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 6, 2013

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GEORGIA DEPARTMENT OF COMMUNITY HEALTH

DRUG UTILIZATION REVIEW BOARD MEETING
AGENDA

2 Peachtree Street - 5th Floor DCH Board Room
Atlanta, Georgia 30303
June 6, 2013 – 10:00 a.m. to 2:00 p.m.

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

- **Manufacturers' Forum**

- **New Drug Reviews**
  - ●Aubagio™
  - ●Bosulif™
  - ●Linzess™
  - ●Myrbetriq™
  - ●Stivarga™
  - ●Synribo™
  - ●Tudorza™
  - ●Xeljanz™

- **Follow-Up Review**
  - ●High-Level Analysis of Human Immunodeficiency Virus Agents

- **Class Reviews – Clinical Updates**

- **Utilization Trends Review**

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

FUTURE AGENDA ITEMS	*Chair*
REVIEW OF DURB RECOMMENDATIONS	*Chair*
ADJOURNMENT OF MEETING	*Chair*

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Department of Community Health
Drug Utilization Review Board (DURB)
MINUTES
Tuesday, March 19, 2013

MEMBERS PRESENT

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

MEMBERS ABSENT

Paul D. Boyce, M.D.
Melissa D. Carter, J.D,

Staff

Linda Wiant, Pharm.D., Pharmacy Director, Pharmacy Services
Turkesia Robertson-Jones, Pharm.D., Pharmacy Operations Manager, Pharmacy Services
Gilletta Gray, R.Ph., Clinical Manager, Pharmacy Services
Lori Garner, MHS, MBA, R.Ph., Pharmacist, Pharmacy Services
Rose Marie Duncan, MBA, Program Associate, Pharmacy Services
Matthew Leigh, Pharm.D. Candidate

NorthStar HealthCare Consulting

Tara R. Cockerham, Pharm.D., Clinical Programs Director
Elizabeth Flores, 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
Christopher Hamilton, R.Ph., Clinical Consultant, Account Management

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

University of Georgia Pharmacy School
Erin Masarello, Pharm.D. Candidate
Leigh Perri, Pharm.D. Candidate

Call to Order
The Drug Utilization Review Board (DURB/DUR Board/Board) held its first meeting for the calendar year on March 19, 2013. The Chair, Laurel E. Ashworth, Pharm.D. , called the meeting to order at 9:01am.

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

1. Pharmacy Students –UGA students, Erin Massarello and Leigh Ann Perri, and Mercer student, Matthew Leigh, were welcomed.
2. Resignations – Arvind Gupta, M.D., has resigned from the DUR Board. Appreciation for his service to the Board was expressed.
3. DUR Board – The Department is seeking nominations for the DUR Board. Nominations can be emailed to DCH.
4. Medicaid Snapshot: Year in Review – A presentation was given to provide an overview of Medicaid expenditures/growth, pharmacy expenditures, specialty drug trending, DUR initiatives and DURB recommendations (see Attachment A).

Minutes from the Previous Meeting
Dr. Ashworth asked for comments regarding the minutes from the December 11, 2012 meeting. There were no corrections. A motion was made, seconded, and carried to approve the minutes as written.

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-two (22) manufacturers participated and provided information regarding the following drugs discussed at the March 2013 DURB meeting:

Manufacturers	Drugs
AbbVie	Humira
Bausch & Lomb	Besivance, Lotemax Gel
Pfizer	Lyrica, Genotropin, Pristiq
Sunovion	Latuda, Zetonna
Amgen	Enbrel
Sanofi	Sklice
Vertex	Incivek
GlaxoSmithKline	Advair, Flovent
Biogen	Avonex

Manufacturers	Drugs
Novartis	Exelon Patch, Fanapt, Gilenya
Janssen	Xarelto, Invega Sustenna
AstraZeneca	Brilinta
United Therapeutics	Adcirca, Tyvaso
Merck	Cosopt PF, Januvia, Victrelis
Teva	ProAir HFA, Qnasl
UCB	Neupro, Cimzia
Bristol-Myers Squibb	Bydureon
Novo Nordisk	Norditropin
Forest	Daliresp
Otsuka	Abilify
Actelion	Tracleer
Ferring	Prepopik

Questions and comments were made on the following: Manufacturer restrictions on data provided, pharmacoeconomic data; budget-impact models. The next forum will be held on Thursday, May 2, 2013 from 9am-5pm at the NorthStar Healthcare Consulting office: 1121 Alderman Drive, Suite 112, Alpharetta, GA 30005.

New Drug Reviews

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

Therapeutic Class	Drugs	Presenter
Antiparkinson	*Neupro*	Tara Cockerham, Pharm.D.
Bowel Preparation	*Prepopik*	Tara Cockerham, Pharm.D.
Topical Scabicide and Pediculicide	*Sklice*	Tara Cockerham, Pharm.D.
Antineoplastics	*Xtandi*	Tara Cockerham, Pharm.D.

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

- Sklice – pregnancy testing to rule out pregnancy; exclusion of pregnant patients in the clinical trial; local resistant patterns

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
Oral Nonsteroidal Antiinflammatory Drugs (NSAIDs)

Comments were provided on usage in older patients and in Coronary Artery Disease (CAD) patients. The Department noted there were no current issues from providers that have come up with this drug class.

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. The following therapeutic categories had updates:

Drug Class/Name
Anticonvulsants – Second Generation
Antiinfectives - Miscellaneous
Beta Adrenergics – Short-Acting Inhalers
Gastrointestinal – Digestive Enzymes
Insulin
Nasal Steroids
Nonsteroidal Antiinflammatory Agents
Ophthalmic Quinolones
Osteoporosis Agents
Platelet Aggregate Inhibitors/Combinations - Miscellaneous
Pulmonary Antihypertensives
Topical – Corticosteroids
Topical – Scabicides and Pediculicides
Adrenergic Combinations
Alzheimer - Cholinomimetics
Androgen/Anabolics
Angiotensin II Receptor Antagonist (ARBs) and Combinations
Anticoagulants
Antidepressants – Selective Norepinephrine Reuptake Inhibitors
Antiemetic Drugs
Antihemophilic Products
Antihistamines - Nasal
Antihistamines – Non-Sedating
Antihyperkinesis Agents
Antimanic Agents
Antineoplastics and Adjunct Therapies
Antiparkinson Agents
Asthma & Bronchodilator Agents
Atypical Antipsychotics
Cardiac – Other
Cephalosporins
Cholesterol Bile Acid Sequestrants
Diabetic – Dipeptidyl Peptidase IV (DPP-IV) Inhibitors
Diabetic – Non-Insulin Injectables

Drug Class/Name - continued
Direct Renin Inhibitors and Combinations
Gastrointestinal – Inflammatory Bowel Agents
Gastrointestinal – Proton Pump Inhibitors
Growth Hormones
Hematopoietic Agents
Hepatitis C
Lipid – Niacin
Lipid-Other
Migraine – Selective Serotonin Agents
Multiple Sclerosis (MS) Agents
Ophthalmic – Antiallergic
Ophthalmic – Antiinflammatory/Steroid Agents
Ophthalmic – Beta Blockers
Ophthalmic Nonsteroidal Antiinflammatory Agents
Ophthalmic Prostaglandins
Opioid Agonists
Opioid Partial Agonists
Progestins
Prostatic Hypertrophy Agents
Topical – Immunomodulators
Triglyceride Lowering Agents
Tumor Necrosis Factor (TNF) Agents

There were no comments or questions from the Board.

DCH Decisions

DCH Decisions from the December 2012 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:

- Utilization Review Activities

Consumer Comments Session

Dr. Bona conducted the Consumer Comments Session. Consumer comments were presented to the Board from the following:

- Camden Pace, Consumer – consider open access for all atypical antipsychotics
- Dr. Tara Cockerham read a consumer comment (received after last meeting) from the Georgia AIDS Coalition, Cathalene Teahan, RN, MSN

Disclosure forms were completed by Camden Pace and Cathalene Teahan and were reviewed by the Department.

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 6, 2013
  Thursday, September 19, 2013
  Tuesday, December 10, 2013

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

  Thursday, May 2, 2013
  Thursday, August 1, 2013
  Thursday, November 7, 2013

Disclosure Forms

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

Dr. Donald Paul disclosed program support from a manufacturer and abstained from voting for products or classes of medications from this manufacturer.

Adjournment of Open Session

The DUR Board voted to close the open meeting pursuant to the Open Meeting Act of Georgia Section 50-14-1 – 50-14-6 and pursuant to Federal Law Section 1396R-8B3D. The individuals recorded in attendance from the Department of Community Health, Goold Health Services, NorthStar HealthCare Consulting, Catamaran and University of Georgia and Mercer pharmacy students attended the closed session with the Board members. A motion was made by Rusty May, Pharm.D., and seconded by Karen Carter, M.D., to adjourn the open session and approve the closed session. There was a unanimous vote approving the closed session. The Chairman,

Dr. Laurel Ashworth, adjourned the open session at approximately 10:47 am, at which time members took a break then reconvened for the executive (closed) session.

Executive Session

The executive session was held from 11:04am to 1:15pm.

Board's Recommendations to the Department

After all clinical and financial evaluations and discussions, the DUR Board reconvene ed in the open session, voted, and presented the Department with the following recommendations for changes to the Preferred Drug List (PDL). All motions and votes are noted in Attachment B.

New Drug Reviews

Antiparkinson Agent

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

Gastrointestinal – Bowel Evacuation Preparation

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

Topical – Scabicides and Pediculicides

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

Antineoplastics

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

Supplemental Rebate Class Reviews

Analgesics - Miscellaneous

The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Butalbital-Aspirin-Caffeine Capsule, Butalbital-Acetaminophen-Caffeine Capsule, Bupap®, Zebutal®, Dolgic® Plus*** and ***Phrenilin® Forte***.

Anticonvulsants

The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Banzel®***, ***Vimpat®*** and ***Lamotrigine Chewable Tablet***.

Antiinfective - Miscellaneous

The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Metronidazole 375mg Capsule***.

Beta Adrenergics – Short-Acting Inhalers

The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Ventolin® HFA*** and ***ProAir® HFA***.

Gastrointestinal – Digestive Enzymes

The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Ultresa®*** and ***Zenpep®***

Gastrointestinal - Laxatives

The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Kristalose®***.

Hyperparathyroid Treatment – Vitamin D Analogs and Calcimimetics

The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** and ***Grandfathering*** for ***Zemplar®***.

Insulins

The DUR Board recommended ***Preferred*** status for ***Humulin® R Vial, Humulin® N Vial*** and ***Levemir® Vial,*** and ***Preferred*** status with ***Prior Authorization*** for ***Levemir® Flexpen***.

Non-Steroidal Antiinflammatory Agents

The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Diclofenac Sodium Extended-Release Tablet, Etodolac Extended-Release Tablet, Fenoprofen Calcium Tablet, Indomethacin Extended-Release Capsule, Ketoprofen Capsule, Ketoprofen Extended-Release Capsule, Meclofenamate Sodium Capsule, Naproxen Delayed-Release Tablet, Oxaprozin Tablet*** and ***Tolmetin Sodium Capsule and Tablet***.

Ophthalmic Quinolones

The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Besivance®*** and ***Ofloxacin***.

Ophthalmic Selective Alpha Adrenergic Agonists

The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Alphagan® P 0.1%***.

Opioid Combinations

The DUR Board recommended ***Preferred*** status for ***Ibudone® 10mg-200mg Tablet*** and ***Non-Preferred*** status with ***Prior Authorization*** for ***Hydrocodone-Ibuprofen 5mg-***

200mg and 7.5mg-200mg Tablets.

Phosphate Binders

The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Renvela® 800mg Tablet***.

Platelet Aggregate Inhibitors and Combinations

The DUR Board recommended ***Preferred*** status for ***Brilinta®***. The DUR Board also requested the Department monitor and report on utilization of Brilinta® in 6 months.

Pulmonary Antihypertensives

The DUR Board recommended ***Preferred*** status with ***Prior Authorization*** for ***Revatio®***.

Steroid Inhalants

The DUR Board recommended ***Preferred*** status for ***Pulmicort® Flexhaler***.

Topical – Acne Preparations

The DUR Board recommended ***Preferred*** status for ***Klaron® Suspension, Tazorac® Cream and Gel*** and ***Ziana®***, ***Preferred*** status with ***Prior Authorization*** for ***Azelex®*** and ***Non-Preferred*** status with ***Prior Authorization*** for ***Benzaclin®, Benzamycin® Pak, Clindagel, Clindamycin Phosphate Swab, Ery® and Erythromycin Swabs, Metrogel Pump, Metronidazole Cream and Lotion*** and ***Sulfacetamide Sodium Suspension.***

Topical – Corticosteroids-Low Potency

The DUR Board recommended ***Preferred*** status for ***Fluocinolone Acetonide Oil*** and ***Non-Preferred*** status with ***Prior Authorization*** for ***Derma-Smoothe® FS, U-Cort®*** and ***Desonide Lotion.***

Topical – Corticosteroids-Medium Potency

The DUR Board recommended ***Preferred*** status for ***Kenalog® Aerosol*** and ***Non-Preferred*** status with ***Prior Authorization*** for ***Amcinonide Cream; Betamethasone Valerate Lotion; Fluocinolone Acetonide Cream, Ointment and Solution; Fluticasone Proprionate Cream and Ointment; Hydrocortisone Butyrate Cream; Mometasone Furoate Cream, Ointment and Solution*** and ***Triamcinolone Acetonide Lotion***.

Topical – Corticosteroids-High Potency

The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Amcinonide Ointment; Apexicon® E Cream; Betamethasone Dipropionate Gel and Ointment; Betamethasone Dipropionate (Augmented) Cream, Lotion and Ointment; Clobetasol Propionate Foam; Desoximetasone Cream, Gel and Ointment*** and ***Diflorasone Diacetate***

Cream and Ointment.

Topical – Scabicides and Pediculicides

The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Natroba***®.

Conclusion

At the conclusion of the executive session, the open session reconvened at 1:29pm and audience participants were invited back into the board room to hear the Board's recommendations submitted to the Department. Dr. Ashworth and Dr. Bona presided over the voting and presented the recommendations from the Board to the Department.

With no other business for discussion, Chair Ashworth adjourned the meeting at 2:24pm.

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

_____
Laurel Ashworth, Pharm.D., Chair

GEORGIA DEPARTMENT OF COMMUNITY HEALTH

Attachment A

Medicaid Snapshot: The Year in Review

Presentation to: Medicaid Drug Utilization Review Board

Presented by: Linda Wiant, Pharmacy Director

March 19, 2013

Mission

The Georgia Department of Community Health

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

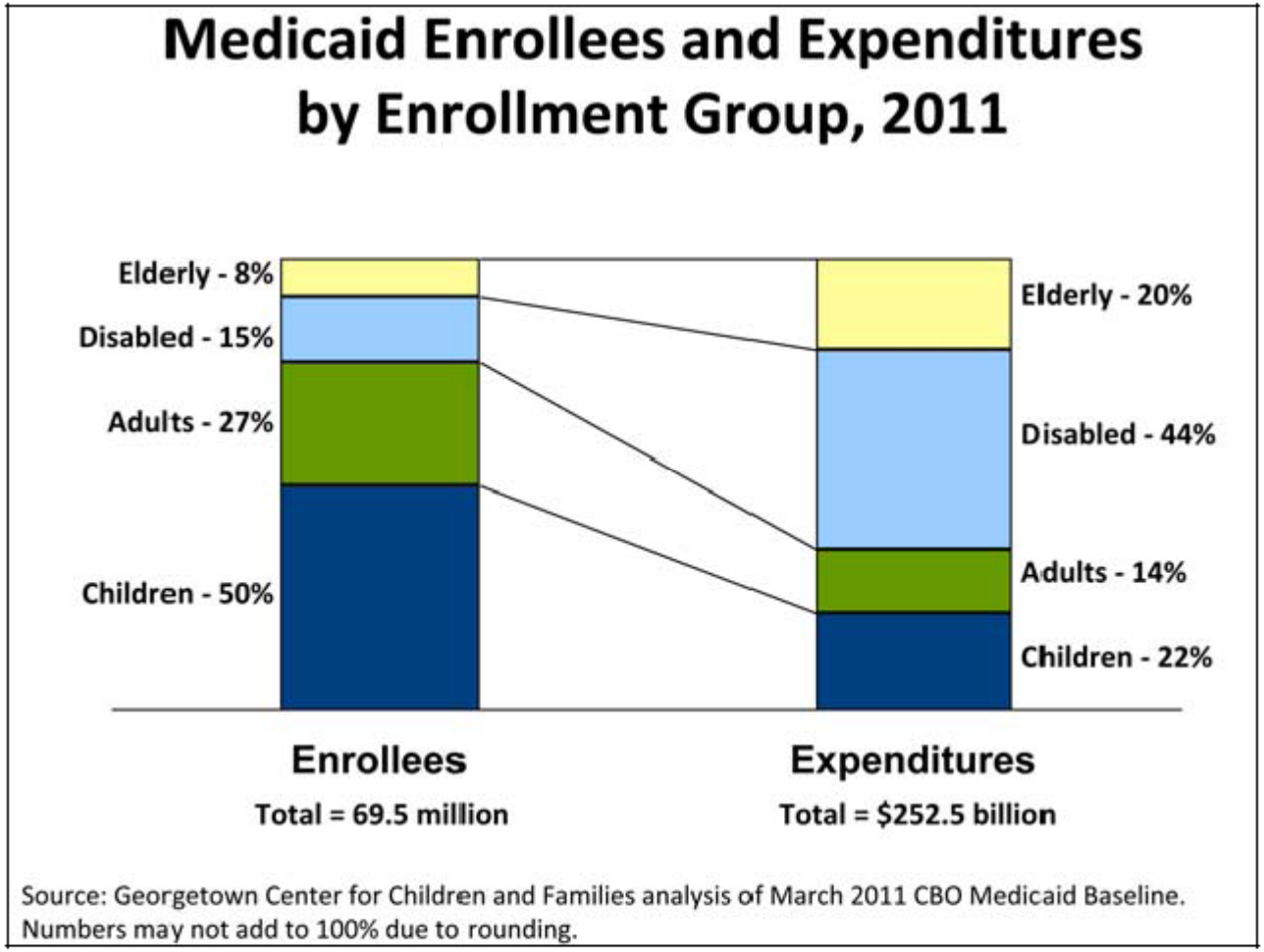
We are dedicated to A Healthy Georgia.

Medicaid Expenditures and Growth

Medicaid Growth Trends – National View

	1966	2000	2010	2020
Enrollees (millions)	4	34	54	85
% of Population	2%	12.5%	17.47%	26.1%
Total Cost (billions)	<$1	$206	$401	$871
% of GDP	<1/2%	2.1%	2.7%	3.7%

Enrollment and Expenditures by Group



Source: Georgetown Center for Children and Families analysis of March 2011 CBO Medicaid Baseline.
Numbers may not add to 100% due to rounding.

Enrollment and Expenditures by Group

Eligibility Group	Number of Enrollees (millions)	Total Medicaid Benefit Spending (billions)	Medicaid Spending per Full-year Equivalent Enrollee
Children	28.3	$68.1	$3,025
Adults	15.4	49.5	4,651
Aged	6.0	78.9	14,945
Disabled	9.1	142.0	17,412
Medicaid-only coverage	*5.6*	*98.2*	*19,682*
Dually enrolled in Medicaid and Medicare	*3.5*	*43.8*	*13,835*
All enrollees	**58.8**	**$338.6**	**$7,267**

Source: MACPAC analysis of Medicaid Statistical Information System (MSIS) Annual Person Summary (APS) data and CMS-64 Financial Management Report (FMR) net expenditure data from CMS

Medicaid Growth Trends – Georgia View

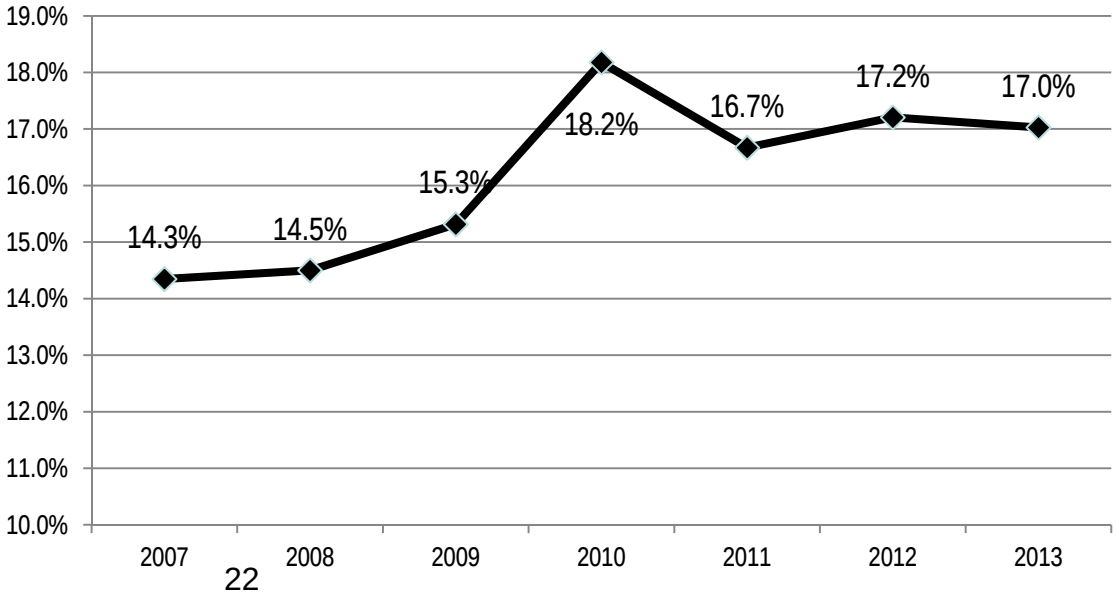
	2000	2010	2020
Enrollees	947,054	1,456,520	1,818,829
% of State Population	11.56%	15.03%	14.92%
State Funds (millions)	$1,393	$1,875	$ 3,889
% of State Revenue	10.2%	12.4%	16.5%

GA Medicaid and PeachCare for Kids

Total FY2012 Expenditures (includes State, Federal and other Fund Sources):

- Medicaid: $8,134,503,878
- PeachCare for Kids: $ 328,621,859
- Average Spend per Day - **$31.4 million per work day**
- Claims Paid per Day – 201,604 per work day
- 59% of total Georgia Births are paid for by Medicaid

Medicaid and PeachCare represents 17% of the state funds budget (excluding motor fuel and lottery)



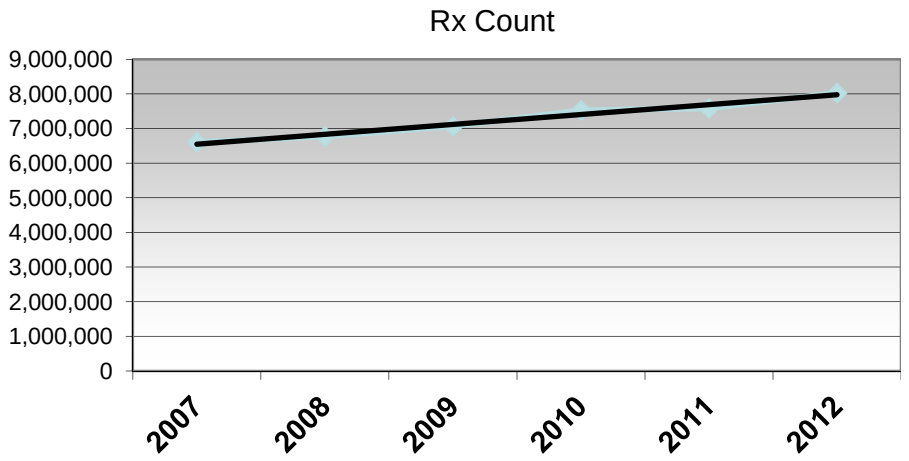
Fee For Service Pharmacy Expenditures

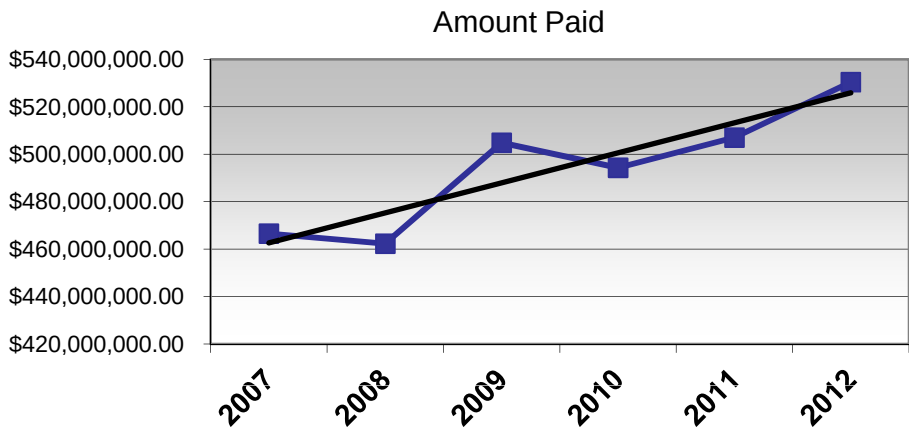
GA Medicaid FFS Prescription Spending

2007-2012

- 4% increase in FFS population (440,569)
- 12.1% increase in expenditures
- 17.7 % increase in Rxs paid
- 2007: $466,554,372.54
- 2012: $530,384,160.01

	PMPM (Rx)	PMPM ($)	PUPM (Rx)	PUPM ($)
2007	1.30	$92.24	4.06	$286.83
2012	1.52	$100.32	4.31	$284.66





Fee For Service Drivers

2008 Totals					
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

2012 Totals				
Drug Grouping Description	Rx Count	Amount Paid	Avg Cost per Rx	Count of Members
ANALGESICS - OPIOID*	627,917	$15,126,768	$24.09	114,061
ANTICONVULSANTS*	563,599	$34,669,181	$61.51	65,289
ANTIDEPRESSANTS*	470,793	$9,826,781	$20.87	66,845
ANTIHYPERTENSIVES*	458,953	$10,655,832	$23.22	65,468
ANTIASTHMATIC AND BRONCHODILATOR AGENTS*	449,568	$53,515,653	$119.04	81,895
ANTIANXIETY AGENTS*	372,391	$3,438,494	$9.23	68,389
ANTIPSYCHOTICS/ANTIMANIC AGENTS*	342,330	$68,699,102	$200.68	38,134
ANTIHISTAMINES*	302,027	$2,587,476	$8.57	105,196
ULCER DRUGS*	292,202	$5,263,348	$18.01	55,236
ANTIDIABETICS*	290,506	$26,930,264	$92.70	28,827

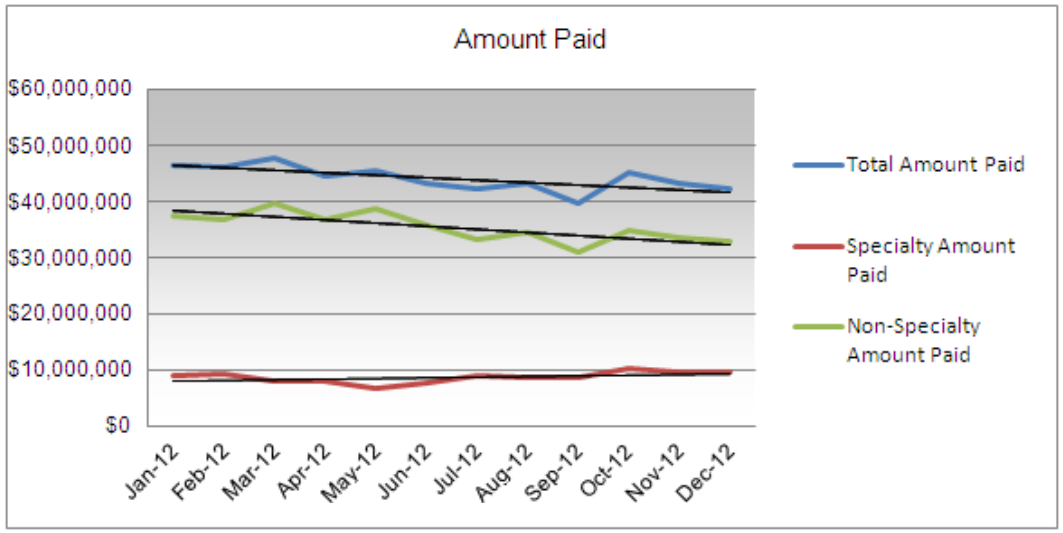
2008 Totals					
Rank	Drug Group Description	Amount Paid	Rx Count	Avg Cost per Rx	Count of Members
1	ANTIPSYCHOTICS/ANTIMANIC AGENTS*	$83,952,701	321,096	$261.46	35,947
2	ANTICONVULSANTS*	$52,446,941	432,456	$121.28	51,456
3	ANTIVIRALS*	$34,488,452	66,820	$516.14	12,631
4	ANTIASTHMATIC AND BRONCHODILATOR 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

2012 Totals				
Drug Group Description	Amount Paid	Rx Count	Avg Cost per Rx	Count of Members
ANTIPSYCHOTICS/ANTIMANIC AGENTS*	$68,699,102	342,330	$200.68	38,134
ANTIVIRALS*	$61,394,489	88,517	$693.59	15,993
ANTIASTHMATIC AND BRONCHODILATOR AGENTS*	$53,515,653	449,568	$119.04	81,895
ANTICONVULSANTS*	$34,669,181	563,599	$61.51	65,289
HEMATOLOGICAL AGENTS - MISC.*	$32,904,820	50,189	$655.62	7,383
ADHD/ANTI-NARCOLEPSY/ANTI-OBESITY/ANOREX	$31,240,380	209,222	$149.32	37,653
ANTIDIABETICS*	$26,930,264	290,506	$92.70	28,827
ANALGESICS - OPIOID*	$15,126,768	627,917	$24.09	114,061
ENDOCRINE AND METABOLIC AGENTS - MISC.*	$14,944,056	37,624	$397.19	6,307
ANTINEOPLASTICS AND ADJUNCTIVE THERAPIES	$11,501,785	24,449	$470.44	5,482

Fee For Service Drivers: Specialty Drug Spending

2012

- Specialty: + 16%
- Nonspecialty: - 12.4%
- Total: +4.61%



DUR Initiatives

Intervention Type	Intervention Name & Description	Number of Profiles Selected for Intervention	Number of Providers or (*Patients) Receiving an Intervention Letter	% Response
PDL Status Change	Therapeutic Appropriateness – PDL status change for Arixtra: Targeted members included patients who had received Arixtra within the previous three months. Mailings were sent to the prescriber.(*letter to patient)	n/a	47 (55*)	n/a
PDL Status Change	Therapeutic Appropriateness – PDL status change for Phoslo: Targeted members included patients who had received Phoslo within the previous three months. Mailings were sent to the prescriber.(*letter to patient)	n/a	37 (48*)	n/a
PDL Status Change	Therapeutic Appropriateness– PDL status change for Gabapentin tablets: To improve the pharmacotherapy by promoting the most clinically appropriate and cost-effective therapy for treatment.	n/a	1850	n/a

DUR Initiatives (Continued)

Intervention Type	Intervention Name & Description	Number of Profiles Selected for Intervention	Number of Providers or (*Patients) Receiving an Intervention Letter	% Response
Drug-Disease Interaction	Drug-Disease stats Interaction – Use of Aliskiren products in diabetics in combination with an ACE/ARB: Targeted members receiving Aliskiren products, plus had a diabetic agent and either an ACE/ARB in their profile. Mailings were sent to the prescriber.(*letter to patient)	n/a	27 (27*)	n/a
Drug Interaction	Drug Information – Drug Interaction with Suboxone: Targeted members included patients who had received suboxone in combination with an opioid or high dose benzodiazepine. Mailings sent to prescribers. (117 letters/profiles to 98 unique MDs)	52	98	25.5%
High Dose	High Dose – Provides warning of high dose utilization based on FDA Alert for Simvastatin: Targeted members who had been receiving doses of Simvastatin greater than 80mg per day, or lower dosages in combination with products that may elevate Simvastatin	362	307	13.7%
Duplicate Therapy	Therapeutic Duplication– Duplicate therapy with Atypical Antipsychotic medications: Targeted members who received two or more different atypicals concurrently for a period of at least three months.	1009	407	10.2%
Duplicate Therapy	Multiple Prescribers-Polypharmacy – Provides info to prescribers on patients utilizing multiple Opiod Pain Relievers (OPRs): Targeted members receiving more than 6 fills of OPRs within a month. Mailings sent to all prescribers in profile.	70	227	16.3%
Drug Information	Drug Information – Safety requirements for LABAs: Targeted the top prescribers of LABA products within the previous three months. Mailings sent to prescribers.	n/a	956	n/a

DUR Board Recommendations

- Opioid Restrictions:
  - 9/1/12: >6 Rxs/month
  - 4/1/13: 5 Rxs/month
- Suboxone:
  - 4/1/13: PA required for concomitant opioid therapy

Drug Utilization Review Board

Motions - Votes

March 19, 2013

New Drug Attachment B

Antiparkinson Agents

Motion: Neupro NP/PA

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Ashworth, Laurel E. Pharm.D. - Chair	N/A	N/A	N/A	N/A	N/A	N/A
2	Bona, Joseph R. M.D. - Co-Chair			√			
3	Carter, Karen L., M.D.			√			
4	Damon, Ann R., Pharm.D.			√			
5	Ellis, Carl, R.Ph.			√			
6	Fincher, Deborah W., M.S., R.Ph.			√			
7	Gore, Thomas B., M.D.	√		√			
8	Greeson, John D., M.D., MBA			√			
9	Jaggers, Rondell C., Pharm.D.		√	√			
10	Jones, Edwina L., Pharm.D., MBA			√			
11	Lorys, Robyn Pharm.D.			√			
12	May, J. Russell, Pharm.D.			√			
13	Miller, Osgood (Drew) A. R.Ph.			√			
14	Paul, Donald A., M.D.			√			
15	Perri, III, Matthew, R,Ph., Ph.D.			√			
16	White, Sandra L., M.D., MBA, FACR			√			
17	Yates, Mary Virginia "Ginny", Pharm.D.			√			
			TOTAL	16	0	0	0

	Board Members - Absent (Highlight, when present)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Boyce, Paul D., M.D.						
2	Carter, Melissa D., J.D.						

Drug Utilization Review Board

Motions - Votes

March 19, 2013

New Drug

GI - Bowel Evacuant Preparations

Motion: Prepokik | NP/PA

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Ashworth, Laurel E. Pharm.D. - Chair	N/A	N/A	N/A	N/A	N/A	N/A
2	Bona, Joseph R. M.D. - Co-Chair			√			
3	Carter, Karen L., M.D.			√			
4	Damon, Ann R., Pharm.D.			√			
5	Ellis, Carl, R.Ph.			√			
6	Fincher, Deborah W., M.S., R.Ph.			√			
7	Gore, Thomas B., M.D.			√			
8	Greeson, John D., M.D., MBA		√	√			
9	Jaggers, Rondell C., Pharm.D.			√			
10	Jones, Edwina L., Pharm.D., MBA			√			
11	Lorys, Robyn Pharm.D.	√		√			
12	May, J. Russell, Pharm.D.			√			
13	Miller, Osgood (Drew) A. R.Ph.			√			
14	Paul, Donald A., M.D.			√			
15	Perri, III, Matthew, R,Ph., Ph.D.			√			
16	White, Sandra L., M.D., MBA, FACR			√			
17	Yates, Mary Virginia "Ginny", Pharm.D.			√			
			TOTAL	16	0	0	0

	Board Members - Absent (Highlight, when present)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Boyce, Paul D., M.D.						
2	Carter, Melissa D., J.D.						

Drug Utilization Review Board

Motions - Votes

March 19, 2013

New Drug

Topical - Scabicides & Pediculicides

Motion:	Sklice	NP/PA	

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

	Board Members - Absent (Highlight, when present)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Boyce, Paul D., M.D.						
2	Carter, Melissa D., J.D.						

Drug Utilization Review Board

Motions - Votes

March 19, 2013

New Drug

Antineoplastics & Adjunctive

	Motion:	Xtandi	P/PA				
	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Ashworth, Laurel E. Pharm.D. - Chair	N/A	N/A	N/A	N/A	N/A	N/A
2	Bona, Joseph R. M.D. - Co-Chair	√		√			
3	Carter, Karen L., M.D.			√			
4	Damon, Ann R., Pharm.D.			√			
5	Ellis, Carl, R.Ph.			√			
6	Fincher, Deborah W., M.S., R.Ph.			√			
7	Gore, Thomas B., M.D.			√			
8	Greeson, John D., M.D., MBA			√			
9	Jaggers, Rondell C., Pharm.D.			√			
10	Jones, Edwina L., Pharm.D., MBA			√			
11	Lorys, Robyn Pharm.D.		√	√			
12	May, J. Russell, Pharm.D.			√			
13	Miller, Osgood (Drew) A. R.Ph.			√			
14	Paul, Donald A., M.D.			√			
15	Perri, III, Matthew, R,Ph., Ph.D.			√			
16	White, Sandra L., M.D., MBA, FACR			√			
17	Yates, Mary Virginia "Ginny", Pharm.D.			√			
			TOTAL	16	0	0	0

	Board Members - Absent (Highlight, when present)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Boyce, Paul D., M.D.						
2	Carter, Melissa D., J.D.						

Drug Utilization Review Board
Motions - Votes
March 19, 2013

ANALGESICS - MISCELLANEOUS

Motion:

Drug	PDL Status	Drug	PDL Status
Butalbital-Aspirin-Caffeine Capsule	**NP/PA**	*Dolgic® Plus*	**NP/PA**
Butalbital-Acetaminophen-Caffeine Capsule	**NP/PA**	*Phrenilin® Forte .*	**NP/PA**
Bupap®	**NP/PA**	*Zebutal®*	**NP/PA**

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Ashworth, Laurel E. Pharm.D. - Chair	N/A	N/A	N/A	N/A	N/A	N/A
2	Bona, Joseph R. M.D. - Co-Chair			√			
3	Carter, Karen L., M.D.			√			
4	Damon, Ann R., Pharm.D.			√			
5	Ellis, Carl, R.Ph.			√			
6	Fincher, Deborah W., M.S., R.Ph.			√			
7	Gore, Thomas B., M.D.			√			
8	Greeson, John D., M.D., MBA			√			
9	Jaggers, Rondell C., Pharm.D.			√			
10	Jones, Edwina L., Pharm.D., MBA			√			
11	Lorys, Robyn Pharm.D.			√			
12	May, J. Russell, Pharm.D.			√			
13	Miller, Osgood (Drew) A. R.Ph.			√			
14	Paul, Donald A., M.D.		√	√			
15	Perri, III, Matthew, R,Ph., Ph.D.			√			
16	White, Sandra L., M.D., MBA, FACR	√		√			
17	Yates, Mary Virginia "Ginny", Pharm.D.			√			
			TOTAL	16	0	0	0

	Board Members - Absent (Highlight, when present)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Boyce, Paul D., M.D.						
2	Carter, Melissa D., J.D.						

Drug Utilization Review Board
Motions - Votes
March 19, 2013

ANTICONVULSANTS

Motion:

Drug	PDL Status
Banzel ®	**NP/PA**
Lamotrigine Chewable Tablet	**NP/PA**
Vimpat ®	**NP/PA**

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

	Board Members - Absent (Highlight, when present)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Boyce, Paul D., M.D.						
2	Carter, Melissa D., J.D.						

Drug Utilization Review Board
Motions - Votes
March 19, 2013

ANTIINFECTIVE - MISCELLANEOUS

Motion:

Drug	PDL Status
Metronidazole 375 mg Capsule	**NP/PA**

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

	Board Members - Absent (Highlight, when present)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Boyce, Paul D., M.D.						
2	Carter, Melissa D., J.D.						

Drug Utilization Review Board
Motions - Votes
March 19, 2013

BETA ADRENERGICS SHORT ACTING INHALERS

Motion:

Drug	PDL Status
ProAir® HFA	**NP/PA**
Ventolin ® HFA	**NP/PA**

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

	Board Members - Absent (Highlight, when present)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Boyce, Paul D., M.D.						
2	Carter, Melissa D., J.D.						

Drug Utilization Review Board
Motions - Votes
March 19, 2013

GASTROINTESTINAL - DIGESTIVE ENZYMES

Motion:

Drug	PDL Status
Ultresa®	**NP/PA**
Zenpep®	**NP/PA**

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

	Board Members - Absent (Highlight, when present)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Boyce, Paul D., M.D.						
2	Carter, Melissa D., J.D.						

Drug Utilization Review Board
Motions - Votes
March 19, 2013

GASTROINTESTINAL - LAXATIVES

Motion:

Drug	PDL Status
Kristalose®	**NP/PA**

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Ashworth, Laurel E. Pharm.D. - Chair	N/A	N/A	N/A	N/A	N/A	N/A
2	Bona, Joseph R. M.D. - Co-Chair			√			
3	Carter, Karen L., M.D.			√			
4	Damon, Ann R., Pharm.D.			√			
5	Ellis, Carl, R.Ph.			√			
6	Fincher, Deborah W., M.S., R.Ph.			√			
7	Gore, Thomas B., M.D.			√			
8	Greeson, John D., M.D., MBA			√			
9	Jaggers, Rondell C., Pharm.D.			√			
10	Jones, Edwina L., Pharm.D., MBA			√			
11	Lorys, Robyn Pharm.D.		√	√			
12	May, J. Russell, Pharm.D.	√		√			
13	Miller, Osgood (Drew) A. R.Ph.			√			
14	Paul, Donald A., M.D.			√			
15	Perri, III, Matthew, R,Ph., Ph.D.			√			
16	White, Sandra L., M.D., MBA, FACR			√			
17	Yates, Mary Virginia "Ginny", Pharm.D.			√			
			TOTAL	16	0	0	0

	Board Members - Absent (Highlight, when present)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Boyce, Paul D., M.D.						
2	Carter, Melissa D., J.D.						

Drug Utilization Review Board
Motions - Votes
March 19, 2013

HYPERPARATHYROID TREATMENT - VITAMIN D ANALOGS AND CALCIMIMETICS

Motion:

Drug	PDL Status
Zemplar®	**NP/PA Grandfathering**

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

	Board Members - Absent (Highlight, when present)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Boyce, Paul D., M.D.						
2	Carter, Melissa D., J.D.						

Drug Utilization Review Board
Motions - Votes
March 19, 2013

INSULIN

Motion:

Drug	PDL Status
Humulin® R Vial	**P**
Humulin® N Vial	**P**
Levemir® Flexpen	**P/PA**
Levemir® Vial	**P**

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Ashworth, Laurel E. Pharm.D. - Chair	N/A	N/A	N/A	N/A	N/A	N/A
2	Bona, Joseph R. M.D. - Co-Chair			√			
3	Carter, Karen L., M.D.			√			
4	Damon, Ann R., Pharm.D.	√		√			
5	Ellis, Carl, R.Ph.			√			
6	Fincher, Deborah W., M.S., R.Ph.		√	√			
7	Gore, Thomas B., M.D.			√			
8	Greeson, John D., M.D., MBA			√			
9	Jaggers, Rondell C., Pharm.D.			√			
10	Jones, Edwina L., Pharm.D., MBA		√	√			
11	Lorys, Robyn Pharm.D.			√			
12	May, J. Russell, Pharm.D.			√			
13	Miller, Osgood (Drew) A. R.Ph.			√			
14	Paul, Donald A., M.D.			√			
15	Perri, III, Matthew, R,Ph., Ph.D.			√			
16	White, Sandra L., M.D., MBA, FACR			√			
17	Yates, Mary Virginia "Ginny", Pharm.D.			√			
			TOTAL	16	0	0	0

	Board Members - Absent (Highlight, when present)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Boyce, Paul D., M.D.						
2	Carter, Melissa D., J.D.						

Drug Utilization Review Board
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March 19, 2013

NASAL STEROIDS

Motion: **No Changes**

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

	Board Members - Absent (Highlight, when present)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Boyce, Paul D., M.D.						
2	Carter, Melissa D., J.D.						

Drug Utilization Review Board
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NON-STEROIDAL ANTIINFLAMMATORY AGENTS

Motion:

Drug	PDL Status	Drug	PDL Status
Diclofenac Sodium Extended-Release Tablet	NP/PA	*Ketoprofen Extended-Release Capsule*	NP/PA
Etodolac Extended-Release Tablet	NP/PA	*Meclofenamate Sodium Capsule*	NP/PA
Fenoprofen Calcium Tablet	NP/PA	*Naproxen Delayed-Release Tablet*	NP/PA
Indomethacin Extended-Release Capsule	NP/PA	*Oxaprozin Tablet*	NP/PA
Ketoprofen Capsule	NP/PA	*Tolmetin Sodium Capsule and Tablet*	NP/PA

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Ashworth, Laurel E. Pharm.D. - Chair	N/A	N/A	N/A	N/A	N/A	N/A
2	Bona, Joseph R. M.D. - Co-Chair			√			
3	Carter, Karen L., M.D.			√			
4	Damon, Ann R., Pharm.D.			√			
5	Ellis, Carl, R.Ph.			√			
6	Fincher, Deborah W., M.S., R.Ph.			√			
7	Gore, Thomas B., M.D.			√			
8	Greeson, John D., M.D., MBA			√			
9	Jaggers, Rondell C., Pharm.D.			√			
10	Jones, Edwina L., Pharm.D., MBA			√			
11	Lorys, Robyn Pharm.D.	√		√			
12	May, J. Russell, Pharm.D.			√			
13	Miller, Osgood (Drew) A. R.Ph.		√	√			
14	Paul, Donald A., M.D.			√			
15	Perri, III, Matthew, R,Ph., Ph.D.			√			
16	White, Sandra L., M.D., MBA, FACR			√			
17	Yates, Mary Virginia "Ginny", Pharm.D.			√			
			TOTAL	16	0	0	0

	Board Members - Absent (Highlight, when present)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Boyce, Paul D., M.D.						
2	Carter, Melissa D., J.D.						

Drug Utilization Review Board
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March 19, 2013

OPHTHALMIC QUINOLONES

Motion:

Drug	PDL Status
Besivance®	**NP/PA**
Ofloxacin	**NP/PA**

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

	Board Members - Absent (Highlight, when present)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Boyce, Paul D., M.D.						
2	Carter, Melissa D., J.D.						

Drug Utilization Review Board
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OPHTHALMIC SELECTIVE ALPHA ADRENERGIC AGONISTS

Motion:

Drug	PDL Status
Alphagan® P 0.1%	NP/PA

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Ashworth, Laurel E. Pharm.D. - Chair	N/A	N/A	N/A	N/A	N/A	N/A
2	Bona, Joseph R. M.D. - Co-Chair			√			
3	Carter, Karen L., M.D.			√			
4	Damon, Ann R., Pharm.D.			√			
5	Ellis, Carl, R.Ph.			√			
6	Fincher, Deborah W., M.S., R.Ph.			√			
7	Gore, Thomas B., M.D.			√			
8	Greeson, John D., M.D., MBA			√			
9	Jaggers, Rondell C., Pharm.D.	√		√			
10	Jones, Edwina L., Pharm.D., MBA			√			
11	Lorys, Robyn Pharm.D.			√			
12	May, J. Russell, Pharm.D.			√			
13	Miller, Osgood (Drew) A. R.Ph.		√	√			
14	Paul, Donald A., M.D.			√			
15	Perri, III, Matthew, R,Ph., Ph.D.			√			
16	White, Sandra L., M.D., MBA, FACR			√			
17	Yates, Mary Virginia "Ginny", Pharm.D.			√			
			TOTAL	16	0	0	0

	Board Members - Absent (Highlight, when present)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Boyce, Paul D., M.D.						
2	Carter, Melissa D., J.D.						

OPIOID - COMBINATIONS

Motion:

Drug	PDL Status
Hydrocodone-Ibuprofen 5mg-200mg Tablet	**NP/PA**
Hydrocodone-Ibuprofen 7.5mg-200mg Tablet	**NP/PA**
Ibudone® 10mg-200mg Tablet	**P**

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Ashworth, Laurel E. Pharm.D. - Chair	N/A	N/A	N/A	N/A	N/A	N/A
2	Bona, Joseph R. M.D. - Co-Chair		√	√			
3	Carter, Karen L., M.D.			√			
4	Damon, Ann R., Pharm.D.			√			
5	Ellis, Carl, R.Ph.			√			
6	Fincher, Deborah W., M.S., R.Ph.			√			
7	Gore, Thomas B., M.D.			√			
8	Greeson, John D., M.D., MBA			√			
9	Jaggers, Rondell C., Pharm.D.			√			
10	Jones, Edwina L., Pharm.D., MBA	√		√			
11	Lorys, Robyn Pharm.D.			√			
12	May, J. Russell, Pharm.D.			√			
13	Miller, Osgood (Drew) A. R.Ph.			√			
14	Paul, Donald A., M.D.			√			
15	Perri, III, Matthew, R,Ph., Ph.D.			√			
16	White, Sandra L., M.D., MBA, FACR			√			
17	Yates, Mary Virginia "Ginny", Pharm.D.			√			
			TOTAL	16	0	0	0

	Board Members - Absent (Highlight, when present)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Boyce, Paul D., M.D.						
2	Carter, Melissa D., J.D.						

Drug Utilization Review Board
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OSTEOPOROSIS AGENTS

Motion: **No Changes**

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

	Board Members - Absent (Highlight, when present)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Boyce, Paul D., M.D.						
2	Carter, Melissa D., J.D.						

Drug Utilization Review Board
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PHOSPHATE BINDERS

Motion:

Drug	PDL Status
Renvela® 800mg Tablet	NP/PA

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Ashworth, Laurel E. Pharm.D. - Chair	N/A	N/A	N/A	N/A	N/A	N/A
2	Bona, Joseph R. M.D. - Co-Chair			√			
3	Carter, Karen L., M.D.			√			
4	Damon, Ann R., Pharm.D.			√			
5	Ellis, Carl, R.Ph.			√			
6	Fincher, Deborah W., M.S., R.Ph.	√		√			
7	Gore, Thomas B., M.D.			√			
8	Greeson, John D., M.D., MBA			√			
9	Jaggers, Rondell C., Pharm.D.			√			
10	Jones, Edwina L., Pharm.D., MBA			√			
11	Lorys, Robyn Pharm.D.			√			
12	May, J. Russell, Pharm.D.			√			
13	Miller, Osgood (Drew) A. R.Ph.			√			
14	Paul, Donald A., M.D.		√	√			
15	Perri, III, Matthew, R,Ph., Ph.D.			√			
16	White, Sandra L., M.D., MBA, FACR			√			
17	Yates, Mary Virginia "Ginny", Pharm.D.			√			
			TOTAL	16	0	0	0

	Board Members - Absent (Highlight, when present)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Boyce, Paul D., M.D.						
2	Carter, Melissa D., J.D.						

Drug Utilization Review Board
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PLATELET AGGREGATE INHIBITORS/COMBINATIONS - MISCELLANEOUS

Motion:	Drug	PDL Status	
	Brilinta®	P	Monitor and report on utilization of Brilinta® in 6 months.

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

	Board Members - Absent (Highlight, when present)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Boyce, Paul D., M.D.						
2	Carter, Melissa D., J.D.						

Drug Utilization Review Board
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PULMONARY ANTI-HYPERTENSIVES

Motion:

Drug	PDL Status
Revatio®	**P/PA**

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Ashworth, Laurel E. Pharm.D. - Chair	N/A	N/A	N/A	N/A	N/A	N/A
2	Bona, Joseph R. M.D. - Co-Chair	√		√			
3	Carter, Karen L., M.D.			√			
4	Damon, Ann R., Pharm.D.			√			
5	Ellis, Carl, R.Ph.			√			
6	Fincher, Deborah W., M.S., R.Ph.			√			
7	Gore, Thomas B., M.D.			√			
8	Greeson, John D., M.D., MBA		√	√			
9	Jaggers, Rondell C., Pharm.D.			√			
10	Jones, Edwina L., Pharm.D., MBA			√			
11	Lorys, Robyn Pharm.D.			√			
12	May, J. Russell, Pharm.D.			√			
13	Miller, Osgood (Drew) A. R.Ph.			√			
14	Paul, Donald A., M.D.			√			
15	Perri, III, Matthew, R,Ph., Ph.D.			√			
16	White, Sandra L., M.D., MBA, FACR			√			
17	Yates, Mary Virginia "Ginny", Pharm.D.			√			
			TOTAL	16	0	0	0

	Board Members - Absent (Highlight, when present)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Boyce, Paul D., M.D.						
2	Carter, Melissa D., J.D.						

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STEROID INHALANTS

Motion:

Drug	PDL Status
Pulmicort® Flexhaler	P

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

	Board Members - Absent (Highlight, when present)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Boyce, Paul D., M.D.						
2	Carter, Melissa D., J.D.						

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TOPICAL - ACNE PREPARATIONS

Motion:

Drug	PDL Status	Drug	PDL Status
Azelex®	P/PA	*Klaron® Suspension*	P
Benzaclin®	NP/PA	*Metrogel Pump*	NP/PA
Benzamycin® Pak	NP/PA	*Metronidazole Cream and Lotion*	NP/PA
Clindagel	NP/PA	*Sulfacetamide Sodium Suspension*	NP/PA
Clindamycin Phosphate Swab	NP/PA	*Tazorac® Cream and Gel*	P
Ery® Swab	NP/PA	*Ziana®*	P
Erythromycin Swab	NP/PA		

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Ashworth, Laurel E. Pharm.D. - Chair	N/A	N/A	N/A	N/A	N/A	N/A
2	Bona, Joseph R. M.D. - Co-Chair			√			
3	Carter, Karen L., M.D.			√			
4	Damon, Ann R., Pharm.D.			√			
5	Ellis, Carl, R.Ph.			√			
6	Fincher, Deborah W., M.S., R.Ph.			√			
7	Gore, Thomas B., M.D.			√			
8	Greeson, John D., M.D., MBA			√			
9	Jaggers, Rondell C., Pharm.D.			√			
10	Jones, Edwina L., Pharm.D., MBA			√			
11	Lorys, Robyn Pharm.D.			√			
12	May, J. Russell, Pharm.D.		√	√			
13	Miller, Osgood (Drew) A. R.Ph.			√			
14	Paul, Donald A., M.D.	√		√			
15	Perri, III, Matthew, R,Ph., Ph.D.			√			
16	White, Sandra L., M.D., MBA, FACR			√			
17	Yates, Mary Virginia "Ginny", Pharm.D.			√			
			TOTAL	16	0	0	0

	Board Members - Absent (Highlight, when present)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Boyce, Paul D., M.D.						
2	Carter, Melissa D., J.D.						

TOPICAL - CORTICOSTEROIDS - LOW

Motion:

Drug	PDL Status	Drug	PDL Status
Derma-Smoothe® FS	NP/PA	*Fluocinolone Acetonide Oil*	P
Desonide Lotion	NP/PA	*U-Cort®*	NP/PA

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Ashworth, Laurel E. Pharm.D. - Chair	N/A	N/A	N/A	N/A	N/A	N/A
2	Bona, Joseph R. M.D. - Co-Chair			√			
3	Carter, Karen L., M.D.			√			
4	Damon, Ann R., Pharm.D.			√			
5	Ellis, Carl, R.Ph.			√			
6	Fincher, Deborah W., M.S., R.Ph.			√			
7	Gore, Thomas B., M.D.			√			
8	Greeson, John D., M.D., MBA			√			
9	Jaggers, Rondell C., Pharm.D.			√			
10	Jones, Edwina L., Pharm.D., MBA	√		√			
11	Lorys, Robyn Pharm.D.			√			
12	May, J. Russell, Pharm.D.			√			
13	Miller, Osgood (Drew) A. R.Ph.			√			
14	Paul, Donald A., M.D.			√			
15	Perri, III, Matthew, R,Ph., Ph.D.			√			
16	White, Sandra L., M.D., MBA, FACR			√			
17	Yates, Mary Virginia "Ginny", Pharm.D.		√	√			
			TOTAL	16	0	0	0

	Board Members - Absent (Highlight, when present)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Boyce, Paul D., M.D.						
2	Carter, Melissa D., J.D.						

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TOPICAL - CORTICOSTEROIDS - MEDIUM

Motion:

Drug	PDL Status	Drug	PDL Status
Amcinonide Cream	NP/PA	*Hydrocortisone Butyrate Cream*	NP/PA
Betamethasone Valerate Lotion	NP/PA	*Kenalog® Aerosol*	P
Fluocinolone Acetonide Cream	NP/PA	*Mometasone Furoate Cream*	NP/PA
Fluocinolone Acetonide Ointment	NP/PA	*Mometasone Furoate Ointment*	NP/PA
Fluocinolone Acetonide Solution	NP/PA	*Mometasone Furoate Solution*	NP/PA
Fluticasone Proprionate Cream	NP/PA	*Triamcinolone Acetonide Lotion*	NP/PA
Fluticasone Proprionate Ointment	NP/PA		

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

	Board Members - Absent (Highlight, when present)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Boyce, Paul D., M.D.						
2	Carter, Melissa D., J.D.						

Drug Utilization Review Board
Motions - Votes
March 19, 2013

TOPICAL - CORTICOSTEROIDS - HIGH

Motion:

Drug	PDL Status	Drug	PDL Status
Amcinonide Ointment	NP/PA	*Clobetasol Propionate Foam*	NP/PA
Apexicon® E Cream	NP/PA	*Desoximetasone Cream*	NP/PA
Betamethasone Dipropionate Gel	NP/PA	*Desoximetasone Gel*	NP/PA
Betamethasone Dipropionate Ointment	NP/PA	*Desoximetasone Ointment*	NP/PA
Betamethasone Dipropionate (Augmented) Cream	NP/PA	*Diflorasone Diacetate Cream*	NP/PA
Betamethasone Dipropionate (Augmented) Lotion	NP/PA	*Diflorasone Diacetate Ointment*	NP/PA
Betamethasone Dipropionate (Augmented) Ointment	NP/PA		

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Ashworth, Laurel E. Pharm.D. - Chair	N/A	N/A	N/A	N/A	N/A	N/A
2	Bona, Joseph R. M.D. - Co-Chair			√			
3	Carter, Karen L., M.D.			√			
4	Damon, Ann R., Pharm.D.			√			
5	Ellis, Carl, R.Ph.			√			
6	Fincher, Deborah W., M.S., R.Ph.			√			
7	Gore, Thomas B., M.D.			√			
8	Greeson, John D., M.D., MBA			√			
9	Jaggers, Rondell C., Pharm.D.			√			
10	Jones, Edwina L., Pharm.D., MBA	√		√			
11	Lorys, Robyn Pharm.D.			√			
12	May, J. Russell, Pharm.D.			√			
13	Miller, Osgood (Drew) A. R.Ph.			√			
14	Paul, Donald A., M.D.		√	√			
15	Perri, III, Matthew, R,Ph., Ph.D.			√			
16	White, Sandra L., M.D., MBA, FACR			√			
17	Yates, Mary Virginia "Ginny", Pharm.D.			√			
			TOTAL	16	0	0	0

	Board Members - Absent (Highlight, when present)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Boyce, Paul D., M.D.						
2	Carter, Melissa D., J.D.						

Drug Utilization Review Board
Motions - Votes
March 19, 2013

TOPICAL SCABICIDES AND PEDICULICIDES

Motion:

Drug	PDL Status
Natroba ®	NP/PA

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

	Board Members - Absent (Highlight, when present)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Boyce, Paul D., M.D.						
2	Carter, Melissa D., J.D.						

Drug Utilization Review Board
Motions - Votes
March 19, 2013

Therapeutic Classes

ADRENERGIC COMBINATIONS	CARDIAC OTHER - ANTIARRHYTHMICS TYPE 3	MULTIPLE SCLEROSIS AGENTS
ALZHEIMER-CHOLINOMIMETICS	CARDIAC OTHER - ANTIANGINAL AGENTS	NEUROPATHIC PAIN AGENTS
ANDROGENS/ANABOLICS: TOPICAL	CEPHALOSPORINS	NON-STEROIDAL ANTIINFLAMMATORY COX-2
ANGIOTENSIN II RECEPTOR ANTAGONISTS & COMBINATIONS	CHOLESTEROL BILE ACID SEQUESTRANTS	OPHTHALMIC ANTIALLERGIC
ANTICOAGULANTS	DIABETIC – DIPEPTIDYL PEPTIDASE IV (DPP - 4)	OPHTHALMIC ANTIINFLAMMATORY
ANTIDEPRESSANTS - MODIFIED CYCLICS	DIABETIC - NON-INSULIN INJECTABLES	OPHTHALMIC BETA - BLOCKERS
ANTIDEPRESSANTS - SELECTIVE NOREPINEPHRINE REUPTAKE INHIBITORS (SNRIs)	DIRECT RENIN INHIBITORS COMBINATIONS	OPHTHALMIC NSAIDS
ANTIEMETIC DRUGS	DIRECT RENIN INHIBITORS	OPHTHALMIC PROSTAGLANDINS
ANTIHEMOPHILIC PRODUCTS	DRUGS AFFECTING THE EAR	OPIOID AGONISTS
ANTIHISTAMINES - NASAL	GI - INFLAMMATORY BOWEL AGENTS	OPIOID PARTIAL AGONISTS
ANTIHISTAMINES - NON-SEDATING	GI - PROTON PUMP INHIBITORS	PROGESTINS
ANTIHYPERKINESIS AGENTS	GROWTH HORMONES	PROSTATIC HYPERTROPHY AGENTS
ANTIMANIC AGENTS	HEMATOPOIETIC AGENTS	RESPIRATORY AGENTS - MISCELLANEOUS
ANTINEOPLASTICS AND ADJUNCTIVE THERAPIES	HEPATITIS C	TOPICAL - IMMUNOMODULATORS
ANTIPARKINSON AGENTS	HIV DRUGS	TRIGLYCERIDE LOWERING AGENTS
ASTHMA & BRONCHDILATOR AGENTS	LIPID - NIACIN	TUMOR NECROSIS FACTOR AGENTS
ATYPICAL ANTIPSYCHOTIC DRUGS	LIPID OTHER	
BETA BLOCKERS	MIGRAINE - SELECTIVE SEROTONIN AGONISTS	

Motion: No PDL status changes for the drugs in classes listed.

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

Drug Utilization Review Board
Motions - Votes
March 19, 2013

	Board Members - Absent (Highlight, when present)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)	RECUSE (√)
1	Boyce, Paul D., M.D.						
2	Carter, Melissa D., J.D.						

Manufacturers' Forum
Manufacturer Presentations

Dates: May 2, 2013

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

Attendees
Department of Community Health
Linda Wiant, PharmD, Pharmacy Director, Pharmacy Services
Turkesia Robertson-Jones, PharmD, Pharmacy Operations Manager, Pharmacy Services

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

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

Drug Summary Documents
Please note that relevant, electronic materials that were provided by manufacturers were forwarded to the Drug Utilization Review Board (DURB). For the drugs presented at the Forum that were either new drugs, drugs not previously presented or existing drugs with new information since last presented, the information is highlighted below. The manufacturers presenting at the Forum referred the audience and the readers of the materials to the prescribing information for additional information on the drug, especially in regards to safety.

Drug Presentations

I. Otsuka
Rod Teat, PharmD, Medical Science Liaison
Bradford Loo, PharmD, Senior Medical Science Liaison
Diana Sedgwick, CMR, Senior Account Executive

Abilify® Maintena® (aripiprazole for extended-release injectable suspension)
Abilify Maintena for extended-release injectable suspension is an atypical antipsychotic indicated for the treatment of schizophrenia.

Clinical Efficacy and Safety
- The efficacy of Abilify Maintena in adult patients for the treatment of schizophrenia was demonstrated in a randomized-withdrawal, double-blind, placebo-controlled, trial in adults. Compared to placebo-treated patients, Abilify Maintena-treated patients showed a statistically significantly longer time to relapse, which was the primary endpoint. The key secondary endpoint, percentage of patients meeting the exacerbation of psychotic symptoms/relapse criteria, was also significantly lower in patients randomized to the Abilify Maintena group (10%) than in the placebo group (40%). The safety profile of Abilify Maintena is expected to be similar to that of oral aripiprazole. Based on a pool of five placebo-controlled trials (four 4-week and one 6-week) in which oral aripiprazole was administered to adults with schizophrenia in doses ranging from 2 mg/day to 30 mg/day, the incidence of discontinuation due to adverse reactions was 7% in oral aripiprazole-treated and 9% in placebo-treated patients. The types of adverse reactions that led to discontinuation were similar for the two treatment groups. The only commonly observed adverse reaction associated with use of oral aripiprazole in patients with schizophrenia (incidence of 5% or greater and aripiprazole incidence at least twice that for placebo) was akathisia (aripiprazole 8%; placebo 4%).
- Boxed Warning for Abilify Maintena: Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Mechanism of Action
- The mechanism of action of ABILIFY is unknown. It is proposed that the efficacy of ABILIFY is mediated through a combination of partial agonist activity at D2 and 5-HT1A receptors and antagonist activity at serotonin 5-HT2A receptors.
- Abilify Maintena is the first approved dopamine D2 partial agonist in an once-monthly extended-release injectable suspension.

Pharmacokinetics
- Aripiprazole absorption into the systemic circulation is slow and prolonged following intramuscular injection due to low solubility of aripiprazole particles. Following a single intramuscular dose, the plasma concentrations of aripiprazole gradually rise to reach maximum plasma concentrations at a median Tmax of 5-7 days.
- The mean aripiprazole terminal elimination half-life was 29.9 days and 46.5 days after every 4-week injection of Abilify Maintena 300 mg and 400 mg, respectively, and steady state concentrations were attained by the fourth dose.

Dosage and Administration
- Abilify Maintena is only to be administered by intramuscular injection by a healthcare professional. For patients who have never taken aripiprazole, establish tolerability with oral aripiprazole prior to initiating treatment with Abilify Maintena. The recommended starting and maintenance dose of Abilify Maintena is 400 mg monthly (no sooner than 26 days after the previous injection).
- After the first Abilify Maintena injection, continue treatment with oral aripiprazole (10 mg to 20 mg) or other oral antipsychotic for 14 consecutive days to maintain therapeutic antipsychotic concentrations during initiation of therapy.
- If there are adverse reactions with the 400 mg dosage, consider reducing the dosage to 300 mg once monthly.

Questions and Answers
Q: Are any other indications being sought?
A: A bipolar indication is being explored.

Q: Were all studies presented today?
A: Yes, all pivotal trials were presented today. There are pharmacoeconomic studies that will be presented at the upcoming American Psychiatric Association (APA) meeting.

Q: Are there any head-to-head trials being conducted?
A: Not at this time as the Food and Drug Administration (FDA) wants placebo-controlled and active-comparator controlled trials.

Q: Where can the injection be administered?
A: The injection is to be given by a healthcare professional (HCP) as a gluteal deep intramuscular injection and can be given in a setting the HCP deems appropriate, such as office, clinic, community-service board or home health.

Q: What are considered the advantages over other long-acting injectable atypical antipsychotics given head-to-head data are not available?
A: There are no head-to-head data comparing the agents. Abilify Maintena has a unique mechanism of action as a partial dopamine-receptor agonist so does not result in certain adverse events, such as extrapyramidal symptoms and change in prolactin levels; simple one dose with no titration needed; and can use lower dosing if needed for concomitant CYP450 interactions if on for longer than 14 days.

II. Pfizer

Tom Heard, RPh, CGP, Associate Director, Medical Outcomes Specialist
Patrick Kelly, PharmD, Inflammation Medical Specialist, Director, Medical Affairs
Betsy MacLean, PharmD, Director, Regional Outcomes Research, Oncology
Cathy Preiser, Regional Specialty Account Manager

Bosulif® (bosutinib)
Bosutinib is a tyrosine kinase inhibitor (TKI) which inhibits the Bcr-Abl kinase that promotes chronic myelogenous leukemia (CML); it is also an inhibitor of Src-family kinases including Src, Lyn, and Hck. Bosutinib inhibited 16 of 18 imatinib-resistant forms of Bcr-Abl expressed in murine myeloid cell lines. Bosutinib is indicated for the treatment of

adult patients with chronic, accelerated, or blast phase Philadelphia chromosome-positive (Ph+) CML with resistance or intolerance to prior therapy.

Clinical Efficacy

- The use of bosutinib was investigated in a single-arm, Phase 1/2 open-label, multicenter trial to evaluate the efficacy and safety in patients with imatinib-resistant or -intolerant CML with separate cohorts for chronic, accelerated, and blast phase disease previously treated with one prior TKI (imatinib) or more than one TKI (imatinib followed by dasatinib and/or nilotinib). The protocol was amended to exclude patients with a known history of the T315I mutation after 396 patients were enrolled in the trial. The efficacy endpoints for patients with chronic phase (CP) CML previously treated with one prior TKI (imatinib) were the rate of attaining major cytogenetic response (MCyR) at week 24 and the duration of MCyR. The efficacy endpoints for patients with CP CML previously treated with both imatinib and at least 1 additional TKI were the cumulative rate of attaining MCyR by week 24 and the duration of MCyR. The efficacy endpoints for patients with previously treated accelerated phase (AP) and blast phase (BP) CML were confirmed complete hematologic response (CHR) and overall hematologic response (OHR).
- The trial enrolled 546 patients with CP, AP or BP CML. Of the total patient population 73% were imatinib-resistant and 27% were imatinib-intolerant. In this trial, 53% of patients were males, 65% were Caucasian, and 20% were 65 years old or older. Of the 546 treated patients, 503 were considered evaluable for efficacy. Patients were evaluable for efficacy if they had received at least one dose of bosutinib and had a valid baseline efficacy assessment. Among evaluable patients, there were 266 patients with CP CML previously treated with one prior TKI (imatinib), 108 patients with CP CML previously treated with both imatinib and at least 1 additional TKI, and 129 patients with advanced phase CML previously treated with at least one TKI.
- Median duration of bosutinib treatment was 22 months in patients with CP CML previously treated with imatinib, 8 months in patients with CP CML previously treated with imatinib and at least one additional TKI, 10 months in patients with AP CML previously treated with at least imatinib, and 3 months in patients with BP CML previously treated with at least imatinib. MCyR rate at 24 weeks was 33.8% (95% CI: [28.2, 39.9]) in CP CML patients treated with one prior TKI (imatinib). The MCyR rate by 24 weeks for the CP CML patients previously treated with both imatinib and at least one additional TKI was 26.9% (95% CI: [18.8, 36.2]). The minimum follow-up was 23 months for patients with CP CML treated with one prior TKI (imatinib) and 13 months for patients with CP CML treated with imatinib and at least one additional TKI. For the 53.4% of patients with CP CML treated with one prior TKI (imatinib) who achieved a MCyR at any time, the median duration of MCyR was not reached. Among these patients, 52.8 % had a MCyR lasting at least 18 months. For the 32.4% of patients with CP CML treated with imatinib and at least one additional TKI who achieved a MCyR at any time, the median duration of MCyR was not reached. Among these patients, 51.4% had a MCyR lasting at least 9 months. Of the 374 evaluable patients with CP CML, 16 patients had confirmed disease transformation to AP or BP while on treatment with bosutinib. In AP CML patients, CHR by week 48 was 30.4% (95% CI: [19.9, 42.7]) and OHR by week 48 was 55.1% (95% CI: [42.6, 67.1]). In BP CML patients, CHR by week 48 was 15% (95% CI: [7.1, 26.6]) and OHR by week 48 was 28.3% (95% CI: [17.5, 41.4]). The CHR and OHR rates were based on a minimum follow-up of 12 months for patients with AP CML and 18 months for patients with BP CML. Of the 69 evaluable patients with AP CML, 4 patients had confirmed disease transformation to BP while on bosutinib treatment.

Clinical Safety

- Adverse reactions of any toxicity grade reported for greater than 20% of patients were diarrhea (82%), nausea (46%), thrombocytopenia (41%), vomiting (39%), abdominal pain (37%), rash (35%), anemia (27%), pyrexia (26%), and fatigue (24%). Serious adverse reactions reported include anaphylactic shock, myelosuppression, gastrointestinal toxicity (diarrhea), fluid retention, hepatotoxicity, and rash. Gastrointestinal toxicity including diarrhea, nausea, vomiting, and abdominal pain may be monitored and managed using standards of care, including antidiarrheals, antiemetics, and/or fluid replacement.
- In the single-arm Phase 1/2 clinical trial, the median time to onset for diarrhea (all grades) was 2 days and the median duration per event was 1 day. Among the patients who experienced diarrhea, the median number of episodes of diarrhea per patient during treatment with bosutinib was 3 (range 1-221). To manage gastrointestinal toxicity, withhold, dose reduce, or discontinue bosutinib as necessary.
- Thrombocytopenia, anemia and neutropenia occur with bosutinib treatment. Patients with CML who are receiving bosutinib should have a complete blood count performed weekly for the first month and then monthly thereafter, or as clinically indicated. To manage myelosuppression, withhold, dose reduce, or discontinue bosutinib as necessary.
- One case consistent with drug induced liver injury (defined as concurrent elevations in alanine aminotransferase (ALT) or aspartate aminotransferase (AST) greater than or equal to 3 x upper limit of normal (ULN) with total bilirubin greater than 2 x ULN and alkaline phosphatase less than 2 x ULN) occurred in a trial of bosutinib in combination with letrozole. The patient recovered fully following discontinuation of bosutinib. This case

represented 1 out of 1209 patients in bosutinib clinical trials. In the Phase 1/2 clinical trial, the incidence of ALT elevation was 17% and AST elevation was 14 %. Twenty percent of patients experienced an increase in either ALT or AST. Most cases of transaminase elevations occurred early in treatment; of patients who experienced transaminase elevations of any grade, more than 80% experienced their first event within the first 3 months. The median time to onset of increased ALT and AST was 30 and 33 days, respectively, and the median duration for each was 21 days. Perform monthly hepatic enzyme tests for the first three months of treatment with bosutinib and as clinically indicated. In patients with transaminase elevations, monitor liver enzymes more frequently. Withhold, dose reduce, or discontinue bosutinib as necessary.

- Fluid retention may manifest as pericardial effusion, pleural effusion, pulmonary edema, and/or peripheral edema. Severe fluid retention was reported in 14 patients (3%). Specifically, 9 patients had a Grade 3 or 4 pleural effusion, 3 patients experienced both Grade 3 or Grade 4 pleural and pericardial effusions, 1 patient experienced Grade 3 peripheral and pulmonary edema, and 1 patient had a Grade 3 edema. Monitor and manage patients using standards of care. Interrupt, dose reduce or discontinue bosutinib as necessary.

Questions and Answers
Q: Is a phase III trial being conducted?
A: A phase III trial as initial therapy was conducted but did not meet its primary endpoint.

Q: Is there any overall survival data available?
A: Overall survival was estimated as a secondary endpoint at 2 years for all treated patients (N=288) at 92%.

Q: Where is the drug placed in the National Comprehensive Cancer Network (NCCN) guidelines?
A: As a 2nd line agent.

Toviaz® (fesoterodine fumarate)
Toviaz (fesoterodine fumarate) is a muscarinic antagonist indicated for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence (UUI), urgency, and frequency. Toviaz has been extensively studied in clinical trials, providing an extensive body of evidence of efficacy, safety, and tolerability in the antimuscarinic drug class. The focus of this document is on 3 recently completed studies that have been presented or published.

Wagg A, Khullar V, Marschall-Kehrel D, et. al. Efficacy and Tolerability of fesoterodine in Older Subjects With Overac.ve Bladder: Results of SOFIA. Poster presentation at AGS, 2011. [Data on file, CSR A0221045; Pfizer Inc, New York, NY]
In order to assess the efficacy and safety of flexible-dose Toviaz (4 mg and 8 mg) in older subjects with OAB, a 24-week study was conducted in subjects aged ≥65 years. Seven hundred and eighty-eight subjects with mean age of 73 years were treated with Toviaz 4 mg, Toviaz 8 mg, or placebo during a 12-week randomized, double-blind, flexible-dose, placebo-controlled phase, and all patients were treated with Toviaz during a subsequent 12-week open-label phase. At week 4, 52% and 66% of subjects in the Toviaz and placebo groups opted for dose escalation, respectively, and by week 8, 64% of Toviaz-treated and 71% of placebo-treated subjects opted for dose escalation. At week 12, the improvement from baseline in urgency episodes (primary endpoint) (-3.47 vs. -1.92; $P<0.001$), micturitions ($P<0.001$), nocturnal micturitions ($P=0.003$), severe urgency episodes ($P<0.001$), and incontinence pad use ($P=0.014$) was significantly greater with Toviaz versus placebo, but not the median change in UUI episodes ($P=0.729$) in the 46% of patients with >0 UUI episodes at baseline. The odds of a patient-reported treatment response on the Treatment Benefit Scale (TBS), OAB Satisfaction Questionnaire (OAB-S), Patient Perception of Bladder Condition (PPBC), and Urgency Perception Scale (UPS) were significantly greater among patients in the Toviaz group versus placebo ($P<0.001$ for TBS, OAB-S, and PPBC; $P=0.001$ for UPS). Improvements in scores on the OAB-q Symptom Bother ($P<0.001$) and HRQL ($P<0.001$) scales and the Coping ($P<0.001$), Concern ($P<0.001$), Sleep ($P=0.003$), and Social Interaction ($P=0.015$) domains were significantly greater for Toviaz versus placebo. Rates of dry mouth and constipation were 34% and 9% with Toviaz and 5% and 3% with placebo, respectively, and similar to those reported in studies enrolling younger subjects. No clinically relevant changes were seen on the Mini-Mental State Examination after 12 weeks of double-blind Toviaz treatment. During open-label treatment, subjects initially given Toviaz maintained improvement in OAB symptoms and those who switched from placebo to Toviaz had improvement similar to those given Toviaz for the entire study period.

Kay GC, Maruff P, Scholfield D, et. al. Evaluation of Cognitive Function in Healthy Older Adults Treated with fesoterodine. Oral presentation at ICS 2011. (Data on file; CSR A0221086; Pfizer Inc, New York, NY)
To characterize the effects of Toviaz on cognitive function, a 5- to 6-week, active- and placebo-controlled, double-blind, double-dummy crossover study was conducted, enrolling 20 male and female healthy volunteers, aged 65 to 85 years, who were given Toviaz 4 mg, Toviaz 8 mg, placebo, or active control (alprazolam 1 mg). Treatment sequence was randomized, with a 3 to 6 day washout between periods. The average patient age was 72.2 years with baseline

Mini–Mental State Exam score ≥26. Subjects completed computer-based cognitive assessments (CogState) and the Rey Auditory Verbal Learning Test (RAVLT) on day 1 (before dosing) and day 6 (after dosing) of each period. Differences in LS mean changes in Detection task scores from baseline to day 6 (primary endpoint) for Toviaz 4 mg or Toviaz 8 mg versus placebo were not statistically significant (P>0.05). No significant changes were seen on the CogState or RAVLT in subjects given Toviaz compared with placebo. Significant impairment in scores on the CogState and RAVLT was noted with the active control alprazolam compared with placebo. No serious adverse events (AEs) were reported; the most common AEs were dry mouth for Toviaz 4 mg (10%) and Toviaz 8 mg (32%) and sedation for alprazolam (53%). There was no reported sedation with fesoterodine. In healthy older adults, Toviaz 4 mg and Toviaz 8 mg once daily had no statistically significant effects versus placebo on any cognitive function assessed, including memory, psychomotor function, and attention; alprazolam produced statistically significant deterioration.

Malhotra B, Darsey E, Crownover P, Fang J, Glue P. Comparison of pharmacokinetic variability of fesoterodine vs. tolterodine extended release in cytochrome P450 2D6 extensive and poor metabolizers. *Br J Clin Pharmacol*. 2011;72(2):226-2341413

After oral administration, Toviaz is rapidly and extensively hydrolyzed by nonspecific esterases to its active metabolite 5-hydroxymethyl tolterodine (5-HMT). A randomized, crossover, open-label, multiple-dose study was designed to provide a within-study comparison of the pharmacokinetic variability in CYP2D6 Extensive Metabolizers (EMs) and Poor Metabolizers (PMs) following administration of Toviaz or Detrol LA (tolterodine tartrate extended release). Subjects received 4 mg once-daily doses for 5 days escalated to 8 mg once daily for 5 days of Toviaz and Detrol LA, in random order, with a 3-day washout period. Pharmacokinetics of active moieties were compared by drug, dose and genotype. Tolterodine and 5-HMT are equipotent active moieties of Detrol LA; 5-HMT is the singular active moiety of Toviaz. Formation of 5-HMT from Toviaz and Detrol LA occurs via esterases and CYP2D6, respectively. Active moiety exposures following Toviaz and Detrol LA increased proportional to dose in EMs and PMs. Following Detrol LA administration, 5-HMT is not formed in PMs of CYP2D6, with the exception of quantifiable but very low (<0.5 ng ml-1) concentrations in some PMs at the 8 mg dose. Furthermore, there was a marked effect of the CYP2D6 genotype on tolterodine exposures (approximately 10-fold higher AUC and 6-fold higher Cmax in PMs). In contrast, 5-HMT was formed in both EMs and PMs when Toviaz was administered, and the exposure was affected only to a modest extent (1.5- to 2-fold higher Cmax and AUC in PMs). In EMs only, coefficients of variation for AUC and Cmax following Toviaz (up to 46% and 48%, respectively) were lower than those following Detrol LA (up to 87% and 87%, respectively). Following Toviaz and Detrol LA administration, active moiety exposures ranged up to 7-fold and 40-fold, respectively. Tolterodine, not 5-HMT, was the principal source of variability after Detrol LA administration. Toviaz delivers 5-HMT with less variability than Detrol LA, regardless of CYP2D6 status, with up to 40% higher bioavailability. The pharmacokinetics of Toviaz were considerably less variable than Detrol LA.

Summary

Toviaz is an effective treatment for OAB symptoms with a demonstrated tolerability profile, including long-term use (up to 3 years) and in those over age 65 years. Powerful efficacy of Toviaz has been demonstrated in reducing UUI, particularly at the 8 mg dose which was shown to be superior to Detrol LA 4 mg in two large trials. The antimuscarinic activity of Toviaz is entirely attributable to 5-HMT, and predictable 5-HMT serum levels are attained with administration of Toviaz, regardless of CYP450 2D6 genotype. Toviaz is available in 2 doses (4mg and 8mg), allowing dose adjustment based on individual patient response. The most frequently reported adverse events (≥4%) for Toviaz were: dry mouth (placebo, 7%; Toviaz 4 mg, 19%; Toviaz 8 mg, 35%) and constipation (placebo, 2%; Toviaz 4 mg, 4%; Toviaz 8 mg, 6%).1 The most frequently reported adverse events (≥4%) for Detrol LA were: dry mouth (placebo, 8%; Detrol LA, 23%), headache (placebo, 4%; Detrol LA, 6%), constipation (placebo, 4%; Detrol LA, 6%), and abdominal pain (placebo, 2%; Detrol LA, 4%).

Questions and Answers

Q: When does the patent expire on Detrol LA?
A: 2018-2019

Xeljanz® (tofacitinib)

Xeljanz (tofacitinib) is a novel, orally administered, small molecule, Janus kinase (JAK) inhibitor for the treatment of moderate to severe rheumatoid arthritis (RA) in adults who have an inadequate response or intolerance to methotrexate. Tofacitinib may be administered as monotherapy or in combination with methotrexate or other non-biologic disease-modifying anti-rheumatic drugs (DMARDs). Xeljanz should not be used in combination with biologic DMARDs or potent immunosuppressants such as azathioprine and cyclosporine. The recommended dose of tofacitinib is 5 mg twice daily. Dose adjustments may be warranted in specific situations.

Disease Background and Burden of Illness

- RA is a chronic, systemic autoimmune disease that affects an estimated 1.5 million patients in the US. Treatment of RA is typically initiated with NSAIDs and/or low-dose glucocorticoids, with the introduction of non-biologic DMARDs (typically methotrexate) as quickly as possible after diagnosis and subsequently initiation of a biologic agent (usually a TNF inhibitor) if further treatment is necessary.
- Despite the availability of multiple therapeutic options, many patients fail to adequately respond to treatment or stop responding over time. There is no reliable way to predict which patients will respond to a given agent. This limited rate of treatment success, and the fact that many patients discontinue or switch their therapies (whether non-biologic or biologic), demonstrates the need for additional therapeutic options in RA.

Clinical Pharmacology

- Xeljanz is a JAK inhibitor. JAKs are intracellular enzymes which transmit signals arising from cytokine or growth factor-receptor interactions on the cellular membrane to influence cellular processes of hematopoiesis and immune cell function.
- Following oral administration of tofacitinib, peak plasma concentrations are reached within 0.5 to 1 hour, the elimination half-life is about 3 hours, and a dose-proportional increase in systemic exposure was observed in the therapeutic dose range. Steady state concentrations are achieved in 24 to 48 hours with negligible accumulation after twice daily administration. Tofacitinib is primarily eliminated via hepatic metabolism (70%) with only 30% attributed to renal excretion. The metabolism of tofacitinib is primarily mediated by CYP3A4 with minor contribution from CYP2C19.

Clinical Efficacy

- In the phase 3 clinical trials which included 3315 patients, those who received tofacitinib 5 mg twice daily achieved statistically significantly greater ACR20 response rates and mean reduction in HAQ-DI scores compared to placebo when used as monotherapy or in combination with nonbiologic DMARDs.
- In addition, in the phase 3 studies including background nonbiologic DMARDs, significantly more patients who received tofacitinib 5 mg twice daily achieved a DAS28-4(ESR) < 2.6 (very low disease activity) compared to placebo.

Clinical Safety

- The most common serious AEs associated with Xeljanz therapy were serious infections, including pneumonia, cellulitis, herpes zoster, and urinary tract infections. Lymphomas and other malignancies were observed in patients treated with Xeljanz. The most commonly reported AEs during the first 3 months of treatment were diarrhea, nasopharyngitis, upper respiratory tract infections, headache, and hypertension.
- Xeljanz should be used in caution with patients that may be at increased risk of gastrointestinal perforations. Laboratory monitoring is recommended due to potential changes in lymphocytes, neutrophils, hemoglobin, liver enzymes, and lipids.

Questions and Answers

Q: Were all pivotal trials presented today?
A: Yes.

Q: Are there any head-to-head trials?
A: No head-to-head trials, but there is an active-comparator trial with adalimumab.

Q: Have you heard of when the American College of Rheumatology (ACR) guidelines on RA may be updated?
A: No.

Q: Any other studies/indications being sought?
A: Studies in psoriasis, irritable-bowel syndrome and ophthalmic for dry eye are being explored.

Q: How are other Medicaid plans covering?
A: MA, RI, KY, AL, ND and SD have put on PDL. TX and ME did not put on PDL and ME requires trial of methotrexate per prescribing information (PI).

Q: Why did the European Medicine Agency (EMA) committee recommend against approval?
A: The EMA committee noted the data were not robust enough, concerns with infections and malignancies and concerns with rheumatology skill set. The same that was provided for FDA approval was submitted to the EMA along with interim data which is allowed by the EMA.

III. Forest
Kara Sperandeo, PharmD, Managed Care Specialist, Medical Affairs
Bill Everage, Regional Account Manager

Linzess® (linaclotide)
Linzess (linaclotide) is the first guanylate cyclase-C (GC-C) agonist approved in adults for the treatment of irritable bowel syndrome with constipation (IBS-C) and in adults for the treatment of chronic idiopathic constipation (CIC).

Pharmacology
- Linaclotide is a GC-C agonist. Both linaclotide and its active metabolite bind to and activate GCC and act locally on the luminal surface of the intestinal epithelium resulting in an increase in both intracellular and extracellular concentrations of cyclic guanosine monophosphate (cGMP). Elevation in intracellular cGMP stimulates secretion of chloride and bicarbonate into the intestinal lumen, mainly through activation of the cystic fibrosis transmembrane conductance regulator (CFTR) ion channel, resulting in increased intestinal fluid and accelerated transit.
- In animal models, linaclotide has been shown to both accelerate GI transit and reduce intestinal pain. The linaclotide induced reduction in visceral pain in animals is thought to be mediated by increased extracellular cGMP, which was shown to decrease the activity of pain-sensing nerves. The clinical relevance to humans of these nonclinical studies on the effect on pain has not been established.

Pharmacokinetics and Drug Interactions
- Linzess is minimally absorbed with low systemic availability following oral administration. Both linaclotide and its active metabolite are proteolytically degraded within the intestinal lumen to smaller peptides and naturally occurring amino acids.
- Linaclotide and its active metabolite are not measurable in plasma following administration of the recommended clinical doses; hence, no systemic drug-drug interactions or drug interactions mediated by plasma protein binding of linaclotide or its metabolite are anticipated. No drug-drug interaction studies have been conducted with Linzess. Linaclotide does not interact with the cytochrome P450 enzyme system based on the results of *in vitro* studies, and is neither a substrate nor an inhibitor of the efflux transporter P-glycoprotein.

Clinical Efficacy
The efficacy of Linzess for the management of symptoms of IBS-C (N = 1604) and CIC (N = 1272) was established in a total of four double-blind, placebo-controlled, randomized, multicenter trials.
- IBS-C: The two IBS-C trials were of identical design through the first 12 weeks, with one including an additional 4-week withdrawal period and the other continued for 14 additional weeks (26 weeks total). The 4 primary efficacy responder endpoints were based on a patient being a weekly responder for either at least 9 out of the first 12 weeks of treatment or at least 6 out of the first 12 weeks of treatment. For IBS-C the combined response endpoint (≥ 30% reduction from baseline in mean abdominal pain and an increase of ≥ 1 Complete Spontaneous Bowel Movements (CSBMs) from baseline, all in the same week, for at least 6 of the first 12 weeks of treatment), there was a significantly greater proportion of combined responders to Linzess 290 mcg daily (Trial 1- 33.6%; Trial 2- 33.7%) vs. placebo (Trial 1- 21%; Trial 2- 13.9%). Significantly greater proportions of Linzess-treated patients also met the three 9 out of 12 week primary endpoints: response rates for abdominal pain (Trial 1- 34.3% Linzess vs. 27.1% placebo; Trial 2- 38.9% Linzess vs. 19.6% placebo), CSBMs (Trial 1- 19.5% Linzess vs. 6.3% placebo; Trial 2- 18.0% Linzess vs. 5.0% placebo), and combined response (Trial 1- 12.1% Linzess vs. 5.1% placebo; Trial 2- 12.7% Linzess vs. 3.0% placebo). For change from baseline in abdominal pain, Linzess began to separate from placebo in Week 1, and maximum effects seen at Weeks 6 - 9 were maintained until the end of the study. Maximum effect on CSBM frequency occurred within Week 1. During the 4-week randomized withdrawal period in Trial 1, patients continuing on Linzess maintained their response to therapy over the additional 4 weeks, and patients on placebo who were allocated to Linzess had an increase in CSBM frequency and abdominal pain levels that were similar to the levels observed in patients taking Linzess during the treatment period. In Linzess-treated patients re-randomized to placebo, CSBM frequency and abdominal pain severity returned toward baseline within 1 week and did not result in worsening compared to baseline.
- CIC: The two CIC trials were of identical design through the first 12 weeks, with one including an additional 4-week withdrawal period. A CIC overall combined responder was defined as ≥ 3 CSBMs and a ≥ 1 increase in number of CSBMs from baseline in a given week for at least 9 weeks. In both trials, there was a significantly greater proportion CSBM overall responders with Linzess 145 mcg daily (Trial 3- 20.3%; Trial 4-15.5%) than with placebo (Trial 3- 3.3%; Trial 4- 5.6%). CSBM frequency reached maximum level during week 1 and was also demonstrated over the remainder of the 12-week treatment periods. During the 4-week randomized withdrawal period in Trial 3, patients continuing on Linzess maintained their response to therapy over the additional 4 weeks, and patients on placebo who were allocated to Linzess had CSBM and SBM frequency increases similar to the levels observed in

Linzess-treated patients during the treatment period. In Linzess-treated patients who were re-randomized to placebo, CSBM and SBM frequency returned toward baseline within 1 week and did not result in worsening compared to baseline.

Clinical Safety

- Adverse Reactions: During clinical development, approximately 2570, 2040, and 1220 patients with either IBS-C or CIC were treated with Linzess for 6 months or longer, 1 year or longer, and 18 months or longer, respectively (not mutually exclusive). In IBS-C clinical trials, the most common adverse reactions in Linzess-treated patients (incidence ≥ 2 % and > placebo) were diarrhea (20% vs 3% placebo), abdominal pain (7% vs 5%), flatulence (4% vs 2%), headache (4% vs 3%), viral gastroenteritis (3% vs 1%) and abdominal distension (2% vs 1%). In CIC clinical trials, the most common adverse reactions in Linzess-treated patients (incidence ≥ 2% and > placebo) were diarrhea (16% vs 5% placebo), abdominal pain (7% vs 6%), flatulence (6% vs 5%), upper respiratory tract infection (5% vs 4%), sinusitis (3% vs 2%) and abdominal distension (3% vs 2%).
- Contraindications, Warnings and Precautions: Linzess has a Boxed Warning regarding pediatric risk and is contraindicated in pediatric patients up to 6 years of age. Linzess caused deaths in young juvenile mice, and although there were no deaths in older juvenile mice, given the deaths in young juvenile mice and the lack of clinical safety and efficacy data in pediatric patients, avoid the use of Linzess in pediatric patients 6 through 17 years of age. Linzess is also contraindicated in patients with known or suspected mechanical gastrointestinal obstruction. Diarrhea was the most common adverse reaction of Linzess-treated patients in the pooled IBS-C and CIC trials. Severe diarrhea was reported in 2% of the Linzess-treated patients. The incidence of diarrhea was similar between the IBS-C and CIC populations. Instruct patients to stop Linzess if severe diarrhea occurs and to contact their healthcare provider, who should consider dose suspension.
- Specific Populations: Linzess is a Pregnancy Category C drug. Linzess should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. It is not known whether linaclotide is excreted in human milk. Caution should be exercised when Linzess is administered to nursing women. The safety and effectiveness in pediatric patients has not been established. Linzess is contraindicated in pediatric patients up to 6 years of age. Avoid the use of Linzess in pediatric patients 6 through 17 years of age. Clinical studies did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. No dose adjustment is necessary based on hepatic or renal function.

Dosing

The recommended dose of Linzess for IBS-C is 290 mcg and for CIC 145 mcg to be taken orally once daily on an empty stomach, at least 30 minutes prior to the first meal of the day. Linzess capsules should be kept in the original container with the desiccant.

Questions and Answers

Q: Were all the pivotal trials presented today?
A: Yes.

Q: How are other Medicaid plans covering?
A: Some cover as Tier 3 with no restrictions; AL does not manage.

Q: What are considered the advantages over Amitiza given there are no head-to-head trials?
A: There are no head-to-head trials comparing Linzess to Amitiza. Linzess may be considered more advantageous due to once daily dosing, no dosing adjustments are needed, different mechanism of action which has a direct impact on pain and clinical analysis showed efficacy in multiple symptoms.

Tudorza® Pressair® (aclidinium bromide inhalation powder)

Tudorza Pressair (aclidinium bromide inhalation powder) is indicated for the long-term, maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema.

Pharmacology

- Tudorza Pressair is a long-acting antimuscarinic agent (LAMA), which is often referred to as an anticholinergic. It has similar affinity to the five subtypes of muscarinic receptors M1 to M5. In the airways, it exhibits pharmacological effects through inhibition of M3 receptor at the smooth muscle leading to bronchodilation.
- The competitive and reversible nature of antagonism was shown with human and animal origin receptors and isolated organ preparations. In preclinical *in vitro* as well as *in vivo* studies, prevention of acetylcholine-induced bronchonconstriction effects was dose-dependent and lasted longer than 24 hours. The clinical relevance of these

findings is unknown. The bronchodilation following inhalation of Tudorza Pressair is predominantly a site-specific effect.

Pharmacokinetics and Drug Interactions

- The absolute bioavailability of Tudorza Pressair is approximately 6% in healthy volunteers. Following twice-daily oral inhalation administration of 400 mcg Tudorza Pressair in healthy adult subjects, peak steady state plasma levels were observed within 10 minutes after inhalation. The major route of metabolism of Tudorza Pressair is hydrolysis, which occurs both chemically and enzymatically by esterases. Tudorza Pressair is rapidly and extensively hydrolyzed to its alcohol and dithienylglycolic acid derivatives, neither of which binds to muscarinic receptors and are devoid of pharmacologic activity.
- Tudorza Pressair and its major metabolites do not inhibit CYP450, 1A2, 2A6, 2B6, 2C8, 2C9, 2C19, 2D6, 2E1, 3A4/5 or 4A9/11 at concentrations up to 1,000-fold higher than the maximum plasma concentration that would be expected to be achieved at the therapeutic dose. Therefore, it is unlikely that Tudorza Pressair causes CYP450 related drug interactions (formal drug interactions studies were not performed). In clinical studies, concurrent administration of Tudorza Pressair and other commonly used COPD medications (short-acting beta2 agonists, methylxanthines, and oral and inhaled steroids) showed no increases in adverse drug reactions. Coadministration with anticholinergic-containing drugs should be avoided as there is potential for an additive interaction with concomitantly used anticholinergic medications.

Clinical Efficacy

- The efficacy of Tudorza Pressair was studied in one dose-finding trial and three confirmatory trials. The confirmatory trials consisted of two three-month and one six-month placebo-controlled trials in 1,276 patients with COPD, age 40 or older, with a mean pre-bronchodilator FEV1 of 48%.
- In these trials, 636 patients were treated with Tudorza Pressair at the recommended dose of 400 mcg twice daily. In all three confirmatory trials, treatment with Tudorza Pressair results in statistically significantly greater bronchodilation compared to placebo as measured by change from baseline in morning pre-dose forced expiratory volume in 1 second (FEV1) at week 12.

Clinical Safety

- Adverse Reactions: In the confirmatory trials, the most common adverse reactions (≥3% and greater than placebo) reported in the Tudorza Pressair treated groups were headache (6.6% in Tudorza-treated groups vs 5% in placebo-treated groups), nasopharyngitis (5.5% in Tudorza-treated groups vs 3.9% in placebo-treated groups), and cough (3% in Tudorza-treated groups vs 2.2% in placebo-treated groups). Tudorza Pressair was studied in three long term safety trials (two double blind and one open label), ranging from 40 to 52 weeks in patients with moderate to severe COPD. The adverse events reported in the long term safety trials were similar to those occurring in the 3- and 6-month placebo-controlled trials; no new safety findings were reported.
- Contraindications, Warnings and Precautions: There are no contraindications for use of Tudorza Pressair. Tudorza Pressair is not indicated for the initial treatment of acute episodes of bronchospasm (i.e. rescue therapy). Inhaled medications, including Tudorza Pressair, may cause paradoxical bronchospasm. If this occurs, treatment with Tudorza Pressair should be stopped and other treatments considered. Tudorza Pressair should be used with caution in patients with narrow-angle glaucoma or urinary retention. Prescribers and patients should be alert for signs and symptoms of acute narrow-angle glaucoma (e.g. eye pain or discomfort, blurred vision, visual halos or colored images in association with red eyes from conjunctival congestion and corneal edema) and prostatic hyperplasia or bladder-neck obstruction (e.g. difficulty passing urine, painful urination). Instruct patients to consult a physician immediately should any of these signs or symptoms develop. Immediate hypersensitivity may occur after administration of Tudorza Pressair. If such a reaction occurs, therapy with Tudorza Pressair should be stopped immediately and alternative treatments should be considered. Given the similar structural formula of atropine to Tudorza Pressair, patients with a history of hypersensitivity reactions to atropine should be closely monitored for similar hypersensitivity reactions to Tudorza Pressair. In addition, Tudorza Pressair should be used with caution in patients with severe hypersensitivity to milk proteins.
- Specific Populations: Tudorza Pressair is pregnancy Category C. While there are no adequate and well controlled studies in pregnant women, adverse development effects were observed in rats and rabbits exposed to aclidinium bromide. Tudorza Pressair should be used during pregnancy, labor, or delivery only if the potential benefit justifies the potential risk to the fetus, and caution should be exercised when used in women who are nursing. The safety and effectiveness of Tudorza Pressair in pediatric patients has not been established. COPD does not normally occur in children. Based on available data, no dose adjustments are warranted in renally impaired or geriatric patients. Other reported clinical experience has not identified differences in responses between elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out. The effects of hepatic impairment on the pharmacokinetics of Tudorza Pressair have not been studied.

Dosing
Tudorza Pressair is a breath-actuated multi-dose dry powder inhaler metering 400 mcg of aclidinium bromide per actuation. The recommended dose of Tudorza Pressair is one oral inhalation of 400 mcg, twice daily. No dosage adjustment is necessary for patients with renal impairment or in the elderly.

Questions and Answers
Q: What is considered the place in therapy?
A: LAMAs are preferred therapy in the COPD GOLD guidelines for patients in group B, C or D and are an alternative therapy for patients in group A.

Q: Were all the pivotal trials presented today?
A: Yes.

Q: Are there any head-to-head studies being conducted?
A: No.

Q: Is there any long-term data?
A: There is a 52-week study that was not part of the pivotal trials submitted for FDA approval.

Q: Are there any outcomes studies?
A: Not at this time.

Q: Are there any combination studies being conducted?
A: A combination study with formoterol.

Q: What are considered the advantages over Spiriva given there are no head-to-head data?
A: There are no head-to-head studies comparing Tudorza to Spiriva; the advantages that may be considered include improvement in night-time symptoms due to twice daily dosing, rapid onset that continues, inhaler is available as a dry powder that can provide ease of use and no renal or hepatic cautions.

IV. Genzyme/Sanofi

Lee T. Martin, PhD, Medical Science Liaison

Aubagio® (teriflunomide)
Aubagio (teriflunomide) is an oral, once daily immunomodulatory disease-modifying treatment (DMT) indicated for patients with relapsing multiple sclerosis (RMS). Aubagio, which has a mechanism of action distinct from other available DMTs, has established efficacy and a manageable safety profile. Aubagio has demonstrated consistent effect *vs* placebo on relapse frequency, relapse severity, confirmed disability progression, and magnetic resonance imaging (MRI) lesions.

Clinical Safety
- **Black Box Warning: Hepatotoxicity and Teratogenicity:**
    - **Hepatotoxicity:** Severe liver injury including fatal liver failure has been reported in patients treated with leflunomide, which is indicated for rheumatoid arthritis. A similar risk would be expected for teriflunomide because recommended doses of teriflunomide and leflunomide result in a similar range of plasma concentrations of teriflunomide. Obtain transaminases and bilirubin levels within 6 months before initiation of Aubagio and monitor ALT levels at least monthly for six months. If drug induced liver injury is suspected, discontinue Aubagio and start accelerated elimination procedure.
    - **Teratogenicity:** Based on animal data, Aubagio may cause major birth defects if used during pregnancy. Aubagio is contraindicated in pregnant women or women of childbearing potential who are not using reliable contraception. Pregnancy must be avoided during Aubagio treatment.
- In TEMSO, both doses of Aubagio were well tolerated and demonstrated a manageable safety profile. A similar number of patients experienced adverse events (AEs) or serious AEs (SAEs) or discontinued treatment in the Aubagio and placebo groups. AEs with an increased incidence in Aubagio groups (*vs* placebo) were diarrhea, nausea, hair thinning/decreased hair density, and elevated aminotransferase (ALT) levels.
- The tolerability and safety profile of Aubagio has been confirmed by TOWER and the long-term exposure rates in the phase II and phase III extension trials where no new or unexpected AEs occurred. The incidence of serious or opportunistic infections was very rare with no signal for malignancy or serious cardiovascular events in the

exposed patient population. The safety profile of Aubagio is supported by more than 4600 patient-years of exposure with Aubagio, including more than 2200 patient-years of exposure with the 14 mg dose.
- In TENERE, both doses of Aubagio were well tolerated, with no occurrence of new or unexpected AEs compared with other studies. The overall number of patients with AEs was similar in the Aubagio and Rebif groups.

Clinical Efficacy
- TEMSO, a phase III, randomized, double-blind study that enrolled 1088 patients with RMS, compared once-daily treatment with either 7 mg or 14 mg oral Aubagio against placebo. In this trial, Aubagio (7 mg or 14 mg once daily) administered for 2 years significantly reduced the ARR by 31.2% (*P*=0.0002) with 7 mg and by 31.5% (*P*=0.0005) with 14 mg; the risk of 12-week sustained disability progression was significantly reduced by 29.8% (*P*=0.0279) with the 14 mg dose versus placebo. The disease activity as measured by MRI across several measures was also significantly reduced by both doses of Aubagio versus placebo. Aubagio also showed significant benefit in reducing the annualized rate of relapse leading to hospitalization by 36% (*P*=0.0151) with the 7 mg dose and 59% with the 14 mg dose (*P*<0.0001) compared with placebo. Annualized rate of relapse with sequelae defined by an increase of Expanded Disability Status Scale (EDSS)/Functional Systems (FS) score 30 days post-relapse were reduced by 37% with the 7 mg dose and 39% with the 14 mg dose versus placebo (*P*=0.0002 for both doses); relapses with sequelae determined by the investigator at the end of a relapse were reduced by 53% with the 14 mg dose (*P*<0.0001).
- The annualized rate of relapse leading to hospitalization was also significantly reduced with Aubagio 14 mg by 32.5% (*P*=0.0223) compared with placebo. The annualized rate of relapse with sequelae defined by an increase of EDSS/FS score 30 days post-relapse was reduced by 26% (*P*=0.0315) with Aubagio 7 mg and by 33% versus placebo with Aubagio 14 mg (*P*=0.0081); the ARR with sequelae determined by the investigator at the end of a relapse was significantly reduced by 53.5% (*P*=0.0004) with Aubagio 14 mg.

Conclusion
- Patients with RMS have variable responses to current DMTs, which do not cure MS; many patients continue to experience relapses and disease progression. The tolerability issues and inconvenient mode of administration (injections) of DMTs also result in treatment discontinuation or—in patients with definite RMS—delaying treatment initiation. There is a clinical unmet need for new treatment alternatives with established efficacy and a manageable safety profile.
- In summary, Aubagio (7 and 14 mg) is a convenient new oral DMT for RMS patients with a unique mechanism of action, demonstrated efficacy, and a manageable safety profile.

Questions and Answers
Q: Are there any head-to-head studies?
A: Not at this time.

Q: Are there any outcomes studies?
A: There are phase IV open-label outcomes studies in progress.

Q: What was the most common cause for discontinuation in clinical trials?
A: Alopecia (hair loss).

V. Astellas
Barbara Kassmann, DNP, PNP-BC, Scientific Manager for Managed Markets

Myrbetriq® (mirabegron extended release tablets)
- First Databank and Wolters Kluwer MediSpan have assigned Myrbetriq to a new therapeutic classification of beta-3 adrenergic agonist which is indicated for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency.
- Myrbetriq represents a distinct mechanism of action by relaxing the detrusor smooth muscle during the storage phase of the urinary bladder fill-void cycle by activation of beta-3 adrenergic receptor (AR). This increases bladder storage capacity, without impairing the magnitude of contraction during bladder emptying.
- The recommended starting dose of Myrbetriq is 25 mg once daily with or without food. Myrbetriq 25 mg is effective within 8 weeks. Based on individual patient efficacy and tolerability the dose may be increased to 50 mg once daily.

Clinical Efficacy

- Myrbetriq was evaluated for safety in 4611 patients with OAB in three 12-week, double-blind, multinational (Europe and North America, Studies 1,2 3).
- The 25 mg and 50 mg doses of Myrbetriq each showed statistically significant improvements versus placebo in both co-primary efficacy endpoints of change from baseline to end of treatment (Week 12) in mean number of incontinence episodes and mean number of micturitions per 24 hours.
- An additional 52-week safety study was conducted in 2444 patients randomized to mirabegron or active control (tolterodine), Study 4). Myrbetriq 50 mg improved key OAB symptoms from first measured time point of 4 weeks and efficacy was maintained throughout the 12 month treatment period.

Clinical Safety

- Most commonly reported adverse reactions (>2% and >placebo) for Myrbetriq 25 mg and 50 mg vs. placebo, respectively, were hypertension (11.3%, 7.5% vs. 7.6%), nasopharyngitis (3.5%, 3.9% vs. 2.5%), urinary tract infection (4.2%, 2.9% vs. 1.8%), and headache (2.1%, 3.2% vs. 3.0%). Atrial fibrillation (0.2%) and prostate cancer (0.1%) were reported as serious adverse events by more than 1 patient and at a rate greater than placebo in studies 1, 2, 3.
- Of 5648 patients who received Myrbetriq in the phase 2 and 3 studies, 2029 (35.9%) were 65 years of age or older, and 557 (9.9%) were 75 years of age or older. No overall differences in safety or effectiveness were observed between patients younger than 65 years of age and those 65 years of age or older in these studies.
- Warnings an Precautions:
  - Myrbetriq can increase blood pressure; periodic blood pressure determinations are recommended, especially in hypertensive patients. Myrbetriq is not recommended for use in patients with severe uncontrolled hypertension.
  - Urinary retention in patients with bladder outlet obstruction (BOO) and in patients taking antimuscarinic medications for the treatment of OAB has been reported in post marketing experience in patients taking mirabegron.
  - Since mirabegron is a moderate CYP2D6 inhibitor, the systemic exposure to CYP2D6 substrates such as is increased when co-administered with mirabegron.

Questions and Answers

Q: Were all pivotal trials presented today?
A: Yes.

Q: What is the cause for the increase in blood pressure?
A: Possibly some affect on B1 receptors but not sure yet so conducting studies to evaluate.

Q: Any combination studies being conducted?
A: Combination with an antimuscarinic is being studied and the findings will be presented at an upcoming urology conference.

Q: What are considered the advantages over antimuscarinics given there are not head-to-head data?
A: There is no head-to-head data comparing Myrbetriq to antimuscarinics for OAB. Efficacy may be considered similar but advantages that may be considered are decreased dry mouth, cardiovascular and other adverse effects associated with antimuscarinics; different mechanism of action which increases bladder storage; and use in elderly and potential decrease in falls (antimuscarinics should be used cautiously in elderly). Studies measuring cognitive issues are being conducted.

VI. Boehringer Ingelheim

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

Combivent® Respimat®

- Combivent® Respimat® (ipratropium bromide and albuterol) is indicated for use in patients with chronic obstructive pulmonary disease (COPD) on a regular aerosol bronchodilator who continue to have evidence of bronchospasm and who require a second bronchodilator.
- The recommended dose of Combivent Respimat is one inhalation four times a day. Patients may take additional inhalations as required; however, the total number of inhalations should not exceed six in 24 hours.

Clinical Efficacy and Safety

- The combination of ipratropium bromide and albuterol, marketed as Combivent Inhalation Aerosol, has been demonstrated to maximize the response to treatment in patients with COPD by reducing bronchospasm through 2 distinctly different mechanisms, anticholinergic (parasympatholytic) and sympathomimetic. Simultaneous administration of both an anticholinergic (ipratropium bromide) and a beta2-sympathomimetic (salbutamol) benefits the patient by producing a greater bronchodilator effect than either drug used alone at its recommended dosage.
- The efficacy of the combination of ipratropium bromide and albuterol delivered by the Respimat inhaler was tested in a 12-week, phase 3 trial of 1460 patients with COPD. In this trial, Combivent Respimat was shown to be clinically comparable (statistically noninferior) to Combivent CFC MDI in terms of FEV1. In this trial, the most common (≥ 2%) adverse reactions for Combivent Respimat were upper respiratory tract infection, nasopharyngitis, cough, bronchitis, headache, and dyspnea.
- A separate 12-week trial evaluated a higher than approved dose of Combivent Respimat in 1118 COPD patients. The overall incidence and nature of adverse reactions observed were similar to the adverse reactions seen with recommended dose of Combivent Respimat.
- Safety and efficacy of additional doses of Combivent Respimat beyond six inhalations/24 hours have not been studied. Also, safety and efficacy of extra doses of ipratropium or albuterol in addition to the recommended doses of Combivent Respimat have not been studied.

Important Safety Information

- Combivent Respimat is contraindicated in patients hypersensitive to any of the ingredients of the drug product or to atropine or its derivatives.
- Combivent Respimat can produce paradoxical bronchospasm that can be life-threatening. If it occurs, therapy with Combivent Respimat should be discontinued immediately and alternative therapy instituted.
- The albuterol sulfate contained in Combivent Respimat can produce a clinically significant cardiovascular effect in some patients. If cardiovascular symptoms occur, Combivent Respimat may need to be discontinued. Combivent Respimat should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension.
- Combivent Respimat contained ipratropium bromide and may increase intraocular pressure which may result in precipitation or worsening of narrow-angle glaucoma.
- Patients should avoid spraying the aerosol into their eyes as this may cause acute eye pain or discomfort, temporary blurring of vision, mydriasis, visual halos, or colored images in association with red eyes from conjunctival or corneal congestion.
- Ipratropium bromide also may cause urinary retention.
- Combivent Respimat should be used with caution in patients with narrow-angle glaucoma, prostatic hyperplasia, or bladder-neck obstruction.
- Since dizziness and blurred vision may occur with the use of Combivent Respimat, caution patients about engaging in activities such as driving a vehicle or operating appliances or machinery.
- Do not exceed recommended dose. Fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs in patients with asthma.
- Hypersensitivity reactions including urticaria, angioedema, rash, bronchospasm, anaphylaxis, and oropharyngeal edema may occur. If such a reaction occurs, therapy with Combivent Respimat should be stopped at once and alternative treatment should be considered.
- Combivent Respimat contains albuterol and should be used with caution in patients with convulsive disorders, hyperthyroidism, or diabetes mellitus, and in patients who are unusually responsive to sympathomimetic amines. Albuterol may produce significant hypokalemia in some patients.
- In clinical trials, the most common adverse reactions reported for Combivent Respimat were upper respiratory tract infection, nasopharyngitis, cough, bronchitis, headache, and dyspnea.
- Combivent Respimat may interact additively with concomitantly used anticholinergic medications. Avoid coadministration with other anticholinergic-containing drugs. Caution is advised in co-administration of other beta-adrenergic agents, beta-receptor blocking agents, and non-potassium sparing diuretics. Extreme caution is advised with monoamine oxidase inhibitors or tricyclic antidepressants.

Questions and Answers

Q: When is supply of the old MDI formulation expected to be exhausted?
A: In June or July of 2013. The MDI formulation has to be removed from the market by the end of 2013 according to the FDA.

Q: What are considered unique qualities of the product?
A: It is the only inhaler that contains albuterol and ipratropium, no contraindications for soy due to solvent used, good for 3 months due to stability, contains a 30-days supply (instead of 25-days supply with MDI formulation) which accounts for priming, dose is 1 puff (instead of 2 puffs with MDI formulation) four times a day not to exceed 6 doses per 24 hours.

Spiriva® HandiHaler® (tiotropium bromide inhalation powder)

- Spiriva HandiHaler (tiotropium bromide inhalation powder) is an anticholinergic indicated for the long-term, once-daily, maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD), and for reducing COPD exacerbations.
- Spiriva capsules must not be swallowed as the intended effects on the lungs will not be obtained. The contents of the Spiriva capsules are only for oral inhalation and should only be used with the HandiHaler device.
- The recommended dose of Spiriva HandiHaler is two inhalations of the powder contents of one Spiriva capsule, once-daily, with the HandiHaler device.
- For administration of the Spiriva HandiHaler, a Spiriva capsule is placed into the center chamber of the HandiHaler device. The Spiriva capsule is pierced by pressing and releasing the green piercing button on the side of the HandiHaler device. The tiotropium formulation is dispersed into the air stream when the patient inhales through the mouthpiece.

Clinical Efficacy

- In a one year study comparing Spiriva with ipratropium, Spiriva produced significant improvements in lung function compared with ipratropium monotherapy.
- Spiriva showed sustained lung function improvement vs control throughout the UPLIFT study, a 4-year clinical trial involving 5992 COPD patients permitted to use all respiratory medications (including inhaled corticosteroids, long-acting beta-agonists, or a fixed dose combination of the two) except for other inhaled anticholinergics. Spiriva did not slow the yearly rate of decline in pre- and post-bronchodilator FEV1 vs control, which were the co-primary endpoints of the study.
- Randomized, double blind, placebo controlled trials have shown that treatment with Spiriva improved pulmonary function and decreased hyperinflation leading to improved exercise endurance time. The impact of this increase in exercise endurance time on usual activities has not been established.
- The effect of Spiriva on COPD exacerbations was evaluated in two clinical trials: a 6-month clinical trial of 1892 COPD patients in Veterans Affairs setting and the aforementioned UPLIFT study. In the VA trial Spiriva significantly reduced the proportion of COPD patients who experienced exacerbations by 14% and also reduced the proportion of patients with exacerbation related hospitalizations compared to placebo, 7.0% in the Spiriva group vs 9.5% in the placebo group (p=0.056).
- In the UPLIFT study, in which exacerbations were evaluated as a secondary outcome, Spiriva significantly reduced the risk of an exacerbation and the risk of exacerbation-related hospitalizations by 14% compared to placebo. The median time to first exacerbation was delayed from 12.5 months in the placebo group to 16.7 months in the Spiriva group.

Clinical Safety

- Spiriva HandiHaler (tiotropium bromide inhalation powder) is contraindicated in patients with a history of hypersensitivity to tiotropium, ipratropium (atropine derivatives), or any components of Spiriva capsules. Immediate hypersensitivity reactions, including urticaria, angioedema (including swelling of the lips, tongue, or throat), rash, bronchospasm, anaphylaxis, or itching, occur after administration of Spiriva. Patients with a history of hypersensitivity reactions to atropine should be closely monitored for similar hypersensitivity reactions to Spiriva. Use with caution in patients with severe hypersensitivity to milk proteins.
- Spiriva HandiHaler is not indicated for the initial treatment of acute episodes of bronchospasm, i.e., rescue therapy. Additionally, inhaled medicines, including Spiriva, may cause paradoxical bronchospasm. If any of these occurs, treatment with Spiriva should be stopped and other treatments considered.
- Spiriva HandiHaler should be used with caution in patients with narrow-angle glaucoma or urinary retention. Prescribers should instruct patients to consult a physician immediately should any signs of narrow-angle glaucoma, or prostatic hyperplasia or bladder-neck obstruction occur.
- Since dizziness and blurred vision may occur with the use of Spiriva HandiHaler, caution patients about engaging in activities such as driving a vehicle or operating appliances or machinery.
- As Spiriva is a predominantly renally excreted drug, Spiriva use should be monitored closely in patients with moderate to severe renal impairment (creatinine clearance of ≤ 50mL/min).
- Spiriva HandiHaler has been used concomitantly with short-acting and long-acting sympathomimetic (beta-agonists) bronchodilators, methylxanthines, and oral and inhaled steroids, without increases in adverse drug

reactions. Spiriva may interact additively with concomitantly used anticholinergic medications. Avoid coadministration with other anticholinergic-containing drugs.
- The most common adverse reactions in the 1-year placebo-controlled trials were dry mouth, upper respiratory tract infection, sinusitis, pharyngitis, non-specific chest pain, and urinary tract infection. In addition, the most commonly reported adverse reactions from the 4-year trial not included above were headache, constipation, depression, insomnia, and arthralgia.
- Spiriva capsules should not be swallowed and should only be inhaled through the mouth (oral inhalation) using the HandiHaler device. The HandiHaler device should not be used for administering other medications. Spiriva capsules should always be stored in the sealed blisters, and only removed immediately before use, or else its effectiveness may be reduced.

Questions and Answers
Q: Is another formulation of Spiriva being investigated?
A: Possibly a device similar to Combivent Respimat.

Q: When does the patent expire?
A: 2013.

Q: What are considered the advantages over Tudorza given there are no head-to-head data?
A: There are no head-to-head data comparing Spiriva to Tudorza. The advantages that may be considered include once daily dosing (vs. twice daily dosing), proven efficacy and safety with long-term data, well-accepted and well-known product, indication includes decreasing exacerbations and a study indicated decreased hospitalizations.

VII. Allergan
Rick Fiscella, PharmD, MPH, Senior Medical Scientific Manager

Restasis® (cyclosporine ophthalmic suspension)
- Restasis (cyclosporine 0.05% ophthalmic suspension- cycA) is the first prescription product approved for keratoconjunctivitis sicca (KCS), also known as Dry Eye Disease (DED) or Dysfunctional Tear Syndrome (DTS)
- The majority of DED sufferers are women based on data from large studies in DED, it is estimated that approximately 3.23 million American women and 1.68 million men aged 50 years or older have DED.
- There is consensus that most cases of Dry Eye is related to inflammation. There is evidence that decreased tear secretion, turnover, and desiccation promote ocular surface inflammation. The ocular surface and lacrimal gland inflammation play a key role in the pathogenesis of DED.
- DED patients have higher levels of inflammatory mediators in their tears that show correlation with clinical disease parameters. The following inflammatory mediators have been reported increased in DED Soluble mediators (cytokines [e.g. IL-1,IL-6,IL-8, TNF-alpha] & proteases) in tear fluid; adhesion molecules [e.g. HLA-Dr, ICAM-1] expression by conj epithelium; T cell infiltration of the conjunctiva.
- Level (L) 1 International Treatment Federation (ITF) guidelines recommend education and environmental modifications, artificial tear substitutes, and modification of offending topical or systemic medications . L2 includes above, lubricants, anti-inflammatory agents (topical corticosteroids and/or cyclosporine), and nutritional supplements; L3 includes above, punctal plugs and oral tetracyclines; L4 includes systemic anti-inflammatory therapy, punctal cautery, surgery, or goggles.
- Traditional treatments (artificial tears or ocular lubricants) do not treat the underlying inflammatory cause of the disease, are palliative at best and may not prevent progression of DED.

Clinical Efficacy
- CycA in DED patients has been shown to reduce cell surface markers of activated T lymphocytes & apoptotic cells in conjunctival biopsies & reduce expression of pro-inflammatory cytokines & increase goblet cell densities.
- Restasis results in an increase in tear production, improvement in DED symptoms and signs, and a healthier tear film.
- In one study, ITF guidelines were implemented over 3 months in newly diagnosed DED patients (N=183). 70% of patients presented without lid margin disease (LMD); patients at severity level 2 (59%) were diagnosed most frequently. If AT and patient education do not resolve L1 complaints eye MD and OD are more likely to use cyclosporine to interrupt inflammatory cycles possibly preventing disease progression.
- Topical cyclosporine shows beneficial effects in all categories of dry eye disease. Symptomatic improvement was greatest in mild group and the best results in improvement of disease signs in patients with severe dry eye disease.

- In a study comparing cycA, punctal occlusion and both combined; “plugs increased wetness initially; cycA appeared to promote long term ocular surface health. The effects may be additive and those with punctal occlusion may benefit from adjunctive cycA.
- Mechanical sensitivity of cornea & conjunctiva to tactile stimulus is reduced in patients with DED. Corneal and conjunctival sensitivities did not change significantly after AT therapy (P 0.05); CycA demonstrated improvement in reduced mechanical sensitivity of the ocular surface.

Clinical Safety
- Prescribed 1 drop each eye twice daily; cyclosporine is safe & well tolerated. Adverse side effects were mild to moderate over a 3 year period.

Questions and Answers
Q: Have there been any updates to the product over the past year?
A: Secondary intraocular infections were removed from the PI.

VIII. Arbor

Elizabeth O. Ofili, MD, MPH, FACC, Morehouse School of Medicine, Department of Medicine, Chief, Section of Cardiology, Professor of Medicine and Director, Clinical Research Center, Associate Dean of Clinical Research
Ed Shutter, President and CEO
Thom Rowland, Vice President, Commercial Operations

Dr. Ofili completed a disclosure form reporting having an agreement, affiliation or financial interest as a consultant with Arbor Pharmaceuticals.

BiDil® (isosorbide dinitrate and hydralazine hydrochloride)
- BiDil is a fixed-dose combination of isosorbide dinitrate, a vasodilator with effects on both arteries and veins, and hydralazine hydrochloride, a predominantly arterial vasodilator.
- The mechanism of action underlying the beneficial effects of BiDil in the treatment of heart failure (HF) has not been established. Isosorbide dinitrate is a vasodilator affecting both arteries and veins. Its dilator properties result from the release of nitric oxide and the subsequent activation of guanylyl cyclase, and ultimate relaxation of vascular smooth muscle. Each BiDil Tablet for oral administration contains 20 mg of isosorbide dinitrate and 37.5mg of hydralazine hydrochloride not available as separate individual components.

Indications and Usage
BiDil is indicated for the treatment of heart failure as an adjunct to standard therapy in self-identified black patients to improve survival, to prolong time to hospitalization for heart failure, and to improve patient-reported functional status.

Clinical Efficacy
The A-HeFT trial evaluated BiDil vs. placebo among 1,050 self-identified black patients (over 95% NYHA class III) at 169 centers in the United States. All patients had stable symptomatic heart failure. The trial was terminated early, at a mean follow-up of 12 months, primarily because of a statistically significant 43% reduction in all-cause mortality in the BiDil treated group ($p=0.012$). The primary endpoint was also statistically in favor of BiDil ($p < 0.021$). The BiDil-treated group also showed a 39% reduction in the risk of a first hospitalization for heart failure ($p<0.001$) and had statistically significant improvement of 107% in response to the Minnesota Living with Heart Failure questionnaire, a self-report of the patient’s functional status, at most time points.

Treatment Guidelines based on Level A Evidence
The 2009 ACCF/AHA Guidelines for the Diagnosis and Management of Heart Failure in Adults stated that the combination of a fixed-dose of isosorbide dinitrate and hydralazine to a standard medical regimen for HF, including angiotensin converting enzyme inhibitors (ACEIs) and beta blockers (BBs), is recommended as a class 1 treatment in order to improve outcomes for patients self-described as African-Americans, with New York Heart Association (NYHA) functional class III or IV HF.

Bioequivalence
The FDA has confirmed and documented that there are no generic or therapeutic equivalents to BiDil. No data is currently available for individual formulations of isosorbide dinitrate and hydralazine hydrochloride to show that they are bioequivalent to BiDil. Neither of the individual components of isosorbide dinitrate nor hydralazine hydrochloride has been proven effective in HF treatment. The FDA has not approved the individual isosorbide dinitrate nor hydralazine hydrochloride for treating HF.

Safety

- Augmentation of the vasodilatory effects of isosorbide dinitrate by phosphodiesterase inhibitors such as sildenafil, vardenafil, or tadalafil could result in severe hypotension. Symptomatic hypotension, particularly with upright posture, may occur with even small doses of BiDil.
- BiDil should be used with caution in patients who may be volume depleted or who are already hypotensive.
- Hydralazine hydrochloride can cause tachycardia potentially leading to myocardial ischemia and angina attacks
- Headache and dizziness were the most frequent adverse events occurring at an incidence greater than 2% in clinical studies compared to placebo.

Questions and Answers

Q: Has a supplemental rebate been offered?
A: An increased supplemental rebate has been submitted.

Q: Are other indications/studies being sought?
A: A National Institutes of Health (NIH) study is being studied in women.

Q: What is the reduction in mortality with BiDil due to?
A: Remodeling of heart, increased ejection fraction and decreased wall thickness.

Q: Why was the A-HeFT trial stopped prematurely?
A: Due to significant improvement.

Q: Why is taking hydralazine and isosorbide dinitrate as 2 separate drugs not bioequivalent to BiDil?
A: Possibly due to when taken separately, patients space the 2 medications apart instead of taking at same time as with BiDil. In BiDil, hydralazine is synergistic to isosorbide dinitrate. The evidence is for the fixed dose of BiDil and not the individual agents and thus the fixed-dose formulation is specified in the guidelines.

Q: If the drug was open on the PDL, do you believe physicians would prescribe outside of indication?
A: No, the drug is only promoted for African Americans. Some physicians find PAs in general cumbersome so will start patients on samples who cannot get access to drug and who have shortness of breath and decreased heart function.

Q: How are other plans coverings/
A: For Medicaid, we know TN covers as preferred with no prior authorization (PA), AL covers as non-preferred with PA and most cover as tier 2 or tier 3 without PA restriction. For commercial lines of business, approximately 70% have as preferred, 6% have as non-preferred, 7% have restricted with PA, 2% have as not covered and 14% do not have listed.

IX. Digestive Care

Mary Ellen, MSN, APNP, Medical Science Liaison
Gwen Whitworth, National Account Manager

Pertzye® (pancrelipase)

- Pertzye (pancrelipase), approved by the FDA in may 2012, is a bicarbonate-buffered pancrelipase indicated for the treatment of exocrine pancreatic insufficiency due to cystic fibrosis and other conditions. Pertzye was formerly marketed as Pancrecarb, which was covered by Medicaid.
- The active ingredient of Pertzye is pancrelipase, and extract derived from porcine pancreatic glands, and contains multiple enzyme classes including lipase, amylase and protease. The inactive ingredients in Pertzye include sodium bicarbonate, sodium carbonate, cellulose, acetate phthalate, sodium starch glycolate, diethyl phthalate, ursodiol, polyvinylpyrrolidone, and talc.
- The choice of the excipients and their concentration was adopted in the Pertzye formulation to achieve an ideal pH and enzyme release profile. The development of a buffered pancrelipase composition centered around the basic concept that lipase activity is pH dependent and optimal at pH 8-9. The inclusion of sodium carbonate/sodium bicarbonate-buffer in the Pertzye formulation helps keep lipases at their optimized pH for maximized enzymatic activity.

Clinical Efficacy

- The efficacy and safety of Pertzye were evaluated in a Phase 3 randomized, double-blind, placebo-controlled, crossover study in patients with exocrine pancreatic insufficiency (EPI) due to cystic fibrosis (CF). Following is a brief overview of the study design and results.
- A total of 24 patients were enrolled, between the ages of 8 to 43 years (mean age = 20 years), including 10 patients between 8 and 17 years of age. The efficacy analysis population included 21 patients who completed both double-blind treatment periods. Patients were randomized to receive Pertzye at individually titrated doses (not to exceed 2,500 lipase units per kilogram per meal) or matching placebo for 6 to 8 days of treatment, followed by crossover to the alternate treatment for an additional 6 to 8 days. The length of exposure to Pertzye during this study was 20-28 days, including the treatment period of 6 to 8 days, and the open label titration and transition periods of 7 to 10 days.
- The primary efficacy endpoint was the mean difference in coefficient of fat absorption (CFA) between Pertzye and placebo treatment. The CFA was determined by a 72-hour stool collection during both treatments, when both fat ingestion and excretion were measured. Mean CFA was 83% with Pertzye treatment compared to 46% with placebo treatment. The mean difference in CFA was 36 percentage points in favor of Pertzye treatment with 95% CI: (28, 45) and $p<0.001$.
- The coefficient of nitrogen absorption (CNA) was determined by a 72-hour stool collection during both treatments, when nitrogen excretion was measured and nitrogen ingestion from a controlled diet was estimated (based on the assumption that proteins contain 16% nitrogen). Each patient's CNA during placebo treatment was used as their no-treatment CNA value. Mean CNA was 79% with Pertzye treatment compared to 47% with placebo treatment. The mean difference in CNA was 32 percentage points in favor of Pertzye treatment and this was a statistically significant change.
- In this study, the safety and efficacy of patients between 8 and 17 years of age were similar to adult patients.

Clinical Safety

- The most common adverse reactions (≥10%) were diarrhea, dyspepsia, and cough. The table below enumerates adverse reactions that occurred in at least 2 patients (greater than or equal to 10%) treated with Pertzye at a higher rate than with placebo.

Adverse Reactions Occurring in at Least 2 Patients (≥ 10%)

Adverse Reaction	Pertzye n=21, n (%)	Placebo n=24, n (%)
Diarrhea	2 (10%)	1 (4%)
Dyspepsia	2 (10%)	1 (4%)
Cough	2 (10%)	1 (4%)

Questions and Answers

Q: Are other strengths being studied?
A: A 4,000 lipase units strength is under FDA review.

Q: Are there any head-to-head studies?
A: No.

Q: How often do prescribers switch medications?
A: Prescribers do not switch medications unless patient is failing therapy.

Q: Do prescribers usually prescriber based on body weight or fat ingested?
A: Primarily by the # of units of lipase per kilogram of body weight per day up to a maximum of 2,500 lipase units/kg/meal or 10,000 lipase units/kg/day per the Cystic Fibrosis (CF) Foundation.

Q: What are considered the advantages over other pancrelipase products given there are no head-to-head data?
A: There are no head-to-head data comparing Pertzye to other pancrelipase products. Advantages that may be considered are the product includes a buffer to create optimum pH for maximum enzyme activity and thus does not require concomitant use of an antacid, buffer decreases the # of capsule requirement by approximately 20% based on practice experience, CF patients need to gain weight and the product increases fat absorption which causes an increase in body mass index of approximately 50%, and capsules contain microspheres that are large and small instead of the same size throughout to enhance gastric distribution.

Q: How many patients on the other pancrelipase products require a concomitant antacid?
A: From practice experience, approximately 85% need a concomitant proton pump inhibitor or histamine-2 antagonist.

Q: How are other Medicaid plans covering?
A: The previously marketed product, Pancrecarb was covered by all plans. After FDA removal of all unapproved pancrelipase product and FDA-approved Pertzye was launched, approximately 50% of Medicaid plans are managing and 50% are not.

Q: Do the CF guidelines recommend one product over another?
A: No, but the guidelines provide an algorithm for patients that have gastrointestinal symptoms.

The following was presented at the February 7th Forum and is included again below since the atypical antipsychotic long-acting injectables are being re-reviewed.

X. Janssen
Megan L. Jones, PharmD, MPA, Senior Liaison, Health Economics & Outcomes Research

Invega® Sustenna® (paliperidone palmitate extended-release injectable suspension)
Invega Sustenna is an atypical antipsychotic extended-release injection indicated for the treatment of schizophrenia in adults. Clinical trials have demonstrated efficacy in acute symptom management and delaying time to relapse in adult patients with schizophrenia.

New Dosing
- Dosing: Initiation: The recommended initiation regimen of Invega Sustenna is with a dose of 234 mg on treatment Day 1 and 156 mg one week later, both administered in the deltoid muscle without the need for oral supplementation. Maintenance: The recommended monthly maintenance dose is 117 mg, administered in either the gluteal or deltoid muscle; some patients may benefit from lower or higher maintenance doses within the additional available strengths (39 mg, 78 mg, 156 mg, and 234 mg).
- August 2012 PI Revision for Dosing: The second initiation dose (Day 8) may be administered within ±4 days (Days 4-12) to help avoid a missed dose (revised from ±2 days). Additionally, information was added to reinitiate Invega Sustenna in patients who may have missed the second initiation dose (Day 8).

Questions and Answers
Q: Does the Baker Act have any impact on obtaining additional doses?
A: In states with Baker Act, 2nd dose can be obtained before leaving facility.

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Manufacturers' Forum
ANNOUNCEMENT
NorthStar HealthCare Consulting
Georgia Department of Community Health

On behalf of the Georgia Department of Community Health (DCH) and in service to the Georgia Medicaid Fee-for-Service (FFS) Drug Utilization Review Board (DURB), NorthStar HealthCare Consulting (NHC), in conjunction with Catamaran, announces the Manufacturers' Forum occurring on Thursday, November 7, 2013.

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

Location: **Manufacturers' Forum - Georgia Department of Community Health**
NorthStar HealthCare Consulting
1121 Alderman Drive
Suite 112
Alpharetta, GA 30005

Appointments: The Manufacturers' Forum is by appointment only. Appointments may be requested and will be scheduled ***after*** the drugs, therapeutic classes and/or supplemental rebate classes up for review are posted to the DCH website at **http://dch.georgia.gov** (under Providers – Pharmacy – Drug Utilization Review Board – Meeting Information) approximately 30 days prior to the Forum. Manufacturers with drugs up for review at the current DURB meeting will be granted preference when seeking appointments. All requests for appointments must be made in writing to **GAMedicaid@nhc-llc.com**.

Guidelines for Participation:
- To ensure equitable treatment of all manufacturers, individual manufacturer participation shall be limited to one 30-minute time segment per Forum. **The presentation shall be limited to 20 minutes with 10 minutes for questions and answers.**
- Manufacturer presentations may be audio-recorded for review after the Forum and the associated information shall be presented by NHC in summary fashion at regularly scheduled DURB meetings.
- For new drugs, manufacturers are highly encouraged to present all clinical information pertinent and relevant to current NHC clinical presentations to the DURB, to DCH drug benefit plan design as posted on the DCH website, and to other drugs within the class. **New drug entities are not reviewed by the DURB until on the market for at least 6 months.**
- For existing drugs, manufacturers are highly encouraged to present new clinical information since the drug was last reviewed by the DURB, especially clinical information related to comparisons of other drugs within the class.
- **An electronic one-page summary of the presentation should be provided one week prior to the presentation via email to GAMedicaid@nhc-llc.com.**

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

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

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Georgia Department of Community Health (GDCH)

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

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

Ongoing Opportunity:

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

Presentation Opportunity:

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

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

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

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

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

Opportunity to Appeal to GDCH:

GDCH Review Process: DURB recommendations are reviewed by GDCH for final decisions. Manufacturers may request an appeal meeting for review directly with GDCH within 10 business days following DURB meetings. **Contact: Shirmary Hodges at (404) 656-4044 or shodges@dch.ga.gov**

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

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2013

Upcoming Meetings

Drug Utilization Review Board Meeting

2 Peachtree Street, N.W.

5th Floor Board Room

Atlanta, Georgia 30303

Thursday, September 19, 2013:	10:00am – 2:00pm
Tuesday, December 10, 2013:	10:00am – 2:00pm

Manufacturers' Forum

NorthStar HealthCare Consulting

1121 Alderman Drive

Suite 112

Alpharetta, Georgia 30005

Thursday, August 1, 2013:	9:00am – 5:00pm
Thursday, November 7, 2013:	9:00am – 5:00pm