir, cobicistat, emtricitabine, and tenofovir disoproxil fumarate)
HIV Disease Background
According to the CDC, approximately 56,300 Americans are newly infected each year with HIV, the virus the causes AIDS. The advent of combination antiretroviral therapy in 1996 markedly reduced morbidity and mortality from AIDS. Currently on the US market, there are over 30 antiretroviral products including several fixed dose combinations and three single tablet regimens. Highly active therapy combines 3 or more antiretrovirals which is required to suppress the

virus and avoid the development of resistance. Many combinations can be complex, involving high pill burden, frequent administration, drug interactions, food interactions, and storage requirements. The U.S. Department of Health and Human Services and the International Antiviral Society – U.S. both unanimously recommend Truvada (FTC/TDF), a fixed dose combination, as the only preferred dual nucleoside component of a complete regimen.

Regimen simplification improves adherence, regimen persistence and clinical outcomes
Current treatment recommendations unanimously take regimen simplicity into account. According to the Department of Health and Human Services Guidelines, prescribing regimens that will facilitate adherence should have the following characteristics: simple to take, have a low pill burden and frequency of dosing, have no food requirements, and have a low incidence and severity of adverse effects. Furthermore, the European treatment guidelines state "Generic HIV drugs are becoming more available and can be used as long as they replace the same drug but do not break recommended fixed dose combinations". A single tablet regimen, Atripla, was associated with 97.9% adherence in its registrational trial. In a retrospective US pharmacy claims analysis of over 37,000 HIV patients in the PharMetrics outcomes database, HIV patients receiving a single tablet regimen had a 61% lower discontinuation rate vs. all other regimens. In another study involving difficult to treat HIV + homeless and marginally housed individuals, patients receiving a single tablet regimen were significantly more adherent and more likely to have viral suppression versus patients receiving multiple pills. In a retrospective chart analysis of over 7,000 HIV patients, patients receiving a single tablet regimen were 1.6 fold more likely to be highly adherent and 24% less likely to be hospitalized versus patients on 3 or more pills per day.

Stribild
Stribild (formerly known as the QUAD pill) is a new single tablet complete regimen composed of the DHHS-preferred treatment backbone, Truvada®, with elvitegravir, a new integrase inhibitor, and cobicistat, a new pharmacoenhancing or "boosting" agent. *STRIBILD® is indicated as a complete regimen for the treatment of HIV-1 infection in adult patients who have no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically-suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen for at least 6 months with no history of treatment failure and no known substitutions associated with resistance to the individual components of STRIBILD Clinical data from studies 121 (STRATEGY-NNRTI) and 115 (STRATEGY-PI), which assessed safety and efficacy outcomes in randomized, open-label, noninferiority trials in adult patients switching to STRIBILD vs continuing on their PI- or NNRTI-based antiretroviral (ARV) regimen, support this new indication.* Stribild has 2 boxed warnings including lactic acidosis/severe hepatomegaly with steatosis and post treatment acute exacerbation of hepatitis B. Coadministration of Stribild is contraindicated with drugs that are highly dependent on CYP3A for clearance and for which elevated plasma concentrations are associated with serious and/or life-threatening events, including lovastatin, simvastatin, triazolam, and midazolam. In registrational trials, Stribild was associated with less nervous system symptoms compared to the Sustiva containing Atripla and less ocular icteris compared to Reyataz containing regimens. Patients on Stribild had more nausea versus the comparator arms. Stribild should not be initiated in patients with CrCl below 70 mL/min and should be discontinued in patients with CrCl below 50 mL/min. Stribild has a pregnancy category B designation. The recommended dose of Stribild is one tablet taken orally once daily with food. No new adverse reactions to STRIBILD through Week 48 were identified in 584 virologically stably suppressed subjects switching to STRIBILD from a regimen containing a RTV-boosted protease inhibitor (PI) or a non-nucleoside reverse transcriptase inhibitor (NNRTI). In a combined analysis of Studies 115 and 121, the frequency of adverse reactions (all grades) was 24% in subjects switching to STRIBILD compared to 6% of subjects in either group who stayed on their baseline antiretroviral regimen, RTV-boosted PI + TRUVADA or NNRTI + TRUVADA. Common adverse reactions that occurred in greater than or equal to 2% of subjects switching to STRIBILD were nausea (4%), flatulence (2%), and headache (2%).

Summary
Simplified antiretroviral regimens, including Stribild, improve adherence which is crucial to suppress viral replication, prevent the emergence of drug resistant mutations, improve quality of life, and increase survival.

Questions and Answers
There were no additional questions and answers.

VI. Genentech

Sapna McManus, MD, MHA, Managed Care Liaison
Chris Kennedy, Regional General Manager

Esbriet® (pirfenidone) es-BREE-et | pir-FEN-i-done

INDICATIONS AND USAGE Esbriet (pirfenidone) is indicated for the treatment of idiopathic pulmonary fibrosis (IPF).

IDIOPATHIC PULMONARY FIBROSIS (IPF) BACKGROUND

- IPF is an irreversible, progressive, unpredictable, and ultimately fatal disease of unknown cause and is characterized by varying degrees of scarring, inflammation, and fibrosis in the lung. There appear to be several possible natural histories for IPF patients – while the majority of patients experience a slow but steady worsening of their disease, some remain stable and others have an accelerated decline. A minority of patients may experience an unpredictable acute exacerbation of their disease, which may be fatal or lead to a substantially worsened condition.
- Approximately 100,000 people in the United States have IPF. The incidence of IPF increase in people over the age of 45, and tends to affect slightly more men than women.4 The median survival time from diagnosis is two to five years, and the five-year survival rate is approximately 20 to 40 percent.

IPF BURDEN OF ILLNESS

- IPF is associated with functional impairment, including dyspnea, cough, fatigue, and emotional impairment, including depression. The emotional well-being of IPF patients is negatively affected by the disease. Patients report having to rearrange their lives extensively to cope with their disease, and feel they are a burden to others. Additionally, 23 to 27% of patients with interstitial lung disease have clinically significant depression, and many struggle with fear, anxiety, worry, and panic. IPF patients experience progressive disability, loss of independence coincident with deterioration in health, and knowledge of the likelihood of death within a few years, all of which have a substantial impact on patients' health-related quality of life.

DOSAGE AND ADMINISTRATION

Recommended dosage: 801 mg (three capsules) three times daily taken with food. Prior to treatment, conduct liver function tests, then monthly for the first 6 months, and every 3 months thereafter. Consider temporary dosage reduction, treatment interruption, or discontinuation for management of adverse reactions. Moderate and strong inhibitors of CYP1A2 increase systemic exposure of Esbriet and may alter its adverse reaction profile.

IPF CLINICAL STUDIES Esbriet has been investigated in three multinational, placebo-controlled Phase 3 clinical studies of 52 weeks' duration (ASCEND, n=555) and 72 weeks' duration (CAPACITY 004, n=435 and CAPACITY 006, n=344).

ASCEND

- Treatment with Esbriet vs. placebo significantly reduced decline in lung function as measured by changes in forced vital capacity [FVC] ($p<0.001$), decreased decline in 6-minute walk distance [6MWT] ($p=0.04$), and increased progression-free survival [PFS] ($p<0.001$). At Week 52, the proportion of patients with a ≥10% decline in % predicted FVC or death was 16.5% in the Esbriet group vs 31.8% in the placebo group (relative reduction of 47.9%). Esbriet was also associated with a reduced relative risk of death or disease progression by 43% compared with placebo (hazard ratio [HR]=0.57; 95% CI, 0.43-0.77; $p<0.001$).
- Gastrointestinal (GI) and skin-related adverse events (AEs) were more common in the Esbriet group but were generally mild to moderate in severity. Elevations in alanine or aspartate aminotransferase levels (3x upper limit of normal [ULN]) occurred in 2.9% (n=8) patients receiving Esbriet, compared with 0.7% (n=2) placebo.
- In a pooled analysis of ASCEND with CAPACITY 004 and 006 at 1 year, Esbriet treatment was associated with a 48% reduced risk of death (HR=0.52; 95% CI, 0.31-0.87; $p=0.01$) and a 68% reduced risk of death from IPF (HR =0.32; 95% CI, 0.14-0.76; $p=0.006$).

CAPACITY 004 and 006

- In CAPACITY 004 (n=435), Esbriet 2403 mg/day (n=174) was associated with significantly reduced decline in FVC vs. placebo (-8.0% vs. -12.4%; $p=0.001$) and improved PFS time (HR =0.64; 95% CI, 0.44-0.95; $p=0.023$). In Study 006 (n=344), a significant Esbriet treatment effect was evident from Week 12 until Week 48 ($p=0.005$), but no significant difference between treatment groups in the mean change in % predicted FVC was evident at Week 72 (-9.0% vs. -9.6%; $p=0.501$).
- An exploratory pooled analysis of data from CAPACITY 004 and 006 demonstrated a significant Esbriet treatment effect on the mean change in % predicted FVC at Week 72 vs placebo (-8.5% vs. -11%; $p=0.005$), PFS time (HR=0.74; 95% CI, 0.57-0.96; $p=0.025$), mean change in 6MWT distance (-53 meters vs. -77 meters; $p<0.001$), and the percentage of patients with a ≥10% decline in % predicted FVC (21% vs. 31%; $p=0.003$).

- The most commonly reported AEs in the pooled Esbriet group were GI disorders, skin disorders, and dizziness, but were generally mild to moderate in severity. More patients in the pooled Esbriet group than in the pooled placebo group had elevations in alanine and aspartate aminotransferases (3x ULN) (4% [n=14] vs. <1% [n=2]).

ADVERSE EVENT PROFILE The most common adverse reactions (≥10%) are nausea, rash, abdominal pain, upper respiratory tract infection, diarrhea, fatigue, headache, dyspepsia, dizziness, vomiting, anorexia, gastro-esophageal reflux disease, sinusitis, insomnia, weight decreased, and arthralgia.

IMPORTANT SAFETY INFORMATION There are no contraindications to the use of Esbriet and no black box warnings. Warnings and precautions include: elevated liver enzymes, photosensitivity reaction or rash, and GI disorders.

Questions and Answers
Q: How many IPF patients are there in GA?
A: Not sure but IPF patients are generally seen at the Centers of Excellence.

Q: How was compliance monitored in clinical trials?
A: By investigator.

VII. Keryx

Anthony Madpak, PharmD, DIBA, Associate Director, Regional Medical Liaison
Mike Broach, Director of Government Accounts

Auryxia™ (ferric citrate) ah-RICKS-ee-ah (FER-ik SI-trate)
INDICATION: Auryxia is an absorbable iron-based phosphate binder indicated for the control of serum phosphorus levels in patients with chronic kidney disease on dialysis.

DOSAGE: Recommended starting dose of ferric citrate is 2 tablets orally 3 times per day with meals.

CLINICAL EFFICACY: The safety and efficacy of ferric citrate was studied in a Phase 3, multicenter, randomized, controlled study in patients with chronic kidney disease on dialysis. After a 2-week washout period, 441 patients were randomized 2:1 to a 52-week, open-label, active control period (ferric citrate [FC; N=292] or active control [AC; calcium acetate and/or sevelamer carbonate; N=149]); the non-inferiority arm. This period was followed by a 4-week, randomized, open-label, placebo control period where patients who completed the FC arm of the active control period were re-randomized 1:1 to receive FC or placebo; the superiority arm. The starting dose of FC was 6 tablets/day, divided with meals. The starting dose of AC was the patient's dose prior to the washout period. The dose of phosphate binder was increased or decreased as needed to maintain serum phosphorus levels between 3.5 and 5.5 mg/dL, to a maximum of 12 tablets/day. Serum phosphorus levels declined following initiation of therapy and was maintained over 52 weeks of treatment; statistically non-inferior between FC- and AC-treated patients. FC controlled phosphorus compared to placebo, with a mean treatment difference of –2.2±0.2 mg/dL (mean±SEM) (P<0.001); the primary study endpoint.

Additional Secondary Endpoints
- Patients on FC had increased ferritin and TSAT compared with patients on AC at Week 52 (mean differences of 281.8±42.9 ng/mL and 9.55%±1.58%, respectively; both P<0.001)
- FC-treated patients required less cumulative IV iron than AC-treated patients during the 52-week active control period (median [interquartile range] dose of 12.9 [1.0–28.9] vs. 26.8 [13.4–47.6] mg/wk; P<0.001)
- FC-treated patients required less cumulative ESA than AC-treated patients during the 52-week active control period (median [interquartile range] dose of 5303 [2023–9695] vs. 6954 [2664–12,375] units/wk; P=0.04)
- Hemoglobin levels were significantly higher in the FC group at Week 52 (11.42±0.10 g/dL for FC vs. 11.14±0.12 g/dL for AC; P=0.02)

CONTRAINDICATIONS: Patients with iron overload syndromes (e.g., hemochromatosis)

WARNINGS & PRECAUTIONS: Iron Overload: Iron absorption from FC may lead to excessive elevations in iron stores. Assess iron parameters prior to initiating FC and while on therapy. Patients receiving IV iron may require a reduction in dose or discontinuation of IV iron therapy.

Accidental Overdose of Iron: Accidental overdose of iron containing products is a leading cause of fatal poisoning in children under 6 years of age. Keep this product out of the reach of children and call a doctor or poison control center immediately in the case of accidental overdose.

ADVERSE REACTIONS: In a pooled safety analysis of the Phase 3 long-term study (52 weeks) and three short-term studies (28 days), adverse events (AEs) reported in more than 5% of patients treated with FC (N=557) in these studies included diarrhea (21%), nausea (11%), constipation (8%), vomiting (7%), and cough (6%). During the active control period of the Phase 3 study, 21% of FC- vs. 14% of AC-treated patients discontinued study drug because of an AE. Patients who were previously intolerant to any of the AC treatments were not eligible to enroll in the study. Gastrointestinal AEs were the most common reason for discontinuing FC (14%).

HEALTH ECONOMIC AND OUTCOMES RESEARCH DATA: A secondary analysis was conducted to quantify the economic impact of FC on the decreased utilization of ESAs and IV iron in FC- vs. AC-treated patients. Steady state doses were lower in the FC group vs. AC with a cumulative 1-year difference of 99,646 U for ESA and 822.2 mg for IV iron/patient. For a managed care plan, this represents $2,447 and $433 ($2,880 total) in annual per patient cost savings, respectively. Because IV iron and ESA doses in the study were lower in both groups than those seen in the US population during this period, estimated savings were higher when the percentage reductions were generalized using US Renal Data System (USRDS) data: 129,106 U ($3,170) for ESA and 1,960.6 mg ($1,032) for IV iron ($4,202 total). Logarithmic curves indicated that dose differences between the FC and AC groups had not yet reached steady state, but rather the treatment associated differences were continuing to increase after 12 months.

A post-hoc analysis was conducted to evaluate hospitalization costs. After normalizing for the 2:1 FC to AC study randomization, there were 181 unique hospitalizations in the FC group vs. 239 in the AC group, for a difference of 58 hospitalizations (decrease of 24.1%, *P*=0.08). Total potential savings was US$867,622 in hospitalization costs in the FC group. After applying the relative hospitalization reduction from FC to the general end-stage renal disease population, the potential cost savings was an estimated US$3002 per patient over the 52-week study period.

Questions and Answers
Q: Any indication of when guidelines may be updated?
A: Working on for November 2015.

Q: How are other states covering?
A: Some states have open due to decrease in use of IV iron and erythropoietin agents as well as decrease in hospitalization associated with Auryxia; some states are not open.

VIII. Aegerion

Ken DiGioia, Senior Medical Scientific Liaison
Austin Gautier, Market Access Director

Juxtapid® (lomitapide)
Lomitapide is a once daily, oral, first-in-class, small-molecule microsomal triglyceride transfer protein (MTP) inhibitor that prevents the formation of apo B-containing lipoproteins in the liver and small intestine. Lomitapide is indicated as an adjunct to a low-fat diet and other lipid-lowering treatments, including LDL apheresis where available, to reduce low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), apolipoprotein B (apo B), and non-high-density lipoprotein cholesterol (non-HDL-C) in patients with homozygous familial hypercholesterolemia (HoFH). The safety and effectiveness of Lomitapide have not been established in patients with hypercholesterolemia who do not have HoFH. The effect of lomitapide on cardiovascular (CV) morbidity and mortality has not been determined. Also, the safety and efficacy of lomitapide in pediatric patients has not been established. Because of the risk of hepatotoxicity, lomitapide is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Juxtapid REMS Program.

About Homozygous Familial Hypercholesterolemia: HoFH is a serious and rare genetic disease characterized by extremely elevated blood LDL-C levels, premature atherosclerosis and increased risk of CV morbidity and mortality. HoFH is most commonly caused by mutations in both alleles of the LDL receptor (LDLR) gene, but can also be caused by mutations in other genes such as the apolipoprotein B and proprotein convertase subtilisin/kexin type 9 (PCSK-9) genes. DNA sequencing for genotypic confirmation of HoFH is not routinely used in clinical practice for several reasons which include a high rate of false negatives (~15-20%) due to inadequate sensitivity of existing tests, and the

fact that the results of genetic testing do not influence treatment strategies once a diagnosis of HoFH has been made. The clinical diagnosis for HoFH typically includes a combination of the following**: a)** assessment of cholesterol levels (total cholesterol or LDL-C), **b)** physical examination for features consistent with HoFH which may include corneal arcus, cutaneous or tendon xanthomas, and **c)** parental history of significant hypercholesterolemia and/or premature cardiovascular disease. In the literature, LDL-C levels for HoFH patients who are not receiving lipid lowering therapies have been reported as ranging from ~450 – >1,000 mg/dL and, for patients receiving traditional lipid lowering therapies, as ranging from ~ 220 - 600 mg/dL. In two recent phase 3 trials in patients with a confirmed diagnosis of HoFH, baseline treated LDL-C levels were in the range of 152 – 704 mg/dL.

Clinical Efficacy: In a single arm, open-label phase III trial of 29 adult HoFH patients on maximal lipid-lowering therapy (with or without apheresis), lomitapide, at individualized maximum tolerated doses (MTDs), reduced LDL-C levels by a mean of 40% from baseline after 26 weeks of treatment. The primary efficacy analysis was based on the intent-to-treat (ITT) population (N=29) with the last observation carried forward (LOCF) for those who discontinued prior to the end of the 26 week efficacy phase (n=6). Of the 23 patients completing 26 weeks of therapy, a 50% mean reduction in LDL-C was observed from baseline to week 26. Patients who continued on lomitapide treatment for the full 78-week study had a mean reduction in LDL-C of 38% from baseline. At one or more times during the 78-week study period, 55% of the ITT patient population achieved a treatment goal of LDL-C <100 mg/dL and 31% achieved the more aggressive goal of <70 mg/dL. The proportion of patients attaining treatment goals was notable given that, from weeks 26 to 78, physicians could alter a patient's background lipid-lowering therapy, including apheresis.

Clinical Safety: Lomitapide has a boxed warning regarding the risk of hepatotoxicity, specifically related to potential increases in liver transaminases and/or hepatic fat. Lomitapide also increases hepatic fat, with or without concomitant increases in transaminases. Hepatic steatosis associated with lomitapide treatment may be a risk factor for progressive liver disease, including steatohepatitis and cirrhosis. Due to the mechanism of action of lomitapide, patients may experience gastrointestinal (GI) adverse events (AEs). To help improve tolerability and minimize AEs, patients should be maintained on a low-fat diet (<20% calories from fat). In the pivotal phase 3 study, lomitapide was generally well tolerated. AEs reported by ≥ 8 patients (28%) included diarrhea, nausea, vomiting, dyspepsia, and abdominal pain. GI symptoms (e.g., diarrhea, nausea) were the most common AE (93%). Throughout the study, 10 patients (34%) had increases in ALT or AST levels (≥3x upper limit of normal [ULN]); 4 (14%) patients had at least one elevation in ALT and/or AST ≥5x ULN. The median absolute increase in hepatic fat was 6% after both 26 weeks and 78 weeks of treatment, from 1% at baseline. The incidence and severity of AEs did not increase during the safety phase of the phase III clinical study. During the 78-week study, no patients discontinued lomitapide treatment based on liver function test elevations or hepatic-related AEs. No deaths or serious AEs related to lomitapide treatment were reported in the trial.

Questions and Answers
Q: What was the LDL levels in clinical trials?
A: The mean was 336 with a range of 152-564.

Q: How much does genetic test cost?
A: Approximately $3000 but does not test for all genetic markers.

Q: What criteria do physicians generally use to diagnose HoFH?
A: Family history, xanthomas or corneal arcus and limited or no response to conventional lipid lowering therapies.

Q: Does Juxtapid efficacy require any LDL receptor function?
A: No, unlike other lipid lowering therapies, Juxtapid does not require LDL receptors to have any functioning.

IX. Pari

Ron Dunbar, Principal, Prescription Alliance

Kitabis™ Pak (tobramycin inhalation solution)
Product Description: KITABIS™ PAK (Ki TAH biss Pak) is a co-packaging of generic Tobramycin Inhalation Solution (drug) and PARI LC PLUS® Reusable Nebulizer (device). One NDC: 24492-850-56. Drug and Device together (with every Rx fill) guarantees 100% access for all patients.

KITABIS PAK is indicated for the management of cystic fibrosis in adults and pediatric patients 6 years of age and older with *P. aeruginosa*1. KITABIS PAK also includes a PARI LC PLUS, the nebulizer handset used exclusively in clinical trials for Tobramycin Inhalation Solution. It is the only nebulizer approved by the FDA to safely and effectively deliver Tobramycin Inhalation Solution.

A CLINICALLY PROVEN DEVICE: The PARI LC PLUS is the most widely used nebulizer in clinical trials for new nebulized drugs for more than 20 years.

The Company: For over 100 years, PARI Respiratory has specialized in aerosol therapy including drug and device. PARI brings expertise to drug development, with inhaled antibiotics, including TOBI®. Tobramycin inhalation solution is specifically formulated for inhalation using a PARI LC PLUS™ Nebulizer handset.2 In fact, the FDA label for ALL inhaled tobramycin solutions specify the PARI LC PLUS Nebulizer to deliver the inhaled product accurately and obtain adequate drug concentrations in the lung to treat pseudomonas infections and help prevent exacerbations.
Despite continued efforts since 1997, PARI has not been able to ensure all patients have ACCESS to the only "clinically proven" device for delivery of tobramycin inhalation solution. If patients have difficulty accessing the LC PLUS Nebulizer, they use unproven, off-label nebulizers to deliver a drug that is essential to managing their disease. The nebulizer handset is the most influential part of the delivery system. Using an un-proven, off-label nebulizer for delivery of tobramycin solution results in highly variable drug delivery to the lungs, which may compromise efficacy.

Even if patients use the clinically proven nebulizer there are no assurances that it is being maintained or working properly. Studies show that a significant majority of CF patients do not correctly clean, disinfect or routinely replace their nebulizer handsets which has possible clinical implications.3, 4 KITABIS PAK includes a new LC PLUS nebulizer handset with each course of treatment decreasing bacterial contamination and ensuring optimal drug delivery which is particularly important in this fragile patient population that are susceptible to chronic lung infections.

KITABIS PAK

- HOW SUPPLIED: A drug / device combination of 56 ampules of generic tobramycin solution, or one course of therapy, and the LC PLUS Nebulizer Handset. It is the only tobramycin preparation that includes a new LC PLUS Nebulizer as part of the packaging with each prescription fill.

- VALUE PROPOSITION: A new LC PLUS Nebulizer Handset with each Rx fill addresses the challenges of Patient Access, Maintenance, Cleaning and Disinfection of the only clinically proven device for nebulized tobramycin.

- NO TREATMENT DELAYS: Providing drug and device together eliminates delivery timing issues and delays in treatment initiation.

Questions and Answers
Q: Is every fill packaged with a nebulizer?
A: Yes; studies have shown that patients may not clean nebulizers properly or consistently and it was found that some patients did not have access to the gold standard and FDA approved nebulizer, PARI LC PLUS, for tobramycin inhaled solution.

Q: Is distribution limited?
A: Yes, to approximately 14 specialty pharmacies but this is growing.

Q: Have any states added to PDL yet?
A: Most are in process of reviewing but Texas added due to access to nebulizer device.

X. Boehringer Ingelheim

Patricia Grossman, PharmD, MBA, Associate Director, Health Economics and Outcomes Research
Dan Doyle, Strategic Account Executive

Ofev® (nintedanib)

Indication and Usage

- OFEV (nintedanib) is indicated for the treatment of idiopathic pulmonary fibrosis (IPF)

Executive Summary of OFEV Efficacy Data
The clinical efficacy of OFEV has been studied in 1231 patients with IPF in one phase 2 (Study 1) and two phase 3 (Studies 2 and 3) studies. These were randomized, double-blind, placebo-controlled studies comparing treatment with OFEV 150 mg twice daily to placebo for 52 weeks.

Study Design Overview
- The study design was identical for Studies 2 and 3 and very similar for Study 1
- Patients were randomized in a 3:2 ratio (1:1 for Study 1) to either OFEV 150 mg or placebo twice daily for 52 weeks. Study 1 also included other treatment arms (50 mg daily, 50 mg twice daily, and 100 mg twice daily) that are not further discussed
- Primary endpoint:
  - Annual rate of decline in Forced Vital Capacity (FVC)
- Secondary endpoints:
  - Time to first acute IPF exacerbation (a key secondary endpoint in Studies 2 and 3 and a secondary endpoint in Study 1)
  - Change from baseline in FVC percent predicted and survival (additional secondary endpoints in all studies)
- Inclusion criteria:
  - Patients with a diagnosis of IPF (ATS/ERS/JRS/ALAT criteria) for <5 years. Diagnoses were centrally adjudicated based on radiologic and, if applicable, histopathologic confirmation
  - ≥40 years of age
  - FVC ≥50% of predicted and a carbon monoxide diffusing capacity (DLCO, corrected for hemoglobin) 30% to 79% of predicted
- Exclusion criteria:
  - Patients with relevant airways obstruction (i.e., pre-bronchodilator FEV1/FVC <0.7) or, in the opinion of the investigator, likely to receive a lung transplant during the studies (being listed for lung transplant was acceptable for inclusion)
  - Patients with >1.5 times ULN of ALT, AST, or bilirubin, patients with a known risk or predisposition to bleeding, patients receiving a full dose of anticoagulation treatment, and patients with a recent history of myocardial infarction or stroke
  - Patients that received other investigational therapy, azathioprine, cyclophosphamide, or cyclosporine A within 8 weeks of entry into this trial, or n-acetyl cysteine and prednisone (>15 mg/day or equivalent) within 2 weeks
- The majority of patients were Caucasian (60%) or Asian (30%) and male (79%). Patients had a mean age of 67 years and a mean FVC percent predicted of 80%

Primary Endpoint
Annual Rate of Decline in Forced Vital Capacity
- A statistically significant reduction in the annual rate of decline of FVC (in mL) was demonstrated in patients receiving OFEV compared to patients receiving placebo based on the random coefficient regression model, adjusted for gender, height, and age. The treatment effect on FVC was consistent in all 3 studies.
  - Study 1- OFEV 150 mg twice daily (n=84) provided an annual rate of decline in FVC of -60 mL compared to -191 mL for placebo (n=83), which represented a statistically significant difference of 131 mL (95% CI: 27, 235) compared to placebo at 52 weeks
  - Study 2- OFEV 150 mg twice daily (n=309) provided an annual rate of decline in FVC of -115 mL compared to -240 mL for placebo (n=204), which represented a statistically significant difference of 125 mL (95% CI: 78, 173) compared to placebo at 52 weeks
  - Study 3- OFEV 150 mg twice daily (n=329) provided an annual rate of decline in FVC of -114 mL compared to -207 mL for placebo (n=219), which represented a statistically significant difference of 94 mL (95% CI: 45, 143) compared to placebo at 52 weeks

WARNINGS AND PRECAUTIONS
Elevated Liver Enzymes
Gastrointestinal Disorders
Embryofetal Toxicity
Arterial Thromboembolic Events
Risk of Bleeding
Gastrointestinal Perforation

Questions and Answers
Q: How are physicians determining which IPF agent to use?
A: Generally physicians are continuing what patient was on in clinical trial but if that agent is not working then physicians are switching.

Q: Is distribution limited?
A: Yes through 4 specialty pharmacies due to the services provided but a pharmacy can submit request to be included.

Q: How are other states covering?
A: Generally on a case by case basis so are not blocking but are not listing on PDL.

The following were presented at previous Manufacturers' Forum or provided electronically for DUR Board review.

XI. Gilead
Michael A. Rodriguez, PharmD, Sr. Medical Scientist, Oncology
Jennifer H. Davidson, Strategic Account Manager

Zydelig® (idelalisib)
ZYDELIG (zye-DEL-ig) is a kinase inhibitor indicated for the treatment of patients with:
- Relapsed chronic lymphocytic leukemia (CLL), in combination with rituximab, in patients for whom rituximab alone would be considered appropriate therapy due to other co-morbidities.
- Relapsed follicular B-cell non-Hodgkin lymphoma (FL) in patients who have received at least two prior systemic therapies.*
- Relapsed small lymphocytic lymphoma (SLL) in patients who have received at least two prior systemic therapies.*

*Accelerated approval was granted for FL and SLL based on overall response rate. Improvement in patient survival or disease related symptoms has not been established. Continued approval for these indications may be contingent.

Unique Mechanism of Action:
ZYDELIG is an oral first-in-class, targeted, highly selective, PI3Kδ kinase inhibitor. PI3Kδ kinase is expressed in normal and malignant B-cells. ZYDELIG induced apoptosis and inhibited proliferation of cell lines derived from malignant B-cells and in primary tumor cells. ZYDELIG inhibits several cell signaling pathways, including B-cell receptor (BCR) signaling and the CXCR4 and CXCR5 signaling, which are involved in trafficking and homing of B-cells to the lymph nodes and bone marrow. Treatment of lymphoma cells with idelalisib resulted in inhibition of chemotaxis and adhesion, and reduced cell viability.

Efficacy in CLL – improved PFS in heavily treated patients with comorbidities:
- ZYDELIG in combination with rituximab showed clinically meaningful improvement over rituximab alone for CLL patients who failed one or more prior CLL therapies.
- ZYDELIG showed improved PFS at interim analysis (82% reduced risk of progression or death compared to rituximab) in a heavily pretreated population.
- The median PFS for patients receiving ZYDELIG in combination with rituximab was not reached during the 12 month phase III trial; the trial was ended early by an independent review committee due to proven efficacy at the interim analysis (See Table 1 and Figure 1)

Table 1 Efficacy Results from Study 1[1]

PFS	**ZYDELIG + R n=110**	**Placebo + R n=110**
Median (months) (95% CI)	NR (10.7, NR)	5.5 (3.8, 7.1)
Hazard ration (95% CI)	0,18 (0.10, 0.32)	
P-value	<0.0001†	

R: rituximab; PFS: progression-free survival; NR: not reached
† The p value for PFS was based on stratified log-rank test.

Efficacy in iNHL (FL and SLL) – achieved high response rate in heavily pretreated patient population
- ZYDELIG provided a 54% and 58% ORR, respectively, for FL/SLL patients who had failed or relapsed on two or more prior systemic treatments.

- ZYDELIG provided a deep response at first follow up for patients who had tried at least two prior systemic therapies.

Table 2 Overall Response Rate (ORR) and Duration of Response (DOR) in Patients with Relapsed Follicular Lymphoma

	N=72
ORR 95% CI	39 (54%) (42, 66%)
CR PR	6 (8%) 33 (46%)
Median DOR, months (range)	Median not evaluable (0.0+, 14.8+)

CI = confidence interval; CR = complete response; PR = partial response

Table 3 Overall Response Rate (ORR) and Duration of Response (DOR) in Patients with Relapsed Small Lymphocytic Lymphoma

	N=26
ORR 95% CI	15 (58%) (37, 77%)
CR PR	0 15 (58%)
Median DOR, months (range)	11.9 (0.0+, 14.7+)

CI = confidence interval; CR = complete response; PR = partial response

Important Safety Information
WARNING: FATAL AND SERIOUS TOXICITIES: HEPATIC, SEVERE DIARRHEA, COLITIS, PNEUMONITIS, and INTESTINAL PERFORATION

- Fatal and/or serious hepatotoxicity occurred in 14% of Zydelig-treated patients. Monitor hepatic function prior to and during treatment. Interrupt and then reduce or discontinue Zydelig.
- Fatal and/or serious and severe diarrhea or colitis occurred in 14% of Zydelig-treated patients. Monitor for the development of severe diarrhea or colitis. Interrupt and then reduce or discontinue Zydelig.
- Fatal and serious pneumonitis can occur in Zydelig-treated patients. Monitor for pulmonary symptoms and bilateral interstitial infiltrates. Interrupt or discontinue Zydelig.
- Fatal and serious intestinal perforation can occur in Zydelig-treated patients across clinical trials. Discontinue Zydelig if intestinal perforation is suspected.

XII. AstraZeneca

Symbicort® (sim-buh-cort), budesonide / formoterol fumarate dihydrate (bue-DES-oh-nide / for-MOE-ter-ol FUEma-rate DYE-hye-drate)

Indications & Dosing

- Asthma: SYMBICORT is indicated for the treatment of asthma in patients 12 years of age and older. The SYMBICORT PI contains a boxed warning stating, LABAs, such as formoterol (one of the active ingredients in SYMBICORT), increase the risk of asthma-related death. 80/4.5 mcg or 160/4.5 mcg, 2 inhalations BID
- COPD: SYMBICORT 160/4.5 is indicated for the twice daily maintenance treatment of airflow obstruction in patients with COPD including chronic bronchitis and emphysema. SYMBICORT 160/4.5 is the only approved dosage for the treatment of airflow obstruction in COPD. 160/4.5 mcg, 2 inhalations BID
- SYMBICORT is NOT indicated for the relief of acute bronchospasm in asthma or COPD.

NOTE: For the asthma and COPD efficacy and safety clinical data presented below, treatments were dosed as 2 inhalations BID unless otherwise noted.

Asthma Specific Population Data:

- In a 12-week, randomized, double-blind, multicenter clinical trial of 311 Black patients aged ≥ 12 years with moderate-to-severe asthma, improvement in predose forced expiratory volume in one second (FEV1) from baseline to the treatment average (primary variable) was significantly greater with SYMBICORT 160/4.5 mcg versus budesonide DPI 180 mcg (0.16 L vs. 0.07 L; p = 0.008); this effect was also observed at weeks 2, 6, and end of treatment (p ≤ 0.032). Reductions in daily asthma symptom score (p = 0.039), total daily rescue medication

use (p = 0.029), and nighttime rescue medication use (p = 0.007) were significantly greater in patients treated with SYMBICORT compared to those treated with budesonide. In a 12-week, randomized, double-blind, multicenter, clinical trial of 250 Hispanic patients, SYMBICORT 160/4.5 mcg improved lung function vs. budesonide pMDI 160 mcg, although the differences were not statistically significant. In both studies, the overall adverse event (AE) profile was similar between treatment groups, with most AEs being mild-to-moderate in intensity.

- In a 52-week, randomized, double-blind, multicenter study, the safety and efficacy of SYMBICORT 160/4.5 mcg was compared to budesonide pMDI 160 mcg in African American patients aged ≥ 12 years (n = 742) with moderate-to-severe asthma. There were a total of 36 and 61 asthma exacerbations (defined as oral/systemic corticosteroid use and/or an asthma-related hospitalization, emergency room visit, or urgent care visit) in the SYMBICORT 160/4.5 mcg (n = 377) and budesonide pMDI 160 mcg (n = 364) groups, respectively. The time to first asthma exacerbation was longer in the SYMBICORT versus budesonide group (p = 0.018). The rate of asthma exacerbations was reduced by 38.5% with SYMBICORT versus budesonide (rate ratio, 0.615; p = 0.002). Patients treated with SYMBICORT showed significant improvements in pulmonary function (predose FEV1, forced vital capacity and morning peak expiratory flow) compared to those treated with budesonide (p ≤ 0.013). No substantial or unexpected patterns of abnormalities were observed in laboratory, electrocardiographic, or Holter monitoring assessments.

COPD Exacerbations Study:

- SYMBICORT is NOT indicated to reduce exacerbations of COPD in patients with a history of exacerbations.
- In a year-long, randomized, double-blind, multicenter study of 1,219 patients with COPD, SYMBICORT 80/4.5 mcg and 160/4.5 mcg reduced exacerbation rates (number per treatment-year) by 25.9% and 34.6%, respectively, compared to formoterol 4.5 mcg (p ≤ 0.002). Exacerbations were defined as worsening of COPD that required treatment with oral corticosteroids and/or hospitalization. In a post-hoc analysis, there was a significant reduction in the number of exacerbations for both doses of SYMBICORT compared to formoterol if antibiotic usage was also included in the definition of an exacerbation (p ≤ 0.023).

Additional Safety - Please see full SYMBICORT Prescribing Information, including Boxed WARNING

- On July 23, 2012, the FDA approved a sNDA eliminating the requirement for the SYMBICORT Risk Evaluation and Mitigation Strategy (REMS). The FDA determined that the REMS had met its goals and is no longer necessary. Therefore, a REMS for SYMBICORT is no longer required.
- Asthma common AEs (incidence of ≥ 5% in any one SYMBICORT group and more commonly than placebo): nasopharyngitis, headache, upper respiratory tract infection (URTI), pharyngolaryngeal pain, sinusitis, and stomach discomfort.
- COPD Common AEs (incidence of ≥ 3% in the SYMBICORT group and more commonly than placebo): nasopharyngitis, URTI viral, oral candidiasis, bronchitis, sinusitis. Lung infections other than pneumonia (mostly bronchitis) occurred in a greater percentage of patients treated with SYMBICORT 160/4.5 mcg (7.9%) compared to placebo (5.1%). Pneumonia did not occur with greater incidence in the SYMBICORT 160/4.5 mcg group compared to placebo in 6-month (1.1% vs. 1.3%) and 12-month (4.0% vs. 5.0%) studies. There were no clinically important or unexpected patterns of abnormalities observed for up to 1 year in chemistry, hematology, ECG, Holter monitor, HPA-axis, bone mineral density and ophthalmology assessments.
- In a retrospective pooled analysis of 7 COPD trials, treatment with budesonide-containing products for 12 months did not increase the risk of pneumonia in patients with COPD.

XIII. GlaxoSmithKline

Tivicay®: TIV-eh-kay; dolutegravir: doll-u-TEG-ra-vir

Treatment Guidelines

For HIV-1–infected patients, the United States Department of Health and Human Services Panel on Antiretroviral Guidelines for Adults and Adolescents rates five regimens as “Recommended” for use in antiretroviral therapy (ART)-naïve patients. (1) These five regimens include *Tivicay* (dolutegravir, DTG) 50 mg once daily with tenofovir/ emtricitabine (TDF/FTC) once daily, and *Triumeq* (a fixed-dose combination of DTG and abacavir/lamivudine [ABC/3TC] in patients who are HLA-B*5701 negative)

Description

Tivicay is an HIV-1 integrase stand-transfer inhibitor (INSTI), available in film–coated tablets for oral administration. Each tablet contains 50 mg dolutegravir as dolutegravir sodium.

Indication
Tivicay is indicated in combination with other antiretroviral agents (ARVs) for the treatment of HIV-1 infection. Use of *Tivicay* in INSTI-experienced patients should be guided by the number and type of baseline INSTI substitutions. The efficacy of *Tivicay* 50 mg twice daily is reduced in patients with an INSTI-resistance Q148 substitution plus 2 or more additional INSTI-resistance substitutions including T66A, L74I/M, E138A/K/T, G140S/A/C, Y143R/C/H, E157Q, G163S/E/K/Q, or G193E/R.

Dosing
Tivicay may be taken without regard to meals. For ART-naïve, and ART-experienced, INSTI-naïve adult and pediatric patients (≥12 years of age and ≥40 kg), the recommended dose of *Tivicay* is 50 mg once daily. When coadministered with potent UGT1A1/CYP3A inducers (efavirenz [EFV], fosamprenavir/ritonavir [FPV/r], tipranavir/ritonavir [TPV/r], or rifampin) the recommended dose of *Tivicay* is 50 mg twice daily. For INSTI-experienced adults with certain INSTI-associated resistance substitutions or clinically-suspected INSTI resistance, *Tivicay* should be dosed 50 mg twice daily (and alternative combinations that do not include metabolic inducers should be considered where possible).

Contraindications
1. Previous hypersensitivity reaction (HSR) to DTG. 2. Coadministration with dofetilide.

Warnings and Precautions
- Hypersensitivity reactions characterized by rash, constitutional findings, and sometimes organ dysfunction, including liver injury, were reported in <1% of subjects in Phase 3 clinical trials of DTG. Discontinue *Tivicay* and other suspect agents immediately if signs or symptoms of hypersensitivity reactions develop, and never restart.
- Patients with underlying hepatitis B or C may be at increased risk for worsening or development of transaminase elevations.
- Redistribution/accumulation of body fat and immune reconstitution syndrome have been reported in patients treated with ART.
- The most common adverse reactions of moderate to severe intensity and incidence ≥2% (in those receiving *Tivicay* in any one adult trial) are insomnia, fatigue, and headache.

Efficacy Data
- SPRING-2 randomized 822 ART-naive subjects to *Tivicay* 50 mg once daily or raltegravir (RAL) 400 mg twice daily, each in combination with investigator-selected, dual-nucleoside reverse transcriptase inhibitor (NRTI) backbone (either ABC/3TC or TDF/FTC once daily). The efficacy analysis included 808 subjects. At Week 96, virologic response rates (HIV-1 RNA <50 copies[c]/mL) were 82% for *Tivicay* +2 NRTIs versus 78% for RAL + 2 NRTIs (treatment difference: 4.9% [95% confidence interval {CI}: -0.6%, 10.3%]). Median changes in CD4 cell count from baseline were +276 and +264 cells/mm3 for DTG and RAL, respectively. No treatment-emergent resistance to DTG or NRTIs was observed.
- SINGLE randomized 833 ART-naive subjects to *Tivicay* 50 mg once daily plus ABC/3TC once daily, or EFV/TDF/FTC once daily. At Week 96, virologic response rates (HIV-1 RNA <50 c/mL) were 80% for *Tivicay* plus ABC/3TC versus 72% for EFV/TDF/FTC (treatment difference: 8.0% [95% CI: 2.3%, 13.8%]). An open-label phase continued from weeks 96–144. At Week 144, virologic response rates were 71% for *Tivicay* 63% for EFV/TDF/FTC (treatment difference: 8.3% [95% CI: 2%,14.6%]). The adjusted mean changes in CD4 count from baseline were +379 and +332 cells/mm3, respectively. No subjects receiving *Tivicay* plus ABC/3TC who met protocol-defined virologic failure had a detectable decrease in susceptibility to DTG, ABC, or 3TC.
- FLAMINGO was an open-label trial that randomized and treated 484 ART-naive subjects to DTG 50 mg once daily or darunavir/r (DRV/r) 800 mg/100 mg once daily, each in combination with investigator-selected NRTI backbone (either ABC/3TC or TDF/FTC). At Week 48, 90% of subjects who received DTG, and 83% of subjects who received DRV/r had HIV-1 RNA <50 copies/mL (treatment difference: 7.1% [95% CI: 0.9, 13.2]). At Week 96, virologic response rates were 80% versus 68% for the DTG versus DRV/r groups, respectively (treatment difference: 12.4% [95% CI: 4.7, 20.2]). Median CD4 count changes from baseline were +260 and +250 cells/mm3, respectively. No treatment-emergent primary resistance substitutions were observed.
- SAILING randomized 719 antiretroviral-experienced, INSTI-naive subjects to receive *Tivicay* 50 mg once daily or RAL 400 mg twice daily, each in combination with investigator-selected background regimen (BR, restricted to ≤2 antiretroviral treatments with at least 1 fully active agent). The efficacy analysis included 715 subjects. At Week 48, virologic response rates were 71% and 64% for patients receiving DTG +BR versus RAL + BR, respectively (treatment difference: 7.4% [95% CI: 0.7%, 14.2%]). The mean CD4 count changes from baseline were +162 and

+153 cells/mm3, respectively. In the DTG arm, treatment-emergent integrase substitutions were observed in 6 of 28 subjects who had virologic failure and resistance data. Five of the 6 subjects' isolates had emergent INSTI substitutions with DTG phenotypic susceptibility changes less than 2-fold. One subject isolate had pre-existing raltegravir resistance substitutions with a corresponding 148-fold reduction in dolutegravir susceptibility at failure. In the RAL arm, 21 of 49 subjects with post-baseline resistance data had evidence of emergent INSTI-resistance substitutions and raltegravir phenotypic resistance.

- VIKING-3 was an open-label, single-arm trial that evaluated TIVICAY 50 mg twice daily in 183 HIV-1-infected, ART-experienced adults with virological failure and current or historical evidence of resistance to RAL or elvitegravir. Mean reduction from baseline in HIV-1 RNA at Day 8 (primary endpoint) was 1.4 log10 (95% CI: 1.3 log10, 1.5 log10). After the functional monotherapy phase, subjects had the opportunity to re-optimize their background regimen when possible. At Week 48, 63% of patients had HIV-1 <50 c/mL, and the median change in CD4 count was 80 cells/mm3. Subjects harboring virus with Q148 and associated secondary substitutions also had a reduced response at Week 48.

Triumeq®: TRI-u-meck; abacavir: a-BAK-a-vir; dolutegravir: doll-u-TEG-ra-vir; lamivudine: la-MIV-u-deen

Treatment Guidelines

For HIV-1–infected patients, the United States Department of Health and Human Services Panel on Antiretroviral Guidelines for Adults and Adolescents rates five regimens as "Recommended" for use in antiretroviral therapy (ART)-naïve patients. These five regimens include *Triumeq* (in patients who are HLA-B*5701 negative), and *Tivicay* (dolutegravir, DTG) 50 mg once daily with tenofovir/emtricitabine once daily.

Description

Triumeq is a fixed-dose combination tablet containing an HIV-1 integrase stand-transfer inhibitor (dolutegravir; DTG) and two nucleoside reverse transcriptase inhibitors (NRTIs; abacavir [ABC] and lamivudine [3TC]). *Triumeq* tablets are film–coated for oral administration. Each tablet contains abacavir sulfate equivalent 600 mg of ABC, dolutegravir sodium equivalent to 50 mg of DTG, and 300 mg of lamivudine.

Indication

Triumeq is indicated for the treatment of HIV-1. *Triumeq* alone is not recommended for use in patients with current or past history of resistance to any components of *Triumeq. Triumeq* alone is not recommended in patients with resistance-associated integrase substitutions or clinically-suspected INSTI resistance, because the dose of DTG in *Triumeq* is insufficient in these subpopulations.

Boxed Warnings

- Serious and sometimes fatal hypersensitivity reactions (HSRs) have been associated with ABC-containing products. Hypersensitivity to ABC is a multi-organ clinical syndrome. Patients who carry the HLAB*5701allele are at a higher risk of an HSR to ABC; however, HSRs have occurred in HLA-B*5701-negative patients. All patients should be screened for the HLAB*5701 allele prior to first use of *Triumeq.* Discontinue *Triumeq* as soon as HSR is suspected and never re-start *Triumeq* or any other product containing ABC. Regardless of HLA-B*5701 status, permanently discontinue *Triumeq* or any other product containing ABC if HSR cannot be ruled out.
- Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogues.
- Severe acute exacerbations of hepatitis B virus (HBV) have been reported in co-infected patients who have discontinued lamivudine.

Dosing

The recommended dosage of *Triumeq* in adults is one tablet once daily orally, with or without food. In patients taking *Triumeq* and efavirenz, fosamprenavir/ritonavir (r), tipranavir/r, or rifampin, an additional tablet of *Tivicay* should be taken, separated by 12 hours from *Triumeq*.

Contraindications

1. Patients who are HLAB*5701-positive. 2. Patients who have had a previous HSR to DTG, ABC, or 3TC. 3. Patients receiving dofetilide. 4. Patients with moderate or severe hepatic impairment.

Warnings and Precautions

- HSRs to DTG were reported in <1% of subjects receiving *Tivicay* in Phase 3 trials and were characterized by rash, constitutional findings, and sometimes organ dysfunction, including liver injury. It is not possible to determine if an

HSR with *Triumeq is caused* by ABC or DTG. Discontinue *Triumeq* immediately if signs/symptoms of HSR develop, and never re-start *Triumeq* or any product containing ABC or DTG.
- Patients with underlying HBV or hepatitis C virus (HCV) may be at increased risk for worsening or development of transaminase elevations.
- Hepatic decompensation (some fatal) has occurred in patients with HIV and HCV receiving ART and interferon alfa, with/ without ribavirin.
- During the initial phase of treatment, immune reconstitution syndrome can occur, which may necessitate further evaluation and treatment.
- Redistribution/accumulation of body fat has been observed in patients receiving ART.
- In a prospective, observational trial evaluating the rate of myocardial infarction (MI) in patients on ART, the use of ABC within the previous 6 months was correlated with an increased risk of MI. A sponsor-conducted pooled analysis of clinical trials found no excess risk of MI in ABC-treated versus control subjects. In totality, available data from the observational cohort and clinical trials are inconclusive. The underlying risk of coronary heart disease should be considered when prescribing ART, including ABC, and modifiable risk factors should be minimized.
- Concomitant administration of *Triumeq* with other products containing ABC or 3TC is not recommended.

Adverse Reactions
The most commonly reported adverse reactions of at least moderate intensity and incidence of at least 2% in patients receiving *Triumeq* were insomnia, headache, and fatigue.

Efficacy Data
- The efficacy of *Triumeq* is supported by the randomized, controlled SINGLE Trial and other trials in ART-naive patients. The efficacy of DTG in ART-experienced, INSTI-naive patients receiving at least two other antiretrovirals is supported by data from the SAILING trial.
- SINGLE randomized 833 antiretroviral-naive subjects to receive *Tivicay* 50 mg once daily plus ABC/3TC once daily, or efavirenz/tenofovir/emtricitabine (EFV/TDF/FTC) once daily. At Week 96, the virologic response rates (HIV-1 RNA <50 copies [c]/mL) were 80% for *Tivicay* plus ABC/3TC and 72% for EFV/TDF/FTC (treatment difference: 8.0% [95% confidence interval {CI}: 2.3%, 13.8%]). The percentage of subjects with baseline viral loads ≤100,000 c/mL achieving HIV-1RNA <50 c/mL was 85% versus 73% for *Tivicay* plus ABC/3TC versus EFV/TDF/FTC, respectively. For subjects with baseline viral loads >100,000 c/mL, response rates were 71% versus 72% for *Tivicay* plus ABC/3TC versus EFV/TDF/FTC, respectively. The adjusted mean change in CD4 count from baseline was +325 for *Tivicay* plus ABC/3TC and +281 cells/mm3 for EFV/TDF/FTC.
- An open-label phase of SINGLE continued from weeks 96–144. At Week 144, the virologic response rates were 71% for *Tivicay* plus ABC/3TC and 63% for EFV/TDF/FTC (treatment difference: 8.3% [95% CI: 2%, 14.6%]). In subjects with baseline viral loads ≤ and >100,000 copies/mL, virologic response rates were 73% versus 64%, and 69% versus 61% for *Tivicay* plus ABC/3TC versus EFV/TDF/FTC, respectively. The adjusted mean changes in CD4 count from baseline were +379 and +332 cells/mm3, respectively. There was no treatment-emergent resistance to DTG, ABC, or 3TC.
- SAILING randomized 719 ART-experienced, INSTI-naive subjects to receive *Tivicay* 50 mg once daily or raltegravir 400 mg twice daily, each in combination with investigator-selected background regimen (BR, restricted to ≤2 antiretrovirals with ≥ 1 fully active agent). The efficacy analysis included 715 subjects. Eight subjects received the components of *Triumeq*. At Week 48, virologic response rates (HIV-1 RNA <50 c/mL) were 71% for *Tivicay* plus BR and 64% for raltegravir plus BR (treatment difference 7.4% [95% CI: 0.7%, 14.2%]).

XIV. Lundbeck

Northera™ (droxidopa)
NORTHERA is indicated for the treatment of orthostatic dizziness, lightheadedness, or the “feeling that you are about to black out” in adult patients with symptomatic neurogenic orthostatic hypotension (NOH) caused by primary autonomic failure [Parkinson's disease, multiple system atrophy, and pure autonomic failure], dopamine beta-hydroxylase deficiency, and non-diabetic autonomic neuropathy. Effectiveness beyond 2 weeks of treatment has not been demonstrated. The continued effectiveness of NORTHERA should be assessed periodically.

NORTHERA is the only FDA-approved therapy for this condition and carries a boxed warning for supine hypertension. There are other serious risks associated with NORTHERA including hyperpyrexia and confusion, cardiovascular risk

and allergic reactions. The most common adverse events in NORTHERA-treated patients in controlled clinical trials were headache, dizziness, nausea and hypertension.

Neurogenic orthostatic hypotension (NOH), a subset of OH, is associated with a deficient sympathetic outflow and reduced norepinephrine release.

The exact mechanism of action of NORTHERA in the treatment of NOH is unknown, but is believed to exert its pharmacological effect through norepinephrine and not through droxidopa or other metabolites. NORTHERA is directly metabolized to norepinephrine by dopa-decarboxylase, the same enzyme that converts levodopa to dopamine. Norepinephrine increases blood pressure by inducing peripheral arterial and venous vasoconstriction.

The capsules are supplied in the following dosage strengths:

Dosage Strength	Quantity	NDC Code Number
100 mg	90 count bottle	67386-820-19
200 mg	90 count bottle	67386-821-19
300 mg	90 count bottle	67386-822-19

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GEORGIA DEPARTMENT OF COMMUNITY HEALTH

Manufacturers' Forum

ANNOUNCEMENT

NorthStar HealthCare Consulting

Georgia Department of Community Health

On behalf of the Georgia Department of Community Health (DCH) and in service to the Georgia Medicaid Fee-for-Service (FFS) Drug Utilization Review Board (DURB), NorthStar HealthCare Consulting (NHC), in conjunction with Catamaran, announces the Manufacturers' Forum occurring Thursday, August 6, 2015.

Date: **Thursday, August 6, 2015 from 9am-5pm EST**

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

Appointments: ***The Manufacturers' Forum is by appointment only*****.** Appointments may be requested and will be scheduled ***after*** the Drugs Under Review are posted to the DCH website at **http://dch.georgia.gov/durb-meeting-information** 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** and include the drug name. New drug entities are generally not reviewed by the DURB until the drug has been on the market for at least 6 months.

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 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 (front only, font 10, not including references) of the presentation should be provided one week prior to the presentation via email to **GAMedicaid@nhc-llc.com** and please include a pronunciation guide of the drug's brand and generic names. The one-page summary along with relevant questions and answers related to the presentation will be provided to the DURB as well as published in the DURB meeting handout that is provided to the public at the meetings and on the DCH website at **http://dch.georgia.gov/durb-meeting-information**.

Comments and Inquiries:

- Manufacturers with comments or inquiries related to Georgia Medicaid FFS **Preferred Drug List, Prior Authorization Criteria, Manufacturers' Forum or DURB** should submit these in writing to **GAMedicaid@nhc-llc.com**.
- Manufacturers with comments or inquiries related to Georgia Medicaid FFS **supplemental rebates** should submit these in writing to **GAOffers@ghsinc.com**.
- Manufacturers with comments or inquiries related to Georgia Medicaid FFS **claims processing** or **drug benefit plan design** should submit these to the address or phone number below:

Catamaran, Inc.
Georgia Department of Community Health
Windward Fairways I, 3025 Windward Plaza Suite 200, Alpharetta, Georgia 30005
Phone: 770-776-2000 Fax: 770-776-2050

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GEORGIA DEPARTMENT OF COMMUNITY HEALTH

Georgia Department of Community Health (GDCH) Opportunities for Pharmaceutical Manufacturer Input on Clinical Recommendations and Clinical Management Strategies by the Drug Utilization Review Board

Clinical Information and Clinical Management Strategies relevant to the GDCH Medicaid Fee-For-Service program will be presented to the Drug Utilization Review Board (DURB) at each meeting through Catamaran by its vendor NorthStar HealthCare Consulting (NHC). Manufacturer input on new and existing drugs is welcomed and appreciated using these opportunities. **Please note that new drug entities are generally not reviewed by the DURB until the drug has been on the market for at least 6 months.**

Ongoing Opportunity:

DUR Board Meeting Process: Drugs, therapeutic classes and/or supplemental rebate classes under review will be posted to the DCH website at **http://dch.georgia.gov/durb-meeting-information** approximately 30 days prior to the Manufacturers' Forum. Input specific to the drugs under review from manufacturers are made directly to NHC via **GAMedicaid@nhc-llc.com** and reported as appropriate by NHC at subsequent DURB meetings. NHC will pass relevant manufacturer-submitted electronic materials to the DURB members via a secure FTP site.

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

Presentation Opportunity:

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

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

2) Clinical information relevant to ongoing NHC/Catamaran clinical management strategies (e.g. review of drug benefit plan designs, new drugs coming to market, new indications, etc.) as deemed necessary by NHC/Catamaran.

Please see the Manufacturers' Forum Announcement at **http://dch.georgia.gov/durb-meeting-information**.

Opportunity to Appeal to GDCH:

GDCH Review Process: DURB recommendations are reviewed by GDCH for final decisions. Manufacturers may request an appeal meeting directly with GDCH after conclusion of each quarterly DURB meeting and **this appeal meeting must be conducted within 10 business days following the DURB meeting**. **Contact: Shirmary Hodges at (404) 656-4044 or shodges@dch.ga.gov**

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

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2015

Upcoming Meetings

Drug Utilization Review Board Meeting

2 Peachtree Street, N.W.

5th Floor Board Room

Atlanta, Georgia 30303

Thursday, September 24, 2015:	9:30am – 1:30pm
Tuesday, December 15, 2015:	9:30am – 1:30pm

Manufacturers' Forum

NorthStar HealthCare Consulting

1121 Alderman Drive

Suite 112

Alpharetta, Georgia 30005

Thursday, August 6, 2015:	9:00am – 5:00pm
Thursday, November 5, 2015:	9:00am – 5:00pm

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Drug Utilization Review Board

Board Member	Credentials	Specialty/Area of Expertise	Company Name
Drew A. Miller, Chair	R.Ph.	Retail Pharmacy	Wynn's Pharmacy
Gurinder J.S. Doad, Vice-Chair	M.D.	Family Practice	Southwest Georgia Family Medicine and Mercer University School of Medicine
Mia Avery	Pharm.D.	Oncology Pharmacy	Emory University Hospital Winship Cancer Institute
Ann R. Damon	Pharm.D.	Long Term Care Pharmacy	United Pharmacy Services
Deborah W. Fincher	R.Ph., M.S.	HIV/AIDS Pharmacy	Pride Medical Pharmacy
M. Celeste Fowler	Pharm.D., HCMBA	Hospital Pharmacy	Piedmont Henry Hospital
Yolanda P. Graham	M.D.	Psychiatry	Devereux Georgia Treatment Network
Thomas B. Gore	M.D.	Internal Medicine, Cardiology	Southern CardioPulmonary Associates
Robyn Lorys	Pharm.D.	Managed Care	Peach State Health Plan
J. Russell May	Pharm.D.	Academia - Professor	University of Georgia College of Pharmacy
Brent L. Rollins	R.Ph., Ph.D.	Academia - Professor	Philadelphia College of Osteopathic Medicine School of Pharmacy
Robert E. Shervette, III	M.D.	Child and Adolescent Psychiatry	Ogeechee Behavioral Health Services