GEORGIA DEPARTMENT OF COMMUNITY HEALTH

# Georgia Department of Community Health

# DRUG UTILIZATION REVIEW BOARD MEETING

Department of Community Health
2 Peachtree Street – 41st Floor Conference Room
Atlanta, Georgia 30303

## June 5, 2014

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GEORGIA DEPARTMENT OF COMMUNITY HEALTH

**DRUG UTILIZATION REVIEW BOARD MEETING**
**AGENDA**
*2 Peachtree Street - 41st Floor Conference Room*
*Atlanta, Georgia 30303*
**Thursday, June 5, 2014**
**9:30 a.m. to 2:30 p.m.**

| | |
|---|---|
| **CALL TO ORDER** | *Joseph Bona, MD, Chair* |
| **COMMENTS FROM THE DEPARTMENT** | *Jerry Dubberly, PharmD, MBA, Chief*<br>*Linda Wiant, PharmD, Pharmacy Director* |
| **MINUTES FROM PREVIOUS MEETING** | *Chair* |
| **CONSUMER COMMENTS SESSION** | *Chair* |
| **ADJOURNMENT OF OPEN SESSION** | *Chair* |
| **EXECUTIVE SESSION** | *Steve Liles, PharmD, Senior Director, Goold* |
| **LUNCH** | |
| **RECONVENING OF OPEN SESSION** | *Chair* |
| **CLINICAL REVIEWS AND DURB VOTES** | *Emily Baker, PharmD, BCPS, NorthStar*<br>*Tara R. Cockerham, PharmD, NorthStar* |

- **Manufacturers' Forum**
- **New Drug Reviews**
  - ●Adempas ●Brintellix ●Imbruvica
  - ●Opsumit ●Fetzima
  - ●Breo Ellipta ●Granix
- **Therapeutic Class Review**
  - ●Anticonvulsants, including new drug Fycompa
- **Supplemental Rebate Class Reviews**
- **Utilization Trends**
- **Drug Information**
  - ●Drug Update Newsletter ●Patent Expiration Report
  - ●Horizon Watch Report ●Clinical Compass Newsletter

| | |
|---|---|
| **FUTURE AGENDA ITEMS** | *Chair* |
| **ADJOURNMENT** | *Chair* |

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# Department of Community Health
# Drug Utilization Review Board (DURB)
# MINUTES
# Tuesday, March 18, 2014

**MEMBERS PRESENT**

Joseph R. Bona, M.D., MBA, Chair
Osgood (Drew) A. Miller, R.Ph., Vice-Chair
Mia Avery, Pharm.D.
Ann R. Damon, Pharm.D.
Gurinder J.S. Doad, M.D.
Deborah W. Fincher, M.S., R.Ph.
Thomas B. Gore, M.D.
John Greeson, M.D., MBA
Edwina L. Jones, Pharm.D.
Robyn Lorys, Pharm.D.
J. Russell May, Pharm.D.
Donald A. Paul, M.D.
Brent L. Rollins, R.Ph., Ph.D.
Robert E. Shervette III, M.D.
Sandra L. White, M.D., MBA, FACR

**MEMBERS ABSENT**

M. Celeste Fowler, Pharm.D.
Mary Virginia "Ginny" Yates, Pharm.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

**NorthStar HealthCare Consulting**

Emily Baker, Pharm.D., BCPS, MHA, MBA, President
Tara R. Cockerham, Pharm.D., Clinical Programs Director
Lauren Ellison, Pharm.D., BCPS, Pharmacy Resident
Rajsi Kale, Pharm. D. Candidate

**Catamaran**

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

**Goold Health Services**

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

## Call to Order

The Drug Utilization Review Board (DURB/DUR Board/Board) held its first meeting for the calendar year on March 18, 2014. The Chair, Joseph R. Bona, M.D., MBA, called the meeting to order at 9:05am.

## Comments from the Department

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

1. Medicaid Snapshot: Year in Review – A presentation was given to provide an overview of Medicaid expenditures/growth, new Medicaid initiatives, pharmacy expenditures, and DUR initiatives (see Attachment A).

## Minutes from the Previous Meeting

Dr. Bona asked for corrections or changes to the minutes from the December 10, 2013 meeting. There were no corrections. A motion was made (Thomas B. Gore, M.D.), seconded (Sandra L. White, M.D., MBA, FACR), and carried to approve the minutes as written.

## Consumer Comments Session

Consumer comments were presented to the Board from the following:

- Dr. Enrique Martinez, Atlanta Gastroenterology Associates – Hepatitis C disease and therapy.
- Mr. Seth Walker, Emory Cystic Fibrosis Center – Cystic Fibrosis disease and tobramycin inhalation therapy.

Disclosure forms were completed by Dr. Enrique Martinez and Mr. Seth Walker and were reviewed by the Department.

## Adjournment of Open Session

The DUR Board voted to close the open meeting pursuant to the Open Meeting Act of Georgia Section 50-14-1 – 50-14-6 and pursuant to Federal Law Section 1396R-8B3D. The individuals recorded in attendance with the Board members were from the Department of Community Health, Goold Health Services, NorthStar HealthCare Consulting, and Catamaran. A motion was made by Robyn Lorys, Pharm.D., and seconded by John Greeson, M.D., MBA , to adjourn the open session and approve the closed session. There was a unanimous vote approving the closed session. The Chairman, Dr. Joseph R. Bona, adjourned the open session at approximately 9:46 am, at which time members took a break then reconvened for the executive (closed) session.

## Executive Session

The Executive Session was held from 9:55am to 11:19am.

## Reconvening of Open Session

The DUR Board reconvened for the open session at 12:18pm.

## 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

seventeen (17) manufacturers participated and provided information regarding the following drugs discussed at the March 2014 DURB meeting:

| Manufacturers | Drugs |
|---|---|
| ViiV Healthcare | Tivicay |
| Vertex | Incivek |
| Purdue | Butrans, OxyContin |
| Gilead | Sovaldi |
| UCB | Cimzia |
| AstraZeneca | Kombiglyze XR, Onglyza, Bydureon |
| Cornerstone | Bethkis |
| Amgen | Enbrel |
| Boehringer Ingelheim | Gilotrif, Tradjenta, Jentadueto |
| GlaxoSmithKline | Mekinist, Tafinlar |
| Novartis | Tobi Podhaler, Gilenya |
| Takeda | Nesina, Oseni, Kazano |
| Novo Nordisk | Norditropin, Victoza |
| Pfizer | Chantix, Toviaz |
| Bristol-Myers Squibb | Atripla, Reyataz |
| Genentech | Actemra |
| Johnson & Johnson | Olysio |

There were no questions or comments. The next forum will be held on Thursday, May 1, 2014 from 9am-5pm at the NorthStar Healthcare Consulting office: 1121 Alderman Drive, Suite 112, Alpharetta, GA 30005.

**Therapeutic Class Review**

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

| Therapeutic Class Name |
|---|
| Direct Inhibitors for Hepatitis C |

Following the therapeutic class review, Lance L. Stein, MD, Transplant Hepatologist at Piedmont Transplant Institute, presented a Hepatitis C overview (see Attachment B). A disclosure form was completed by Dr. Lance L. Stein and reviewed by the Department. Questions and comments were made from the Board and Dr. Stein provided answers/comments on the following:

- Compliance rates (real-world) – better than before; physicians/nurses are able to 'select out' patients where there may be compliance issues; non-compliance not as much as it used to be; interventions to improve compliance-Direct Observation Therapy; side effects of prior new therapies were more pronounced than originally thought and physicians may have halted therapy; newer drugs-not seeing same side effects as much and doing less blood work; Interferon based therapy- between 12-24 weeks start to see drop outs; overall, still may have compliance issues but not as much as before.

- Lifespan of drugs/ cross resistance – data still immature; sofosbuvir-associated with single marker for resistance but not clinical significant; simeprevir-clinical significance not known; impact of resistance not known.
- Data to show cost savings down the line – other Managed Care Organizations suggest there are savings down the road; preliminary mathematical models suggest savings; Dr. Stein agreed to provide consultation on design and methodology for a retrospective study for the Department.
- Risk factors for reinfection (what can be done) – education; biggest risk factors are IV drug abuse and unprotected male to male sex.
- Treatment by non-specialists – possible with education; education assistance from PhARMA; federal guidelines requiring testing of all baby boomers will bring more awareness to primary care physicians; newer generation of drugs will have 12 weeks of treatment and fewer side effects, so this may be viewed as identifying an infection and then treating.
- Mutation testing with sofosbuvir and simeprevir treatment – probably not as significant; response guided therapy not as significant with simeprevir.

The Board voted and made recommendations on the Antivirals, Hepatitis C Agents noted in the Board's Recommendations to the Department.

**New Drug Reviews**

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

| Therapeutic Class | Drugs | Presenter |
|---|---|---|
| | | |
| Biologic Immunomodulator | *Actemra SC* | Emily Baker, Pharm.D., BCPS |
| | | |
| Antineoplastic | *Gilotrif* | Emily Baker, Pharm.D., BCPS |
| | | |
| Hematopoietic | *Injectafer* | Emily Baker, Pharm.D., BCPS |
| | | |
| Antineoplastic | *Mekinist* | Emily Baker, Pharm.D., BCPS |
| | | |
| Antineoplastic | *Tafinlar* | Emily Baker, Pharm.D., BCPS |
| | | |
| Antiretroviral | *Tivicay* | Emily Baker, Pharm.D., BCPS |

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

- Gilotrif – access to specialty pharmacy; no known problems

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

## Supplemental Rebate Drugs – New Clinical Information Review

Clinical updates to the Supplemental Rebate categories were listed in the Supplemental Rebate section of the DURB binder and presented to the Board by Dr. Lauren Ellison. The following therapeutic categories had updates:

| Drug Class/Name |
|---|
| Analgesics, Opioids (includes Opioid Abuse, Short Acting Non-Combination, Nonsteroidal Combinations and Long Acting subclasses) |
| Antianginal Agents |
| Antibiotics, Inhaled |
| Antidiabetics, Insulin |
| Antidiabetics, Noninsulin |
| Antihyperlipidemics |
| Dermatologic, Corticosteroids (Low, Medium, High Potency) |
| Multiple Sclerosis Agents |
| Nasal, Antiallergic |
| Nasal, Steroids |
| Ophthalmic, Adrenergics |
| Ophthalmic, Antiinfectives |
| Ophthalmic, Nonsteroidal Antiinflammatory Drugs |
| Ophthalmic, Prostaglandins |
| Smoking Deterrents |
| Urinary Antispasmodics |

There were no comments or questions from the Board.

## DCH Decisions

DCH Decisions from the December 2013 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:

- Hepatitis C Pharmacoeconomic Study

**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 5, 2014
  Thursday, September 18, 2014
  Thursday, December 4, 2014

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

  Thursday, May 1, 2014
  Thursday, August 7, 2014
  Thursday, November 6, 2014

**Disclosure Forms**

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

**Board's Recommendations to the Department**

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

## New Drugs and Supplemental Rebate Classes

**Biologic Immunomodulators**

The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Actemra® (Subcutaneous) Syringe*** and ***Orencia® (Subcutaneous) Syringe***.

**Antineoplastics, Epidermal Growth Factor Receptor (EGFR) Inhibitors**

The DUR Board recommended ***Preferred*** status with ***Prior Authorization*** for ***Gilotrif™ (Oral) Tablet***.

**Hematopoietic Agents, Iron Injectable**

The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Injectafer™ (Intravenous) Vial***.

**Antineoplastics, Braf Inhibitors**

The DUR Board recommended ***Preferred*** status with ***Prior Authorization*** for ***Mekinist™ (Oral) Tablet*** and ***Tafinlar® (Oral) Capsule***.

**Antiretrovirals, Integrase Inhibitors (INSTIs)**

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

**Antiretrovirals, Nucleoside Reverse Transcriptase Inhibitors (NRTIs)**

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

**Antiretrovirals, Protease Inhibitors (PIs)**

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

**Antivirals, Hepatitis C Agents**

The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Olysio™ (Oral) Capsule, Sovaldi™ (Oral) Tablet*** and ***Moderiba (Oral) Tablet and Tablet Dose Pack***.

**Opiate Agonists, Long-Acting**

The DUR Board recommended ***Preferred*** status for ***Butrans® (Transdermal) Patch***.

**Antibiotics, Inhaled**

The DUR Board recommended ***Preferred*** status for ***Bethkis® (Inhalation) Ampule-Neb*** and ***Non-Preferred*** status with ***Prior Authorization*** for ***Tobi® (Inhalation) Ampule-Neb***.

**Antidiabetics, Insulin**

The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Novolog® (Subcutaneous) Vial, Novolog® Mix 70-30 (Subcutaneous) Vial, Novolin® R (Injection) Vial, Novolin® 70-30 (Subcutaneous) Vial*** and ***Novolin® N (Subcutaneous) Vial***.

**Antihyperlipidemics**

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

***Antara®** (Oral) Capsule, Cholestyramine (Oral) Powder Pack* and ***Cholestyramine Light (Oral) Powder Pack***.

**Corticosteroids, Oral**

The DUR Board recommended ***Preferred*** status for ***Prednisolone Sodium Phosphate (Oral) Solution 25 MG/5 ML*** and ***Non-Preferred*** status with ***Prior Authorization*** for ***Millipred® (Oral) Solution, Tablet and Tablet Dose Pack***.

**Dermatologics, Corticosteroids Low-Potency**

The DUR Board recommended ***Preferred*** status for ***Hydrocortisone Acetate*** (***Topical***) ***Gel*** and ***Non-Preferred*** status with ***Prior Authorization*** for ***Derma-Smoothe-FS® (Topical) Oil*** and ***Desonide (Topical) Cream and Ointment***.

**Dermatologics, Scabicides-Pediculocides**

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

**Multiple Sclerosis (MS) Agents**

The DUR Board recommended ***Preferred*** status for ***Extavia®*** (***Subcutaneous***) ***Kit*** and ***Non-Preferred*** status with ***Prior Authorization*** for ***Betaseron® (Subcutaneous) Kit***.

**Multivitamins, Prenatal with Docosahexaenoic Acid (DHA)**

The DUR Board recommended considering a Maximum Allowable Cost (MAC) for the agents.

**Nasal Steroids**

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

**Ophthalmics, Adrenergic/Carbonic Anhydrous Inhibitors**

The DUR Board recommended ***Preferred*** status for ***Iopidine® (Ophthalmic) Drops*** and ***Simbrinza® (Ophthalmic) Drops Suspension***.

**Ophthalmics, Antiinfectives**

The DUR Board recommended ***Preferred*** status for ***Trifluridine (Ophthalmic) Drops*** and ***Non-Preferred*** status with ***Prior Authorization*** for ***Bleph-10® (Ophthalmic) Drops, Ilotycin® (Ophthalmic) Ointment*** and ***Viroptic® (Ophthalmic) Drops***.

## Ophthalmics, Nonsteroidal Antiinflammatory Drugs (NSAIDs)

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

## Ophthalmics, Steroids

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

## Phosphate Binders

The DUR Board recommended ***Preferred*** status for ***Calcium Acetate (Oral) Capsule and Tablet*** and ***Phoslyra® (Oral) Solution***.

## Urinary Antiinfectives

The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Hiprex® (Oral) Tablet, Methenamine Hippurate (Oral) Tablet, UR N-C® (Oral) Tablet, Urimar-T® (Oral) Tablet*** and ***Urogesic Blue® (Oral) Tablet***.

## Conclusion

At the conclusion of the reconvened open session and no other business for discussion, there was a unaminous decision to adjourn the meeting. Chair Bona adjourned the meeting at 2:15pm.

THESE MINUTES ARE HEREBY APPROVED AND ADOPTED, THIS THE _____ DAY OF _____, 2014.

_____

Joseph R. Bona, M.D., MBA, Chair

Georgia Department of Community Health

# Medicaid Snapshot: The Year in Review

Presentation to: Medicaid Drug Utilization Review Board

Presented by: Linda Wiant, Pharmacy Director

March 19, 2013

Georgia Department of Community Health

# Mission

## The Georgia Department of Community Health

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

*We are dedicated to A Healthy Georgia.*

GEORGIA DEPARTMENT
OF COMMUNITY HEALTH

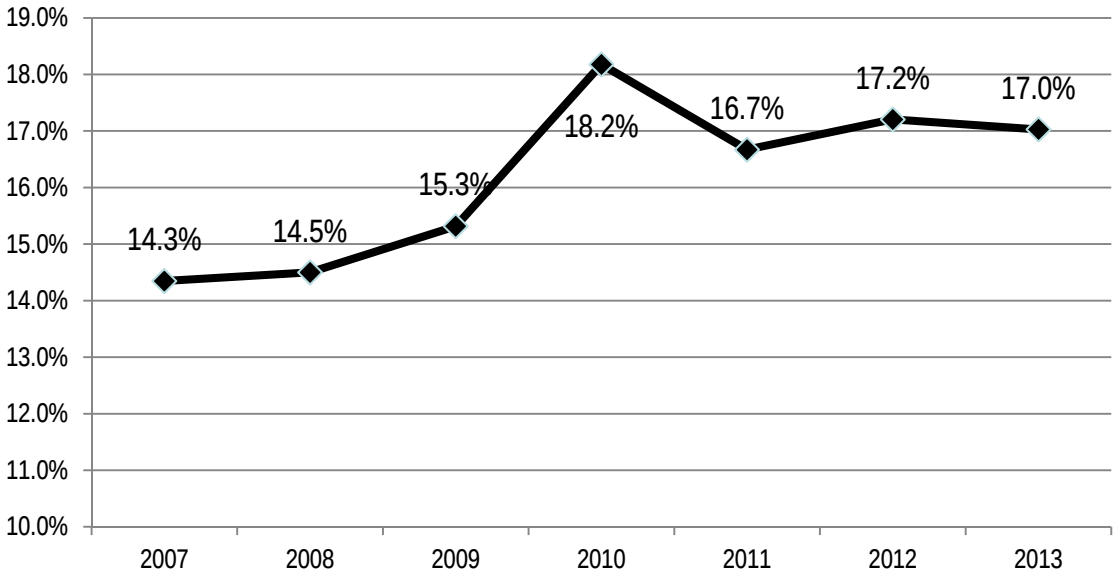
# Medicaid Expenditures and Growth

# GA Medicaid and PeachCare for Kids

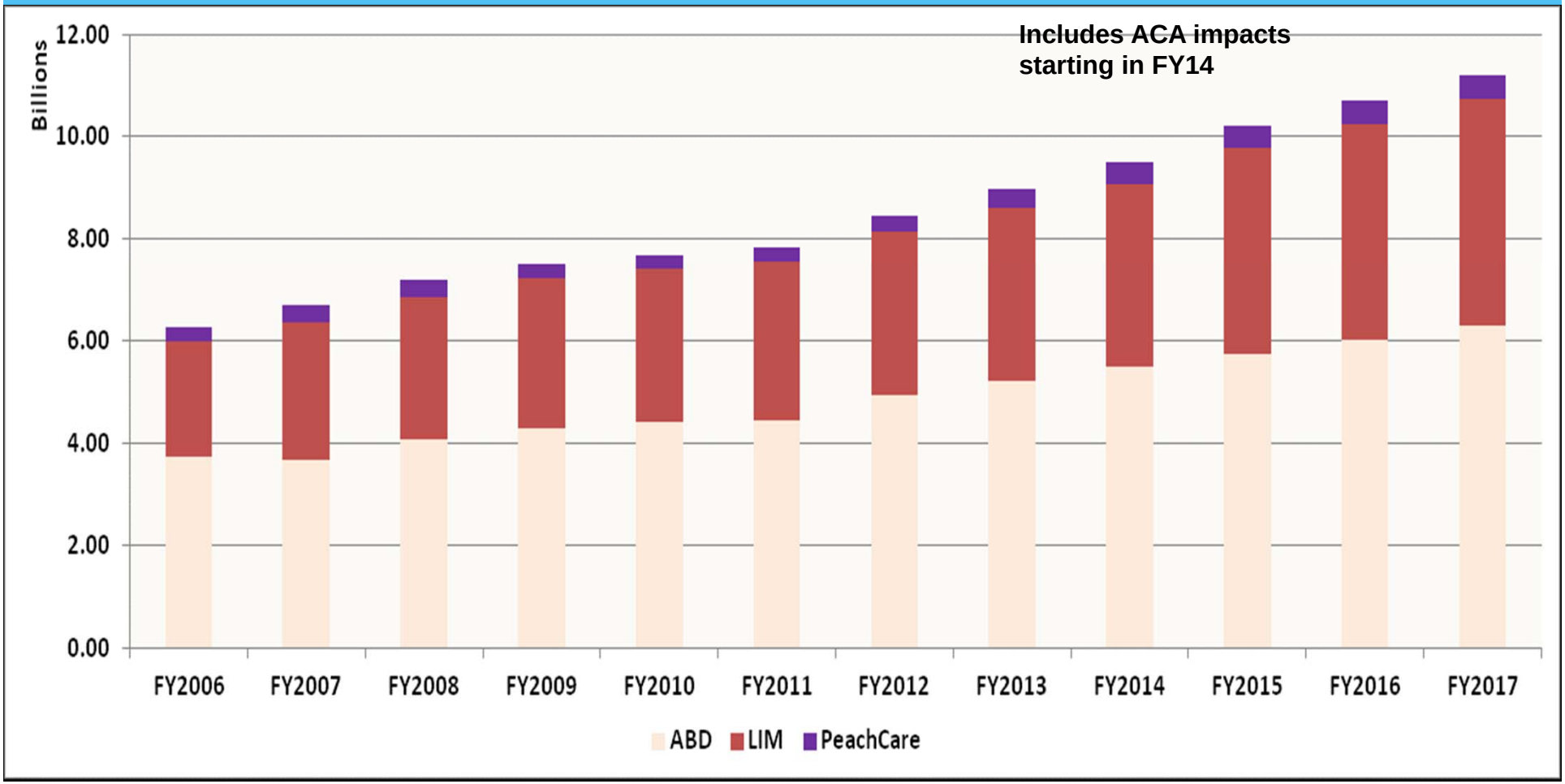
Total FY2013 Expenditures (includes State, Federal and other Fund Sources):

- Medicaid: $ 8,593,286,076
- PeachCare for Kids: $ 371,557,165
- Average Spend per Day - **$34.5 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) (2012)



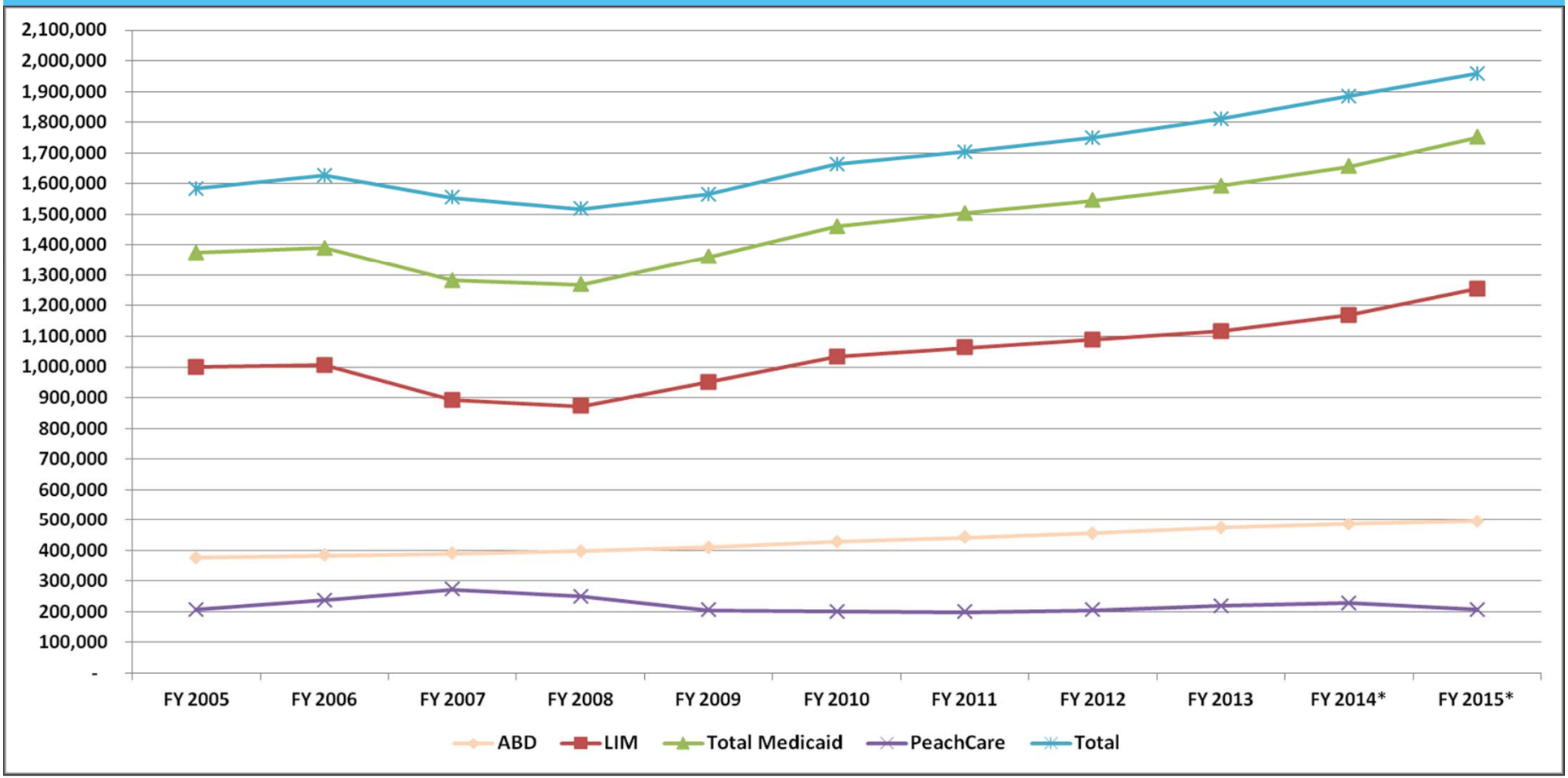
# Medicaid and PeachCare Total Funds Cost Trends



# Medicaid and PeachCare Growth Trends – Georgia View

| | 2000 | 2010 | 2014 | 2020 |
|---|---|---|---|---|
| Enrollees | 1,044,406 | 1,662,756 | 1,885,330 | 2,396,016 |
| % of State Population | 11.56% | 17.16% | 18.56% | 21.15% |
| State Funds (millions) | $1,409 | $1,681 | $2,850 | $3,907 |
| % State Revenue | 10.20% | 11.58% | 15.57% | 16.59% |
| Total Funds | $3,537 | $7,684 | $9,496 | $12,840 |
| PMPM | $282.18 | $385.08 | $419.74 | $446.59 |

# GA Medicaid and CHIP Enrollment Trend



# Medicaid Initiatives – 2014/2015

# New Medicaid Initiatives

- EBNE Impact:
  - 46,000 (FY14)
  - 65,000 (FY 15)
- Foster Care Transition to Managed Care
  - 3/3/14
  - Approximately 27,000 children

# New Medicaid Initiatives

- ABD Care Coordination
  - Single statewide vendor
  - Fee-for-Service environment
  - Care coordination, case management, disease management
  - Patient Centered Medical Home
  - Primary Care Case Management Model
  - Provider Engagement
  - Value Based Purchasing

# New Medicaid Initiatives

- Enhanced Eligibility System
  - Multi-agency (DCH, DHS, DPH, DECAL, GTA, OPB, DOAS )
- Replace Eligibility System for Public Assistance Programs
  - Medicaid; TANF; Food Stamps; Subsidized Child Care; Low Income Energy Programs

Georgia Department of Community Health

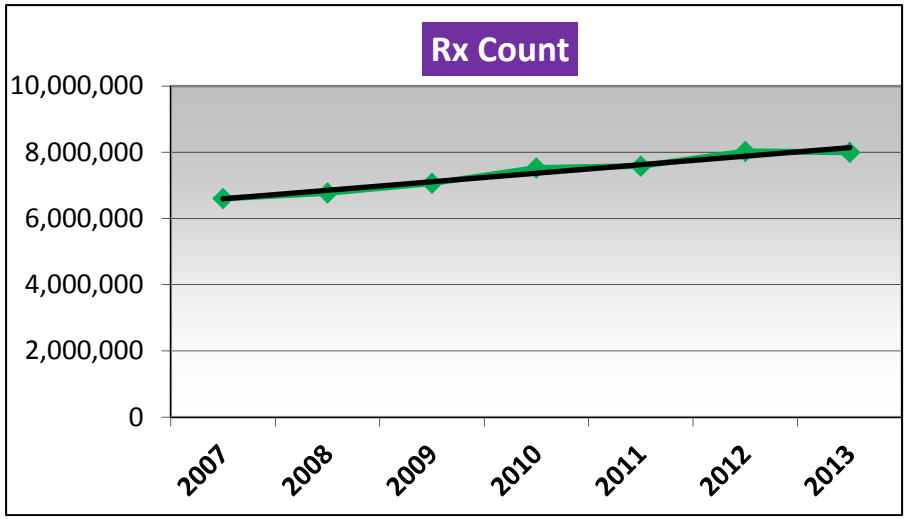
# Fee For Service Pharmacy Expenditures

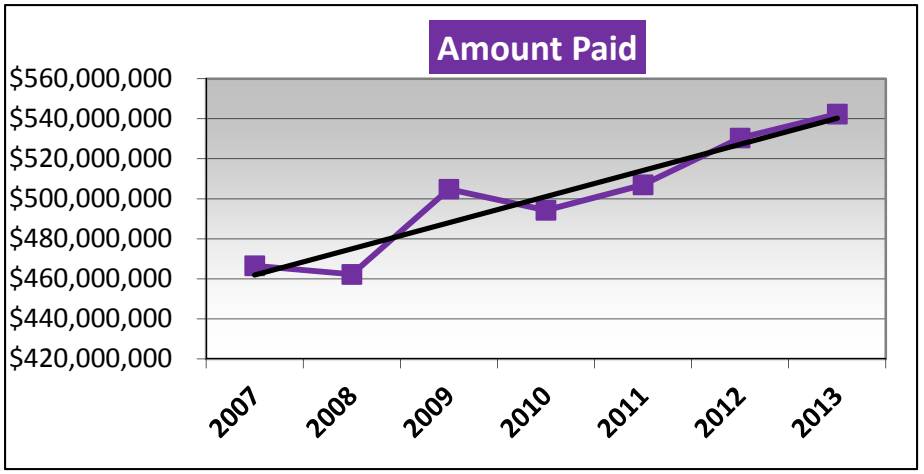
# GA Medicaid FFS Prescription Spending

## 2007-2013

- increase in FFS population (440,569)
- increase in expenditures
- increase in Rxs paid
- 2007: $ 466,554,372.54
- 2013: $ 542,349,879.86

| | PMPM (Rx) | PMPM ($) | PUPM (Rx) | PUPM ($) |
|---|---|---|---|---|
| 2007 | 1.30 | $92.24 | 4.06 | $286.83 |
| 2013 | 1.51 | $102.50 | 4.59 | $311.14 |



# Fee For Service Drivers

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

| | 2013 | | | | |
|---|---|---|---|---|---|
| Drug Grouping Description | Rx Count | Amount Paid | Avg Cost per Rx | Count of Members |
| ANALGESICS - OPIOID* | 614,530 | $15,232,606 | $24.79 | 110,280 |
| ANTICONVULSANTS* | 550,400 | $41,022,164 | $74.53 | 62,229 |
| ANTIDEPRESSANTS* | 496,528 | $9,346,264 | $18.82 | 67,690 |
| ANTIHYPERTENSIVES* | 479,400 | $9,642,028 | $20.11 | 67,712 |
| ANTIASTHMATIC AND BRONCHODILATOR AGENTS* | 454,963 | $54,455,111 | $119.69 | 80,318 |
| ANTIPSYCHOTICS/ANTIMANIC AGENTS* | 352,188 | $46,143,058 | $131.02 | 38,765 |
| ANTIHISTAMINES* | 309,701 | $2,358,668 | $7.62 | 103,935 |
| ULCER DRUGS* | 302,208 | $6,119,733 | $20.25 | 55,948 |
| ANTIDIABETICS* | 295,430 | $30,125,705 | $101.97 | 29,147 |
| ANTIHYPERLIPIDEMICS* | 279,165 | $9,918,578 | $35.53 | 38,410 |

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

| | 2013 | | | | |
|---|---|---|---|---|---|
| Drug Group Description | Amount Paid | Rx Count | Avg Cost per Rx | Count of Members |
| ANTIVIRALS* | $68,213,695 | 94,483 | $721.97 | 17,267 |
| ANTIASTHMATIC AND BRONCHODILATOR AGENTS* | $54,455,111 | 454,963 | $119.69 | 80,318 |
| ANTIPSYCHOTICS/ANTIMANIC AGENTS* | $46,143,058 | 352,188 | $131.02 | 38,765 |
| ANTICONVULSANTS* | $41,022,164 | 550,400 | $74.53 | 62,229 |
| ADHD/ANTI-NARCOLEPSY/ANTI-OBESITY/ANOREX | $33,098,017 | 215,472 | $153.61 | 38,057 |
| ANTIDIABETICS* | $30,125,705 | 295,430 | $101.97 | 29,147 |
| HEMATOLOGICAL AGENTS - MISC.* | $29,863,536 | 50,800 | $587.86 | 7,492 |
| ENDOCRINE AND METABOLIC AGENTS - MISC.* | $16,216,478 | 36,923 | $439.20 | 6,105 |
| ANALGESICS - OPIOID* | $15,232,606 | 614,530 | $24.79 | 110,280 |
| ANTINEOPLASTICS AND ADJUNCTIVE THERAPIES | $15,091,233 | 25,148 | $600.10 | 5,480 |

# Fee For Service Drivers

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

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

# Fee For Service Drivers

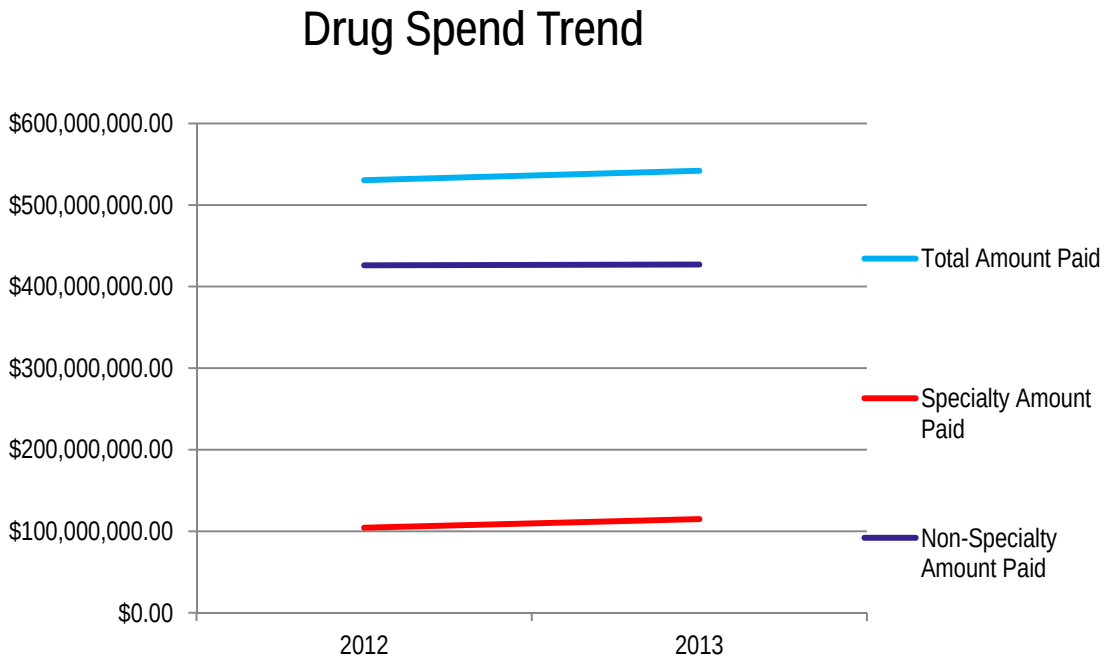
## 10 Biggest Approved Drugs of 2013

| Rank | Product | Generic Name | FDA Approval Date | Company | 2018e Annual Sales US ($m) |
|---|---|---|---|---|---|
| 1 | Sovaldi | sofosbuvir | December 06 | Gilead Sciences | 5,221 |
| 2 | Tecfidera | dimethyl fumarate | March 27 | Biogen Idec | 3,299 |
| 3 | Kadcyla | ado-trastuzumab emtansine | February 22 | Roche | 3,049 |
| 5 | Imbruvica | ibrutinib | November 13 | Pharmacyclics | 2,453 |
| 4 | Tivicay | dolutegravir | August 12 | GlaxoSmithKline | 2,132 |
| 6 | Breo Ellipta | fluticasone furoate; vilanterol trifenatate | May 10 | GlaxoSmithKline | 1,332 |
| 7 | Anoro Ellipta | umeclidinium bromide; vilanterol trifenatate | December 18 | GlaxoSmithKline | 1,242 |
| 9 | Gazyva | obinutuzumab | November 01 | Roche | 1,149 |
| 8 | Brintellix | vortioxetine | September 30 | Takeda | 875 |
| 10 | Xofigo | radium Ra-223 dichloride | May 15 | Bayer | 829 |

EvaluatePharma Report. (see previous slide)

# Fee For Service Drivers: Specialty Drug Spending

- Specialty Spending
  - 19.7% (2012)
  - 21.2% (2013)
- Trends
  - 2.16 % (overall)
  - 0.2 % (non-specialty)
  - 10.1% (specialty)
- Drug Cost (Avg Cost/Rx)
  - $4,042.09 (2012)
  - $4,536.56 (2013)



# Fee For Service Drivers

Top 10 Drugs by Prescription Count and Amount Paid

| Rank | GPI Name | Product Name | Rx Count | Paid Amount | Average Cost/Rx |
|---|---|---|---|---|---|
| 1 | PALIVIZUMAB SOLN | Synagis | 1,225 | $ 3,083,412.27 | $2,517.07 |
| 2 | ARIPIPRAZOLE TABS | Abilify | 3,503 | $ 3,044,781.72 | $869.19 |
| 3 | SOFOSBUVIR TABS | Sovaldi | 88 | $ 2,549,476.45 | $28,971.32 |
| 4 | INSULIN GLARGINE SOLN | Lantus | 7,903 | $ 2,265,958.72 | $286.72 |
| 5 | EMTRICITABINE-TENOFOVIR DISOPROXIL FUMARATE TAB | Truvada | 1,917 | $ 2,221,504.45 | $1,158.84 |
| 6 | FLUTICASONE-SALMETEROL AER POWDER BA | Advair Diskus | 7,184 | $ 2,146,142.90 | $298.74 |
| 7 | LISDEXAMFETAMINE DIMESYLATE CAPS | Vyvanse | 10,321 | $ 2,033,363.63 | $197.01 |
| 8 | EFAVIRENZ-EMTRICITABINE-TENOFOVIR DF TAB | Atripla | 1,011 | $ 1,923,672.92 | $1,902.74 |
| 9 | PALIPERIDONE PALMITATE SUSP | Invega Sustenna | 1,105 | $ 1,537,808.18 | $1,391.68 |
| 10 | METHYLPHENIDATE HCL TBCR | | 8,903 | $ 1,483,759.93 | $166.66 |

| Rank | GPI Name | Product Name | Rx Count | Paid Amount | Average Cost/Rx |
|---|---|---|---|---|---|
| 1 | HYDROCODONE-ACETAMINOPHEN TAB | | 46,016 | $ 737,798.32 | $16.03 |
| 2 | LISINOPRIL TABS | | 27,180 | $ 111,188.46 | $4.09 |
| 3 | ALBUTEROL SULFATE AERS | Proventil HFA | 24,236 | $ 1,478,853.56 | $61.02 |
| 4 | RANITIDINE HCL TABS | | 22,061 | $ 197,013.29 | $8.93 |
| 5 | AMLODIPINE BESYLATE TABS | | 21,240 | $ 78,892.91 | $3.71 |
| 6 | GABAPENTIN CAPS | | 20,783 | $ 317,481.09 | $15.28 |
| 7 | TRAMADOL HCL TABS | | 17,641 | $ 123,775.35 | $7.02 |
| 8 | LORATADINE TABS | | 17,322 | $ 75,696.24 | $4.37 |
| 9 | RISPERIDONE TABS | | 16,967 | $ 348,284.51 | $20.53 |
| 10 | SIMVASTATIN TABS | | 16,508 | $ 133,597.68 | $8.09 |

# DUR Initiatives

| Intervention Type | Intervention Name & Description | Drug or Drug Class Reviewed | Number of Profiles Produced | Number of Profiles Selected for Intervention | Number of Providers Receiving an Intervention Letter | % Response |
|---|---|---|---|---|---|---|
| Drug Information | Drug Information – Provides warnings for use of ketoconazole tablets based on FDA Alert: Targeted members who had been receiving Ketoconazole within the previous two months. Mailing were sent to the prescriber. | KTC | 42 | 42 | 35 | 26.2% |
| Drug Interaction | Drug Information – Drug Interaction with Suboxone: Targeted members included patients who had received suboxone in combination with an opioid. Mailings sent to prescribers. (97 letters/profiles to 79 unique MDs) | SBX | 46 | 46 | 79 | 20.30% |
| Drug Interaction | Drug-Drug Interaction– Plavix (clopidoprel)/omeprazole: Targeted members who received clopidogrel concurrently with either omeprazole or esomeprazole (Nexium). | CLP | 140 | 140 | 134 | 14.9% |
| Duplicate Therapy | Multiple Prescribers-Polypharmacy – Provides info to prescribers on patients utilizing multiple Opioid Pain Relievers (OPRs): Targeted members receiving more than 5 fills of OPRs within a month. Mailings sent to all prescribers in profile. | OPR | 56 | 56 | 160 | 22.50% |
| Duplicate Therapy | Therapeutic Duplication– Duplicate therapy with NSAID medications: Targeted members who received two or more different NSAIDs concurrently for a period of at least two months. Mailings sent to each prescriber of NSAIDs in profile. | NSD | 288 | 288 | 253 | 14.2% |
| Medication Overuse | Drug Information– Medication overuse- Triptan therapy: Targeted members who had received a prescription for a triptan in 2 out of 3 consecutive months, but did not receive a medication for headache prophylaxis. | TRP | 211 | 211 | 193 | 15.5% |
| PDL Change | Therapeutic Appropriateness– PDL status change for Trazodone 300mg tablets: To improve the pharmacotherapy by promoting the most clinically appropriate and cost-effective therapy for treatment. | TRZ | n/a | n/a | 51 | n/a |
| PDL Change | Therapeutic Appropriateness– PDL status change for Renvela: To improve the pharmacotherapy by promoting the most clinically appropriate and cost-effective therapy for treatment. | RNV | n/a | n/a | 168 | n/a |
| PDL Change | Therapeutic Appropriateness– PDL status change for ranitidine 150mg capsules: To improve the pharmacotherapy by promoting the most clinically appropriate and cost-effective therapy for treatment. Mailing were sent to the prescriber. | RTD | n/a | n/a | 471 | n/a |
| | | | 783 | 783 | 1,544 | 15.9% |

# Questions?

Attachment B

# Georgia Medicaid Drug Utilization Review Board Meeting Hepatitis C

Lance L Stein MD

3/18/14

# Conflict of interest disclosures

- Speaking: Vertex Pharmaceuticals, Gilead Pharmaceuticals

# HCV Burden

- Hep C Burden
  - 2.7-3.9 million Americans infected (1.3% of US) – estimates exclude incarcerated and homeless persons
  - 50-75% don't know they are infected
  - Rising mortality rates for HCV infected patients (increased by 50% from 1999-2007)
  - New CDC data suggests -16% incidence from 2003-2010 (decrease explained by rising deaths rates from HCC/cirrhosis in baby boomers (born 1945-1965))
  - Georgia not immune from these estimates
- CDC Screening recommendations
  - 2012 – risk factor based + added age based screening cohort 1945-1965
- USPSTF HCV Screening Recommendations 2013 – Grade B requiring CMS to fund 1 time testing for participants

Denniston M, et al. Annals of Int Med. 2014 Mar.;1160(5)293
www.CDC.gov
www.uspreventiveservicestaskforce.org/uspstf/uspshepc.htm

- Focus needs to be on identification of HCV infected and eradication of HCV prior to development of complications
- Why is this?

# Economic Costs of HCV

- Medicaid: FL – Advanced liver disease costs due to HCV are substantial
  - All-cause inpt use within 1 year was greater (75% vs 24% for matched controls)
  - Per patient per eligible month costs were $4,956 vs $1,735 for controls which = 2.39 greater all cause PPPM costs)
  - Costs largely driven by inpatient costs
- Birth cohort testing/identification cost effectiveness
  - $28,602 if 91% tested and 278,000 receive treatment
  - Treatment of those with advanced liver fibrosis decreases costs by $7.5 billion and 59,035 fewer HCV-related complications
  - Conclusion: Total QALYs maximized and complications reduced when txt starts as soon as possible after positive testing

Menzin J et al. *BMC Health Serv Res*. 2012 Dec; 15(12):459
McEwan P et al. *Hepatology*. 2013; 58(1):54
Younossi ZM et al. *Alimen Pharmacol Ther*. 2014 Mar;39(5):518

# Importance of clearing virus

- HCV leads to:
  - Cirrhosis
  - HCC
  - non hepatic manifestations (skin, autoimmune, renal)
  - increased rates of DM II
  - decreased QOL measures
- Major cause for resource utilization
- Increase rates of death
- Increase costs to care for HCV infected individuals

McEwan P et al. *Hepatology*. 2013; 58(1):54
Younossi ZM et al. *Alimen Pharmacol Ther*. 2014 Mar;39(5):518

# Cost Benefits of HCV Treatment

- Costs of HCV Treatment Failure
  - British health study of treated patients (SVR vs no SVR)
    - No patient cured (SVR) progressed to more severe liver disease
    - Annual transition of Non-SVR from hepatitis to cirrhosis was 7.4% and cirrhosis to decompensated liver disease was 4.9%
    - Over 5 years: costs of failure to achieve SVR was increased 13-fold compared to cured patients
      - Patients who were then re-treated increased costs 56-fold
  - Kaiser:
    - Healthcare utilization and costs after SVR are significantly lower.
    - Costs driven by liver-related tests, outpatient drugs and hospitalizations.
    - Adjusted difference in yearly means costs were $2648.
    - Hospitalization rates for non-SVR rise year after year

Backx M, et al. J Viral Hepat. 2014 Mar;21(3):208
Manos MM, et al. *J Manag Care Pha*rm. 2013;Jul:19(6):438

# Benefits of HCV Treatment

- Association between SVR and all-cause mortality in HCV pts with advanced liver fibrosis
  - Western Europe: Mean f/u of 8.4 years
    - All-cause mortality of SVR vs non-SVR was 8.9% vs 26%
    - SVR = reduced rate of all cause mortality (HR=0.26) and reduced risk of liver related mortality and liver transplant (HR=0.06)
    - 10 year cumulative incidence of liver failure was 2.1% vs 29.9% and HCC was 5.1%vs 21.8% (SVR vs non-SVR)
  - US: Cost-effectiveness of boceprevir/PEG-IFN/RBV vd PEG-IFN/RBV
    - More expensive BOC+PR found to be cost effective compared to cheaper PR
    - BOC increased QALYs and reduced life-time incidence of liver related complications

Van der Meer AJ, et al. *JAMA*. 2012 Dec;308(24):2584
Chhatwal J, et al. *Value Health*. 2013 Sept;16(6):973

# Impact of New Direct Acting Antivirals (DAAs)

- Decision model based on treatment of genotype 1
- IFN based vs non-IFN all oral DAA regimens
- Treating all patients regardless of liver status with oral IFN-free regimens was more cost effective with an incremental cost effectiveness ratio of $15,709/QALY
- Treating all HCV+ patients with oral IFN-free regimens reduced # of pts developing advanced liver disease and increased life expectancy
- IFN free regimens without staging of disease may be the most cost effective approach

Younossi ZM, et al. *J Hepatol*. 2014 Mar;60(3):530

# “Older” Treatment Options

- Genotype 1 HCV infection
  - Pegylated interferon (PegIFN)+ ribavirin (RBV) x 48 weeks or more (standard until 2011)
    - SVR (or cure) = about 40% all comers (range 20-60%)
  - Peg-IFN+RBV + protease inhibitor (telaprevir (TVR) or boceprevir (BOC)) (standard 2011-12/2013)
    - SVR = about 60% all comers
  - 12/2013 FDA approved two new drugs including the first all oral IFN free regimen

AASLD/IDSA HCV guidelines. www.hcvguidelines.org

# 1st Generation DAAs

- Telaprevir and boceprevir
  - No longer considered standard of care
  - Inferior SVR rates
  - Frequent dosing with high pill burden
  - Longer duration treatment and complex dosing strategies
  - Multiple drug-drug interactions
  - Adverse events
  - Intensity of monitoring for continuation and stopping
  - Requirement to be taken with food or high fat meals
  - Viral resistance in treatment failures?

# New Standards of Care for HCV

- Simeprevir (SMV)
  - One daily dosing oral NS3/4A protease inhibitor
  - Effective in GT1/4 only
  - FDA approved for use as daily SMV 150mg x 12 weeks plus Peg-IFN+RBV x 24 weeks
  - SVR about 80%
  - Cautioned use in patients with liver impairment

AASLD/IDSA HCV guidelines. www.hcvguidelines.org

# New Standards of Care for HCV Treatment

- Sofosbuvir
  - Once daily dosing
  - NS5B RNA dependent RNA polymerase inhibitor
  - Effective in all genotypes
  - FDA approved for multiple indications
    - GT1 with Peg-IFN/RBV x 12 weeks
      - SVR = 92% in those without cirrhosis
      - SVR = 80% in those with cirrhosis
  - FDA approved for use without IFN in IFN ineligible patients
    - GT1 SOF+RBV x 24 weeks
      - Overall SVR of 72% in clinical trials

AASLD/IDSA HCV guidelines. www.hcvguidelines.org

# AASLD/IDSA Hepatitis C Guidelines 2014

- IFN-Eligible GT1
  - SOF+PegIFN+RBV x 12 weeks (recommended)
  - SMV x 12 weeks + PEG-IFN+RBV x 24 weeks (alternative)
- IFN-Ineligble GT1
  - SOF+SMV +/- RBV x 12 weeks (recommended)
  - SOF+RBV x 24 weeks (alternate)

AASLD/IDSA HCV guidelines. www.hcvguidelines.org

# Why are 2 DAAs Recommended in Guidelines for IFN-Ineligible Patients?

- SOF+RBV x 24 weeks = SVR range 50-84%
  - mean SVR = 72%
- COSMOS trial
  - SOF+SMV +/- RBV x 24 weeks
    - Ongoing phase 2 trial. Prelim data reported in 2013
    - Studying classically hard to cure populations (previous null response to IFN or null response with advanced fibrosis)
    - SVR rates of 79-100% reported

AASLD/IDSA HCV guidelines. www.hcvguidelines.org

# Genotypes 2-6

- GT 2 treatment naive: SOF+RBV x 12 weeks
  - SVR = 94%
- GT 2 treatment experienced
  - SOF+PegIFN+RBV x 12 weeks
  - SVR = 96%
- GT 3
  - FDA approved SOF+RBV x 24 weeks
    - SVR = 84% (txt naïve 93% and 77% txt experienced)
  - Alternate is SOF+PegIFN+RBV x 12 weeks
    - SVR = 93% for txt naïve
- GT4 – FDA and guideline recommendations mirror GT1
- GT5-6 – not enough data but with SOF+PEGIFN+RBV x 12 weeks shown to have efficacy

AASLD/IDSA HCV guidelines. www.hcvguidelines.org

# Special Populations

- **Advanced liver disease (+/- HCC)**
  - IFN is relatively contraindicated in decompensated cirrhotic patients due to risk of death
  - FDA approved SOF+RBV use for up to 48 weeks while waiting for a liver transplant
    - Clinic trial data in HCC pts awaiting OLT support a 62% SVR post transplant with higher rates seen if patients were undetectable viral load and transplanted > 30 days after starting treatment
  - Guidelines support use with or without HCC while waiting for liver transplant
- **Co-infection with HIV**
  - Guidelines mirror HCV moninfected patients
  - For the first time: SVR rates in HIV/HCV are similar to HCV monoinfection in treatment with SOF and or SMV

AASLD/IDSA HCV guidelines. www.hcvguidelines.org

# Current Standard of Care: 2014

- Use of DAAs has markedly improved treatment outcomes for HCV
- Newer agents benefits:
  - Improved compliance due to daily dosing
  - shorter duration therapy
  - less side effects
  - less on treatment clinical monitoring (labs and visits)
  - Reduced used of medications to support IFN/RBV side effects
  - higher SVR rates
  - All oral interferon free regimens
- Combination DAA therapy for certain subgroups (SOF+SMV) likely to yield higher SVR: eg. IFN intolerant prior null or partial responders and/or cirrhotics

# Future

- More DAA combinations are expected to come to market late 2014, early 2015
- All oral, likely 12 weeks, IFN free for GT1
- Phase 2 trials with SVR rates persistently near 95%
- Possible DAA combo regimens expected within next 12 months:
  - Sofosbuvir+ledipasvir+/-RBV
  - Daclatasvir+asunaprevir
  - ABT-450+/-ritonovir+ABT-267+ABT-333 +/- RBV
  - Possible benefit of combination of above plus currently approved, ie. Sofobuvir + daclatasvir
  - Others currently in trials/development

# Summary

- Exciting time to treat HCV patients
- Cure rates (SVR) which used to be < 20-50%, then became 50-70% in 2011 are now in the 75-95% range for most subgroups
- Treatment is shorter, better tolerated, fewer side effects than in past
- SVR is a sustained cure
- SVR associated with improved QOL, reduced hepatic decompensation and liver cancer, and reduced future medical costs
- Pipeline of new HCV drugs is ripe with new FDA approvals expected in 2014-2015

# Drug Utilization Review Board

Motions - Votes - **New Drugs**

**March 18, 2014**

**Attachment C**

| New Drug | Drug | PDL Status | Motion - Recommendations | Additional Comments |
|---|---|---|---|---|
| Biologic Immunomodulators | Actemra® Subcutaneous<br>Orencia | NP/PA<br>P/PA | NP/PA<br>NP/PA | |

| | Board Members - Present<br>(Strike out, when absent) | Motion Maker (√) | Seconded By (√) | VOTES<br>YES (√) | NO (√) | ABSTAIN (√) |
|---|---|---|---|---|---|---|
| 1 | Avery, Mia, Pharm.D. | | | √ | | |
| 2 | Bona, Joseph R. M.D. - **Chair** | | | √ | | |
| 3 | Damon, Ann R., Pharm.D. | | | √ | | |
| 4 | Doad, Gurinder J.S., M.D. | | | √ | | |
| 5 | Fincher, Deborah W., M.S., R.Ph. | | | √ | | |
| 6 | Gore, Thomas B., M.D. | | | √ | | |
| 7 | Jones, Edwina L., Pharm.D., MBA | | | √ | | |
| 8 | Lorys, Robyn Pharm.D. | √ | | √ | | |
| 9 | May, J. Russell (Rusty) | | | √ | | |
| 10 | Miller, Osgood (Drew) A. R.Ph. - **Vice** | | | √ | | |
| 11 | Paul, Donald A., M.D. | | √ | √ | | |
| 12 | Rollins, Brent L., R.Ph., Ph.D. | | | √ | | |
| 13 | Shervette III, Robert E., M.D. | | | √ | | |
| 14 | White, Sandra L., M.D., MBA, FACR | | | √ | | |
| | | | TOTAL | 14 | 0 | 0 |

| | Board Members - Absent<br>(Highlight, when present) |
|---|---|
| 1 | Fowler, M. Celeste, Pharm.D. |
| 2 | Greeson, John D., M.D., MBA |
| 3 | Yates, Mary Virginia "Ginny", Pharm.D. |

# Drug Utilization Review Board

Motions - Votes - **New Drugs**

**March 18, 2014**

**Attachment C**

| New Drug | Drug | PDL Status | Motion - Recommendations | Additional Comments |
|---|---|---|---|---|
| Antineoplastic | Gilotrif™ | P/PA | P/PA | |

| | Board Members - Present (Strike out, when absent) | Motion Maker (√) | Seconded By (√) | VOTES YES (√) | NO (√) | ABSTAIN (√) |
|---|---|---|---|---|---|---|
| 1 | Avery, Mia, Pharm.D. | √ | | √ | | |
| 2 | Bona, Joseph R. M.D. - **Chair** | | | √ | | |
| 3 | Damon, Ann R., Pharm.D. | | | √ | | |
| 4 | Doad, Gurinder J.S., M.D. | | | √ | | |
| 5 | Fincher, Deborah W., M.S., R.Ph. | | | √ | | |
| 6 | Gore, Thomas B., M.D. | | | √ | | |
| 7 | Jones, Edwina L., Pharm.D., MBA | | | √ | | |
| 8 | Lorys, Robyn Pharm.D. | | | √ | | |
| 9 | May, J. Russell (Rusty) | | √ | √ | | |
| 10 | Miller, Osgood (Drew) A. R.Ph.-**Vice** | | | √ | | |
| 11 | Paul, Donald A., M.D. | | | √ | | |
| 12 | Rollins, Brent L., R.Ph., Ph.D. | | | √ | | |
| 13 | Shervette III, Robert E., M.D. | | | √ | | |
| 14 | White, Sandra L., M.D., MBA, FACR | | | √ | | |
| | | | TOTAL | 14 | 0 | 0 |

| | Board Members - Absent (Highlight, when present) |
|---|---|
| 1 | Fowler, M. Celeste, Pharm.D. |
| 2 | Greeson, John D., M.D., MBA |
| 3 | Yates, Mary Virginia "Ginny", Pharm.D. |

# Drug Utilization Review Board

Motions - Votes - **New Drugs**

**March 18, 2014**

**Attachment C**

| New Drug | Drug | PDL Status | Motion - Recommendations | Additional Comments |
|---|---|---|---|---|
| Hematopoietic | Injectafer™ | NP/PA | NP/PA | |

| | Board Members - Present (Strike out, when absent) | Motion Maker (√) | Seconded By (√) | VOTES YES (√) | NO (√) | ABSTAIN (√) |
|---|---|---|---|---|---|---|
| 1 | Avery, Mia, Pharm.D. | | | √ | | |
| 2 | Bona, Joseph R. M.D. - **Chair** | | | √ | | |
| 3 | Damon, Ann R., Pharm.D. | | √ | √ | | |
| 4 | Doad, Gurinder J.S., M.D. | | | √ | | |
| 5 | Fincher, Deborah W., M.S., R.Ph. | | | √ | | |
| 6 | Gore, Thomas B., M.D. | | | √ | | |
| 7 | Jones, Edwina L., Pharm.D., MBA | | | √ | | |
| 8 | Lorys, Robyn Pharm.D. | | | √ | | |
| 9 | May, J. Russell (Rusty) | | | √ | | |
| 10 | Miller, Osgood (Drew) A. R.Ph.-**Vice** | | | √ | | |
| 11 | Paul, Donald A., M.D. | | | √ | | |
| 12 | Rollins, Brent L., R.Ph., Ph.D. | | | √ | | |
| 13 | Shervette III, Robert E., M.D. | | | √ | | |
| 14 | White, Sandra L., M.D., MBA, FACR | √ | | √ | | |
| | | | TOTAL | 14 | 0 | 0 |

| | Board Members - Absent (Highlight, when present) |
|---|---|
| 1 | Fowler, M. Celeste, Pharm.D. |
| 2 | Greeson, John D., M.D., MBA |
| 3 | Yates, Mary Virginia "Ginny", Pharm.D. |

# Drug Utilization Review Board

Motions - Votes - **New Drugs**

**March 18, 2014**

**Attachment C**

| New Drug | Drug | PDL Status | Motion - Recommendations | Additional Comments |
|---|---|---|---|---|
| Antineoplastics | Mekinist™ | P/PA | P/PA | |
| | Tafinlar® | P/PA | P/PA | |

| | Board Members - Present (Strike out, when absent) | Motion Maker (√) | Seconded By (√) | VOTES YES (√) | NO (√) | ABSTAIN (√) |
|---|---|---|---|---|---|---|
| 1 | Avery, Mia, Pharm.D. | √ | | √ | | |
| 2 | Bona, Joseph R. M.D. - **Chair** | | | √ | | |
| 3 | Damon, Ann R., Pharm.D. | | | √ | | |
| 4 | Doad, Gurinder J.S., M.D. | | | √ | | |
| 5 | Fincher, Deborah W., M.S., R.Ph. | | | √ | | |
| 6 | Gore, Thomas B., M.D. | | | √ | | |
| 8 | Jones, Edwina L., Pharm.D., MBA | | | √ | | |
| 9 | Lorys, Robyn Pharm.D. | | | √ | | |
| 10 | May, J. Russell (Rusty) | | | √ | | |
| 11 | Miller, Osgood (Drew) A. R.Ph.-**Vice** | | | √ | | |
| 12 | Paul, Donald A., M.D. | | √ | √ | | |
| 13 | Rollins, Brent L., R.Ph., Ph.D. | | | √ | | |
| 14 | Shervette III, Robert E., M.D. | | | √ | | |
| 15 | White, Sandra L., M.D., MBA, FACR | | | √ | | |
| | | | TOTAL | 14 | 0 | 0 |

| | Board Members - Absent (Highlight, when present) |
|---|---|
| 1 | Fowler, M. Celeste, Pharm.D. |
| 2 | Greeson, John D., M.D., MBA |
| 3 | Yates, Mary Virginia "Ginny", Pharm.D. |

# Drug Utilization Review Board

Motions - Votes - **New Drugs**

**March 18, 2014**

**Attachment C**

| New Drug | Drug | PDL Status | Motion - Recommendations | Additional Comments |
|---|---|---|---|---|
| Antiretroviral | Tivicay® | P/PA | P/PA | |

| | Board Members - Present (Strike out, when absent) | Motion Maker (√) | Seconded By (√) | VOTES YES (√) | NO (√) | ABSTAIN (√) |
|---|---|---|---|---|---|---|
| 1 | Avery, Mia, Pharm.D. | | | √ | | |
| 2 | Bona, Joseph R. M.D. - **Chair** | | | √ | | |
| 3 | Damon, Ann R., Pharm.D. | | | √ | | |
| 4 | Doad, Gurinder J.S., M.D. | | | √ | | |
| 5 | Fincher, Deborah W., M.S., R.Ph. | √ | | √ | | |
| 6 | Gore, Thomas B., M.D. | | | √ | | |
| 7 | Jones, Edwina L., Pharm.D., MBA | | | √ | | |
| 8 | Lorys, Robyn Pharm.D. | | | √ | | |
| 9 | May, J. Russell (Rusty) | | | √ | | |
| 10 | Miller, Osgood (Drew) A. R.Ph.-**Vice** | | √ | √ | | |
| 11 | Paul, Donald A., M.D. | | | | | √ |
| 12 | Rollins, Brent L., R.Ph., Ph.D. | | | √ | | |
| 13 | Shervette III, Robert E., M.D. | | | √ | | |
| 14 | White, Sandra L., M.D., MBA, FACR | | | √ | | |
| | | | TOTAL | 13 | 0 | 1 |

| | Board Members - Absent (Highlight, when present) |
|---|---|
| 1 | Fowler, M. Celeste, Pharm.D. |
| 2 | Greeson, John D., M.D., MBA |
| 3 | Yates, Mary Virginia "Ginny", Pharm.D. |

**Drug Utilization Review Board**

**Motions - Votes**

Therapeutic Class Review

**March 18, 2014**

| Therapeutic Class Review | Drug | PDL Status | Motion - Recommendations | Additional Comments |
|---|---|---|---|---|
| Antivirals, Hepatitis C Agents | Incivek® | P | P | |
| | Olysio™ | NP/PA | NP/PA | |
| | Sovaldi™ | NP/PA | NP/PA | |
| | Victrelis® | P | P | |
| | Moderiba® | | NP/PA | |

| | Board Members - Present (Strike out, when absent) | Motion Maker (√) | Seconded By (√) | VOTES YES (√) | NO (√) | ABSTAIN (√) |
|---|---|---|---|---|---|---|
| 1 | Avery, Mia, Pharm.D. | | | √ | | |
| 2 | Bona, Joseph R. M.D. - **Chair** | | | √ | | |
| 3 | Damon, Ann R., Pharm.D. | | | √ | | |
| 4 | Doad, Gurinder J.S., M.D. | | | √ | | |
| 5 | Fincher, Deborah W., M.S., R.Ph. | | | √ | | |
| 6 | Gore, Thomas B., M.D. | | | √ | | |
| 7 | Greeson, John D., M.D., MBA | | √ | √ | | |
| 8 | Jones, Edwina L., Pharm.D., MBA | √ | | √ | | |
| 9 | Lorys, Robyn Pharm.D. | | | √ | | |
| 10 | May, J. Russell (Rusty) | | | √ | | |
| 11 | Miller, Osgood (Drew) A. R.Ph.-**Vice** | | | √ | | |
| 12 | Paul, Donald A., M.D. | | | | | √ |
| 13 | Rollins, Brent L., R.Ph., Ph.D. | | | √ | | |
| 14 | Shervette III, Robert E., M.D. | | | √ | | |
| 15 | White, Sandra L., M.D., MBA, FACR | | | √ | | |
| | | | TOTAL | 14 | 0 | 1 |

| | Board Members - Absent (Highlight, when present) |
|---|---|
| 1 | Fowler, M. Celeste, Pharm.D. |
| 2 | Yates, Mary Virginia "Ginny", Pharm.D. |

## ARVS, NRTIS

**Motion:**

| Drug | PDL Status |
|---|---|
| *Epivir® (Oral) Tablet* | NP/PA |
| *Lamivudine (Oral) Tablet* | P |

| | Board Members - Present (Strike out, when absent) | Motion Maker (√) | Seconded By (√) | VOTES YES (√) | NO (√) | ABSTAIN (√) |
|---|---|---|---|---|---|---|
| 1 | Avery, Mia, Pharm.D. | | | √ | | |
| 2 | Bona, Joseph R. M.D. - **Chair** | | | √ | | |
| 3 | Damon, Ann R., Pharm.D. | | | √ | | |
| 4 | Doad, Gurinder J.S., M.D. | | | √ | | |
| 5 | Fincher, Deborah W., M.S., R.Ph. | | | √ | | |
| 6 | Gore, Thomas B., M.D. | | | √ | | |
| 7 | Jones, Edwina L., Pharm.D., MBA | | | √ | | |
| 8 | Lorys, Robyn Pharm.D. | √ | | √ | | |
| 9 | May, J. Russell (Rusty) | | | √ | | |
| 10 | Miller, Osgood (Drew) A. R.Ph. - **Vice** | | | √ | | |
| 11 | Paul, Donald A., M.D. | | √ | √ | | |
| 12 | Rollins, Brent L., R.Ph., Ph.D. | | | √ | | |
| 13 | Shervette III, Robert E., M.D. | | | √ | | |
| 14 | White, Sandra L., M.D., MBA, FACR | | | √ | | |
| | | | TOTAL | 14 | 0 | 0 |

| | Board Members - Absent (Highlight, when present) |
|---|---|
| 1 | Fowler, M. Celeste, Pharm.D. |
| 2 | Greeson, John D., M.D., MBA |
| 3 | Yates, Mary Virginia "Ginny", Pharm.D. |

## ARVS, Protease Inhibitors

**Motion:**

| | Drug | PDL Status |
|---|---|---|
| | *Norvir® (Oral) Tablet* | P |

| | Board Members - Present (Strike out, when absent) | Motion Maker (√) | Seconded By (√) | VOTES YES (√) | NO (√) | ABSTAIN (√) |
|---|---|---|---|---|---|---|
| 1 | Avery, Mia, Pharm.D. | | | √ | | |
| 2 | Bona, Joseph R. M.D. - **Chair** | | | √ | | |
| 3 | Damon, Ann R., Pharm.D. | | | √ | | |
| 4 | Doad, Gurinder J.S., M.D. | | | √ | | |
| 5 | Fincher, Deborah W., M.S., R.Ph. | | | √ | | |
| 6 | Gore, Thomas B., M.D. | | | √ | | |
| 7 | Jones, Edwina L., Pharm.D., MBA | | √ | √ | | |
| 8 | Lorys, Robyn Pharm.D. | √ | | √ | | |
| 9 | May, J. Russell (Rusty) | | | √ | | |
| 10 | Miller, Osgood (Drew) A. R.Ph. - **Vice** | | | √ | | |
| 11 | Paul, Donald A., M.D. | | | | | √ |
| 12 | Rollins, Brent L., R.Ph., Ph.D. | | | √ | | |
| 13 | Shervette III, Robert E., M.D. | | | √ | | |
| 14 | White, Sandra L., M.D., MBA, FACR | | | √ | | |
| | | | TOTAL | 13 | 0 | 1 |

| | Board Members - Absent (Highlight, when present) |
|---|---|
| 1 | Fowler, M. Celeste, Pharm.D. |
| 2 | Greeson, John D., M.D., MBA |
| 3 | Yates, Mary Virginia "Ginny", Pharm.D. |

## Antivirals, NNRTIs

**Motion: No PDL status change for the drugs in this class**

| | Board Members - Present | Motion | Seconded | VOTES | | |
|---|---|---|---|---|---|---|
| | (Strike out, when absent) | Maker (√) | By (√) | YES (√) | NO (√) | ABSTAIN (√) |
| 1 | Avery, Mia, Pharm.D. | | | √ | | |
| 2 | Bona, Joseph R. M.D. - **Chair** | | | √ | | |
| 3 | Damon, Ann R., Pharm.D. | | | √ | | |
| 4 | Doad, Gurinder J.S., M.D. | | | √ | | |
| 5 | Fincher, Deborah W., M.S., R.Ph. | | | √ | | |
| 6 | Gore, Thomas B., M.D. | | | √ | | |
| 7 | Jones, Edwina L., Pharm.D., MBA | | | √ | | |
| 8 | Lorys, Robyn Pharm.D. | | | √ | | |
| 9 | May, J. Russell (Rusty) | √ | | √ | | |
| 10 | Miller, Osgood (Drew) A. R.Ph. - **Vice** | | | √ | | |
| 11 | Paul, Donald A., M.D. | | | √ | | |
| 12 | Rollins, Brent L., R.Ph., Ph.D. | | √ | √ | | |
| 13 | Shervette III, Robert E., M.D. | | | √ | | |
| 14 | White, Sandra L., M.D., MBA, FACR | | | √ | | |
| | | | TOTAL | 14 | 0 | 0 |

| | Board Members - Absent |
|---|---|
| | (Highlight, when present) |
| 1 | Fowler, M. Celeste, Pharm.D. |
| 2 | Greeson, John D., M.D., MBA |
| 3 | Yates, Mary Virginia "Ginny", Pharm.D. |

## ARVs, CCR5 Receptor Antagonists

**Motion: No PDL status change for the drugs in this class**

| | Board Members - Present (Strike out, when absent) | Motion Maker (√) | Seconded By (√) | VOTES YES (√) | NO (√) | ABSTAIN (√) |
|---|---|---|---|---|---|---|
| 1 | Avery, Mia, Pharm.D. | | | √ | | |
| 2 | Bona, Joseph R. M.D. - **Chair** | | | √ | | |
| 3 | Damon, Ann R., Pharm.D. | | | √ | | |
| 4 | Doad, Gurinder J.S., M.D. | | | √ | | |
| 5 | Fincher, Deborah W., M.S., R.Ph. | | | √ | | |
| 6 | Gore, Thomas B., M.D. | | | √ | | |
| 7 | Jones, Edwina L., Pharm.D., MBA | | | √ | | |
| 8 | Lorys, Robyn Pharm.D. | | | √ | | |
| 9 | May, J. Russell (Rusty) | √ | | √ | | |
| 10 | Miller, Osgood (Drew) A. R.Ph. - **Vice** | | | √ | | |
| 11 | Paul, Donald A., M.D. | | | √ | | |
| 12 | Rollins, Brent L., R.Ph., Ph.D. | | √ | √ | | |
| 13 | Shervette III, Robert E., M.D. | | | √ | | |
| 14 | White, Sandra L., M.D., MBA, FACR | | | √ | | |
| | | | TOTAL | 14 | 0 | 0 |

| | Board Members - Absent (Highlight, when present) |
|---|---|
| 1 | Fowler, M. Celeste, Pharm.D. |
| 2 | Greeson, John D., M.D., MBA |
| 3 | Yates, Mary Virginia "Ginny", Pharm.D. |

## ARVs, Multiclass Combinations

**Motion:** **No PDL status change for the drugs in this class**

| | Board Members - Present (Strike out, when absent) | Motion Maker (√) | Seconded By (√) | VOTES YES (√) | NO (√) | ABSTAIN (√) |
|---|---|---|---|---|---|---|
| 1 | Avery, Mia, Pharm.D. | | | √ | | |
| 2 | Bona, Joseph R. M.D. - **Chair** | | | √ | | |
| 3 | Damon, Ann R., Pharm.D. | | | √ | | |
| 4 | Doad, Gurinder J.S., M.D. | | | √ | | |
| 5 | Fincher, Deborah W., M.S., R.Ph. | | | √ | | |
| 6 | Gore, Thomas B., M.D. | | | √ | | |
| 8 | Jones, Edwina L., Pharm.D., MBA | | | √ | | |
| 9 | Lorys, Robyn Pharm.D. | | | √ | | |
| 10 | May, J. Russell (Rusty) | √ | | √ | | |
| 11 | Miller, Osgood (Drew) A. R.Ph. - **Vice** | | | √ | | |
| 12 | Paul, Donald A., M.D. | | | √ | | |
| 13 | Rollins, Brent L., R.Ph., Ph.D. | | √ | √ | | |
| 14 | Shervette III, Robert E., M.D. | | | √ | | |
| 15 | White, Sandra L., M.D., MBA, FACR | | | √ | | |
| | | | TOTAL | 14 | 0 | 0 |

| | Board Members - Absent (Highlight, when present) |
|---|---|
| 1 | Fowler, M. Celeste, Pharm.D. |
| 2 | Greeson, John D., M.D., MBA |
| 3 | Yates, Mary Virginia "Ginny", Pharm.D. |

## Analgesics, Opioid Abuse

**Motion: No PDL status change for the drugs in this class**

| | Board Members - Present (Strike out, when absent) | Motion Maker (√) | Seconded By (√) | VOTES YES (√) | NO (√) | ABSTAIN (√) |
|---|---|---|---|---|---|---|
| 1 | Avery, Mia, Pharm.D. | | √ | √ | | |
| 2 | Bona, Joseph R. M.D. - **Chair** | | | √ | | |
| 3 | Damon, Ann R., Pharm.D. | | | √ | | |
| 4 | Doad, Gurinder J.S., M.D. | | | √ | | |
| 5 | Fincher, Deborah W., M.S., R.Ph. | | | √ | | |
| 6 | Gore, Thomas B., M.D. | | | √ | | |
| 7 | Jones, Edwina L., Pharm.D., MBA | | | √ | | |
| 8 | Lorys, Robyn Pharm.D. | | | √ | | |
| 9 | May, J. Russell (Rusty) | | | √ | | |
| 10 | Miller, Osgood (Drew) A. R.Ph. - **Vice** | | | √ | | |
| 11 | Paul, Donald A., M.D. | √ | | √ | | |
| 12 | Rollins, Brent L., R.Ph., Ph.D. | | | √ | | |
| 13 | Shervette III, Robert E., M.D. | | | √ | | |
| 14 | White, Sandra L., M.D., MBA, FACR | | | √ | | |
| | | | TOTAL | 14 | 0 | 0 |

| | Board Members - Absent (Highlight, when present) |
|---|---|
| 1 | Fowler, M. Celeste, Pharm.D. |
| 2 | Greeson, John D., M.D., MBA |
| 3 | Yates, Mary Virginia "Ginny", Pharm.D. |

## Analgesics, Opioid Short Acting (Non-Combination)

**Motion: No PDL status change for the drugs in this class**

| | Board Members - Present (Strike out, when absent) | Motion Maker (√) | Seconded By (√) | VOTES YES (√) | NO (√) | ABSTAIN (√) |
|---|---|---|---|---|---|---|
| 1 | Avery, Mia, Pharm.D. | | √ | √ | | |
| 2 | Bona, Joseph R. M.D. - **Chair** | | | √ | | |
| 3 | Damon, Ann R., Pharm.D. | | | √ | | |
| 4 | Doad, Gurinder J.S., M.D. | | | √ | | |
| 5 | Fincher, Deborah W., M.S., R.Ph. | | | √ | | |
| 6 | Gore, Thomas B., M.D. | | | √ | | |
| 7 | Jones, Edwina L., Pharm.D., MBA | | | √ | | |
| 8 | Lorys, Robyn Pharm.D. | | | √ | | |
| 9 | May, J. Russell (Rusty) | | | √ | | |
| 10 | Miller, Osgood (Drew) A. R.Ph. - **Vice** | | | √ | | |
| 11 | Paul, Donald A., M.D. | √ | | √ | | |
| 12 | Rollins, Brent L., R.Ph., Ph.D. | | | √ | | |
| 13 | Shervette III, Robert E., M.D. | | | √ | | |
| 14 | White, Sandra L., M.D., MBA, FACR | | | √ | | |
| | | | TOTAL | 14 | 0 | 0 |

| | Board Members - Absent (Highlight, when present) |
|---|---|
| 1 | Fowler, M. Celeste, Pharm.D. |
| 2 | Greeson, John D., M.D., MBA |
| 3 | Yates, Mary Virginia "Ginny", Pharm.D. |

## Analgesics, Opioid NSAID Combination

**Motion: No PDL status change for the drugs in this class**

| | Board Members - Present (Strike out, when absent) | Motion Maker (√) | Seconded By (√) | VOTES YES (√) | NO (√) | ABSTAIN (√) |
|---|---|---|---|---|---|---|
| 1 | Avery, Mia, Pharm.D. | | √ | √ | | |
| 2 | Bona, Joseph R. M.D. - **Chair** | | | √ | | |
| 3 | Damon, Ann R., Pharm.D. | | | √ | | |
| 4 | Doad, Gurinder J.S., M.D. | | | √ | | |
| 5 | Fincher, Deborah W., M.S., R.Ph. | | | √ | | |
| 6 | Gore, Thomas B., M.D. | | | √ | | |
| 7 | Jones, Edwina L., Pharm.D., MBA | | | √ | | |
| 8 | Lorys, Robyn Pharm.D. | | | √ | | |
| 9 | May, J. Russell (Rusty) | | | √ | | |
| 10 | Miller, Osgood (Drew) A. R.Ph. - **Vice** | | | √ | | |
| 11 | Paul, Donald A., M.D. | √ | | √ | | |
| 12 | Rollins, Brent L., R.Ph., Ph.D. | | | √ | | |
| 13 | Shervette III, Robert E., M.D. | | | √ | | |
| 14 | White, Sandra L., M.D., MBA, FACR | | | √ | | |
| | | | TOTAL | 14 | 0 | 0 |

| | Board Members - Absent (Highlight, when present) |
|---|---|
| 1 | Fowler, M. Celeste, Pharm.D. |
| 2 | Greeson, John D., M.D., MBA |
| 3 | Yates, Mary Virginia "Ginny", Pharm.D. |

## Opiate Agonists, Long Acting

**Motion:**

| Drug | PDL Status |
|---|---|
| *Butrans® (Transdermal) Patch* | P |

| | Board Members - Present (Strike out, when absent) | Motion Maker (√) | Seconded By (√) | VOTES YES (√) | NO (√) | ABSTAIN (√) |
|---|---|---|---|---|---|---|
| 1 | Avery, Mia, Pharm.D. | | | √ | | |
| 2 | Bona, Joseph R. M.D. - **Chair** | | | √ | | |
| 3 | Damon, Ann R., Pharm.D. | | | √ | | |
| 4 | Doad, Gurinder J.S., M.D. | | | √ | | |
| 5 | Fincher, Deborah W., M.S., R.Ph. | | | √ | | |
| 6 | Gore, Thomas B., M.D. | | | √ | | |
| 7 | Jones, Edwina L., Pharm.D., MBA | | | √ | | |
| 8 | Lorys, Robyn Pharm.D. | √ | | √ | | |
| 9 | May, J. Russell (Rusty) | | | √ | | |
| 10 | Miller, Osgood (Drew) A. R.Ph. - **Vice** | | | √ | | |
| 11 | Paul, Donald A., M.D. | | √ | √ | | |
| 12 | Rollins, Brent L., R.Ph., Ph.D. | | | √ | | |
| 13 | Shervette III, Robert E., M.D. | | | √ | | |
| 14 | White, Sandra L., M.D., MBA, FACR | | | √ | | |
| | | | TOTAL | 14 | 0 | 0 |

| | Board Members - Absent (Highlight, when present) |
|---|---|
| 1 | Fowler, M. Celeste, Pharm.D. |
| 2 | Greeson, John D., M.D., MBA |
| 3 | Yates, Mary Virginia "Ginny", Pharm.D. |

## Antianginal Agents

**Motion: No PDL status change for the drugs in this class**

| | Board Members - Present (Strike out, when absent) | Motion Maker (√) | Seconded By (√) | VOTES YES (√) | NO (√) | ABSTAIN (√) |
|---|---|---|---|---|---|---|
| 1 | Avery, Mia, Pharm.D. | | √ | √ | | |
| 2 | Bona, Joseph R. M.D. - **Chair** | | | √ | | |
| 3 | Damon, Ann R., Pharm.D. | | | √ | | |
| 4 | Doad, Gurinder J.S., M.D. | | | √ | | |
| 5 | Fincher, Deborah W., M.S., R.Ph. | | | √ | | |
| 6 | Gore, Thomas B., M.D. | | | √ | | |
| 7 | Jones, Edwina L., Pharm.D., MBA | | | √ | | |
| 8 | Lorys, Robyn Pharm.D. | | | √ | | |
| 9 | May, J. Russell (Rusty) | | | √ | | |
| 10 | Miller, Osgood (Drew) A. R.Ph. - **Vice** | | | √ | | |
| 11 | Paul, Donald A., M.D. | √ | | √ | | |
| 12 | Rollins, Brent L., R.Ph., Ph.D. | | | √ | | |
| 13 | Shervette III, Robert E., M.D. | | | √ | | |
| 14 | White, Sandra L., M.D., MBA, FACR | | | √ | | |
| | | | TOTAL | 14 | 0 | 0 |

| | Board Members - Absent (Highlight, when present) |
|---|---|
| 1 | Fowler, M. Celeste, Pharm.D. |
| 2 | Greeson, John D., M.D., MBA |
| 3 | Yates, Mary Virginia "Ginny", Pharm.D. |

## Antibiotics, Inhaled For Cystic Fibrosis

**Motion:**

| Drug | PDL Status |
|---|---|
| *Bethkis® (Inhalation) Ampul-Neb* | P |
| *Tobi® (Inhalation) Ampul-Neb* | NP/PA |

| | Board Members - Present (Strike out, when absent) | Motion Maker (√) | Seconded By (√) | VOTES YES (√) | NO (√) | ABSTAIN (√) |
|---|---|---|---|---|---|---|
| 1 | Avery, Mia, Pharm.D. | | | √ | | |
| 2 | Bona, Joseph R. M.D. - **Chair** | | | √ | | |
| 3 | Damon, Ann R., Pharm.D. | | √ | √ | | |
| 4 | Doad, Gurinder J.S., M.D. | | | √ | | |
| 5 | Fincher, Deborah W., M.S., R.Ph. | | | √ | | |
| 6 | Gore, Thomas B., M.D. | | | √ | | |
| 7 | Jones, Edwina L., Pharm.D., MBA | √ | | √ | | |
| 8 | Lorys, Robyn Pharm.D. | | | √ | | |
| 9 | May, J. Russell (Rusty) | | | √ | | |
| 10 | Miller, Osgood (Drew) A. R.Ph. - **Vice** | | | √ | | |
| 11 | Paul, Donald A., M.D. | | | √ | | |
| 12 | Rollins, Brent L., R.Ph., Ph.D. | | | √ | | |
| 13 | Shervette III, Robert E., M.D. | | | √ | | |
| 14 | White, Sandra L., M.D., MBA, FACR | | | √ | | |
| | | | TOTAL | 14 | 0 | 0 |

| | Board Members - Absent (Highlight, when present) |
|---|---|
| 1 | Fowler, M. Celeste, Pharm.D. |
| 2 | Greeson, John D., M.D., MBA |
| 3 | Yates, Mary Virginia "Ginny", Pharm.D. |

## Antidiabetics - Insulins

**Motion:**

| Drug | PDL Status |
|---|---|
| *Novolin 70-30 (Sub-Q) Vial 70-30/Ml* | NP/PA |
| *Novolin N (Sub-Q) Vial* | NP/PA |
| *Novolin R (Injection) Vial* | NP/PA |
| *Novolog (Sub-Q) Vial* | NP/PA |
| *Novolog Mix 70-30 (Sub-Q) Vial* | NP/PA |

| | Board Members - Present (Strike out, when absent) | Motion Maker (√) | Seconded By (√) | VOTES YES (√) | NO (√) | ABSTAIN (√) |
|---|---|---|---|---|---|---|
| 1 | Avery, Mia, Pharm.D. | | | √ | | |
| 2 | Bona, Joseph R. M.D. - **Chair** | | | √ | | |
| 3 | Damon, Ann R., Pharm.D. | | | √ | | |
| 4 | Doad, Gurinder J.S., M.D. | | | √ | | |
| 5 | Fincher, Deborah W., M.S., R.Ph. | | | √ | | |
| 6 | Gore, Thomas B., M.D. | | | √ | | |
| 7 | Jones, Edwina L., Pharm.D., MBA | | | √ | | |
| 8 | Lorys, Robyn Pharm.D. | | √ | √ | | |
| 9 | May, J. Russell (Rusty) | | | √ | | |
| 10 | Miller, Osgood (Drew) A. R.Ph. - **Vice** | | | √ | | |
| 11 | Paul, Donald A., M.D. | | | √ | | |
| 12 | Rollins, Brent L., R.Ph., Ph.D. | | | √ | | |
| 13 | Shervette III, Robert E., M.D. | | | √ | | |
| 14 | White, Sandra L., M.D., MBA, FACR | √ | | √ | | |
| | | | TOTAL | 14 | 0 | 0 |

| | Board Members - Absent (Highlight, when present) |
|---|---|
| 1 | Fowler, M. Celeste, Pharm.D. |
| 2 | Greeson, John D., M.D., MBA |
| 3 | Yates, Mary Virginia "Ginny", Pharm.D. |

## Antidiabetics - Non-Insulins

**Motion:** **No PDL status change for the drugs in this class**

| | Board Members - Present (Strike out, when absent) | Motion Maker (√) | Seconded By (√) | VOTES YES (√) | NO (√) | ABSTAIN (√) |
|---|---|---|---|---|---|---|
| 1 | Avery, Mia, Pharm.D. | | | √ | | |
| 2 | Bona, Joseph R. M.D. - **Chair** | | | √ | | |
| 3 | Damon, Ann R., Pharm.D. | | | √ | | |
| 4 | Doad, Gurinder J.S., M.D. | | | √ | | |
| 5 | Fincher, Deborah W., M.S., R.Ph. | | √ | √ | | |
| 6 | Gore, Thomas B., M.D. | | | √ | | |
| 7 | Jones, Edwina L., Pharm.D., MBA | | | √ | | |
| 8 | Lorys, Robyn Pharm.D. | | | √ | | |
| 9 | May, J. Russell (Rusty) | √ | | √ | | |
| 10 | Miller, Osgood (Drew) A. R.Ph. - **Vice** | | | √ | | |
| 11 | Paul, Donald A., M.D. | | | | | √ |
| 12 | Rollins, Brent L., R.Ph., Ph.D. | | | √ | | |
| 13 | Shervette III, Robert E., M.D. | | | √ | | |
| 14 | White, Sandra L., M.D., MBA, FACR | | | √ | | |
| | | | TOTAL | 13 | 0 | 1 |

| | Board Members - Absent (Highlight, when present) |
|---|---|
| 1 | Fowler, M. Celeste, Pharm.D. |
| 2 | Greeson, John D., M.D., MBA |
| 3 | Yates, Mary Virginia "Ginny", Pharm.D. |

## Antihyperlipidemics

**Motion:**

| Drug | PDL Status |
|---|---|
| *Antara® (Oral) Capsule* | NP/PA |
| *Cholestyramine (Oral) Powder* | NP/PA |
| *Cholestyramine Light (Oral) Powder Pack* | NP/PA |

| | Board Members - Present (Strike out, when absent) | Motion Maker (√) | Seconded By (√) | VOTES YES (√) | NO (√) | ABSTAIN (√) |
|---|---|---|---|---|---|---|
| 1 | Avery, Mia, Pharm.D. | | √ | √ | | |
| 2 | Bona, Joseph R. M.D. - **Chair** | | | √ | | |
| 3 | Damon, Ann R., Pharm.D. | | | √ | | |
| 4 | Doad, Gurinder J.S., M.D. | | | √ | | |
| 5 | Fincher, Deborah W., M.S., R.Ph. | | | √ | | |
| 6 | Gore, Thomas B., M.D. | | | √ | | |
| 7 | Jones, Edwina L., Pharm.D., MBA | √ | | √ | | |
| 8 | Lorys, Robyn Pharm.D. | | | √ | | |
| 9 | May, J. Russell (Rusty) | | | √ | | |
| 10 | Miller, Osgood (Drew) A. R.Ph. - **Vice** | | | √ | | |
| 11 | Paul, Donald A., M.D. | | | | | √ |
| 12 | Rollins, Brent L., R.Ph., Ph.D. | | | √ | | |
| 13 | Shervette III, Robert E., M.D. | | | √ | | |
| 14 | White, Sandra L., M.D., MBA, FACR | | | √ | | |
| | | | TOTAL | 13 | 0 | 1 |

| | Board Members - Absent (Highlight, when present) |
|---|---|
| 1 | Fowler, M. Celeste, Pharm.D. |
| 2 | Greeson, John D., M.D., MBA |
| 3 | Yates, Mary Virginia "Ginny", Pharm.D. |

## Cephalosporins - Oral

**Motion: No PDL status change for the drugs in this class**

| | Board Members - Present (Strike out, when absent) | Motion Maker (√) | Seconded By (√) | VOTES YES (√) | NO (√) | ABSTAIN (√) |
|---|---|---|---|---|---|---|
| 1 | Avery, Mia, Pharm.D. | | | √ | | |
| 2 | Bona, Joseph R. M.D. - **Chair** | | | √ | | |
| 3 | Damon, Ann R., Pharm.D. | | | √ | | |
| 4 | Doad, Gurinder J.S., M.D. | | | √ | | |
| 5 | Fincher, Deborah W., M.S., R.Ph. | | | √ | | |
| 6 | Gore, Thomas B., M.D. | | | √ | | |
| 7 | Jones, Edwina L., Pharm.D., MBA | | | √ | | |
| 8 | Lorys, Robyn Pharm.D. | | | √ | | |
| 9 | May, J. Russell (Rusty) | √ | | √ | | |
| 10 | Miller, Osgood (Drew) A. R.Ph. - **Vice** | | | √ | | |
| 11 | Paul, Donald A., M.D. | | | √ | | |
| 12 | Rollins, Brent L., R.Ph., Ph.D. | | | √ | | |
| 13 | Shervette III, Robert E., M.D. | | | √ | | |
| 14 | White, Sandra L., M.D., MBA, FACR | | √ | √ | | |
| | | | TOTAL | 14 | 0 | 0 |

| | Board Members - Absent (Highlight, when present) |
|---|---|
| 1 | Fowler, M. Celeste, Pharm.D. |
| 2 | Greeson, John D., M.D., MBA |
| 3 | Yates, Mary Virginia "Ginny", Pharm.D. |

## Corticosteroids, Oral

**Motion:**

| Drug | PDL Status |
|---|---|
| *Millipred (Oral) Solution 10mg/5 Ml* | NP/PA |
| *Millipred (oral) Tablet* | NP/PA |
| *Millipred DP (Oral) Tab DS Pk* | NP/PA |
| *Prednisolone Sodium Phosphate (Oral) Solution 25mg/5ml* | P |

| | Board Members - Present (Strike out, when absent) | Motion Maker (√) | Seconded By (√) | VOTES YES (√) | NO (√) | ABSTAIN (√) |
|---|---|---|---|---|---|---|
| 1 | Avery, Mia, Pharm.D. | | √ | √ | | |
| 2 | Bona, Joseph R. M.D. - **Chair** | | | √ | | |
| 3 | Damon, Ann R., Pharm.D. | | | √ | | |
| 4 | Doad, Gurinder J.S., M.D. | | | √ | | |
| 5 | Fincher, Deborah W., M.S., R.Ph. | | | √ | | |
| 6 | Gore, Thomas B., M.D. | | | √ | | |
| 7 | Jones, Edwina L., Pharm.D., MBA | | | √ | | |
| 8 | Lorys, Robyn Pharm.D. | | | √ | | |
| 9 | May, J. Russell (Rusty) | | | √ | | |
| 10 | Miller, Osgood (Drew) A. R.Ph. - **Vice** | | | √ | | |
| 11 | Paul, Donald A., M.D. | √ | | √ | | |
| 12 | Rollins, Brent L., R.Ph., Ph.D. | | | √ | | |
| 13 | Shervette III, Robert E., M.D. | | | √ | | |
| 14 | White, Sandra L., M.D., MBA, FACR | | | √ | | |
| | | | TOTAL | 14 | 0 | 0 |

| | Board Members - Absent (Highlight, when present) |
|---|---|
| 1 | Fowler, M. Celeste, Pharm.D. |
| 2 | Greeson, John D., M.D., MBA |
| 3 | Yates, Mary Virginia "Ginny", Pharm.D. |

## Dermatologics, Anti-Inflammatory Agents

**Motion: No PDL status change for the drugs in this class**

| | Board Members - Present | Motion | Seconded | VOTES | | |
|---|---|---|---|---|---|---|
| | (Strike out, when absent) | Maker (√) | By (√) | YES (√) | NO (√) | ABSTAIN (√) |
| 1 | Avery, Mia, Pharm.D. | | | √ | | |
| 2 | Bona, Joseph R. M.D. - **Chair** | | | √ | | |
| 3 | Damon, Ann R., Pharm.D. | | | √ | | |
| 4 | Doad, Gurinder J.S., M.D. | | | √ | | |
| 5 | Fincher, Deborah W., M.S., R.Ph. | | | √ | | |
| 6 | Gore, Thomas B., M.D. | | | √ | | |
| 7 | Jones, Edwina L., Pharm.D., MBA | | | √ | | |
| 8 | Lorys, Robyn Pharm.D. | | | √ | | |
| 9 | May, J. Russell (Rusty) | √ | | √ | | |
| 10 | Miller, Osgood (Drew) A. R.Ph. - **Vice** | | √ | √ | | |
| 11 | Paul, Donald A., M.D. | | | √ | | |
| 12 | Rollins, Brent L., R.Ph., Ph.D. | | | √ | | |
| 13 | Shervette III, Robert E., M.D. | | | √ | | |
| 14 | White, Sandra L., M.D., MBA, FACR | | | √ | | |
| | | | TOTAL | 14 | 0 | 0 |

| | Board Members - Absent (Highlight, when present) |
|---|---|
| 1 | Fowler, M. Celeste, Pharm.D. |
| 2 | Greeson, John D., M.D., MBA |
| 3 | Yates, Mary Virginia "Ginny", Pharm.D. |

## Dermatologics, Antipsoriatics

**Motion: No PDL status change for the drugs in this class**

| | Board Members - Present | Motion | Seconded | VOTES | | |
|---|---|---|---|---|---|---|
| | (Strike out, when absent) | Maker (√) | By (√) | YES (√) | NO (√) | ABSTAIN (√) |
| 1 | Avery, Mia, Pharm.D. | | | √ | | |
| 2 | Bona, Joseph R. M.D. - **Chair** | | | √ | | |
| 3 | Damon, Ann R., Pharm.D. | | | √ | | |
| 4 | Doad, Gurinder J.S., M.D. | | | √ | | |
| 5 | Fincher, Deborah W., M.S., R.Ph. | | | √ | | |
| 6 | Gore, Thomas B., M.D. | | | √ | | |
| 7 | Jones, Edwina L., Pharm.D., MBA | | | √ | | |
| 8 | Lorys, Robyn Pharm.D. | | | √ | | |
| 9 | May, J. Russell (Rusty) | √ | | √ | | |
| 10 | Miller, Osgood (Drew) A. R.Ph. - **Vice** | | √ | √ | | |
| 11 | Paul, Donald A., M.D. | | | √ | | |
| 12 | Rollins, Brent L., R.Ph., Ph.D. | | | √ | | |
| 13 | Shervette III, Robert E., M.D. | | | √ | | |
| 14 | White, Sandra L., M.D., MBA, FACR | | | √ | | |
| | | | TOTAL | 14 | 0 | 0 |

| | Board Members - Absent (Highlight, when present) |
|---|---|
| 1 | Fowler, M. Celeste, Pharm.D. |
| 2 | Greeson, John D., M.D., MBA |
| 3 | Yates, Mary Virginia "Ginny", Pharm.D. |

## Dermatologics, Corticosteroids - Low Potency

**Motion:**

| Drug | PDL Status |
|---|---|
| *Derma-Smoothe-FS (Topical) Oil* | NP/PA |
| *Desonide (Topical) Cream* | NP/PA |
| *Desonide (Topical) Oint* | NP/PA |
| *Hydrocortisone Acetate (Topical) Gel* | P |

| | Board Members - Present (Strike out, when absent) | Motion Maker (√) | Seconded By (√) | VOTES YES (√) | NO (√) | ABSTAIN (√) |
|---|---|---|---|---|---|---|
| 1 | Avery, Mia, Pharm.D. | | | √ | | |
| 2 | Bona, Joseph R. M.D. - **Chair** | | | √ | | |
| 3 | Damon, Ann R., Pharm.D. | | | √ | | |
| 4 | Doad, Gurinder J.S., M.D. | | | √ | | |
| 5 | Fincher, Deborah W., M.S., R.Ph. | | | √ | | |
| 6 | Gore, Thomas B., M.D. | | | √ | | |
| 7 | Jones, Edwina L., Pharm.D., MBA | | | √ | | |
| 8 | Lorys, Robyn Pharm.D. | | | √ | | |
| 9 | May, J. Russell (Rusty) | | | √ | | |
| 10 | Miller, Osgood (Drew) A. R.Ph. - **Vice** | | √ | √ | | |
| 11 | Paul, Donald A., M.D. | | | √ | | |
| 12 | Rollins, Brent L., R.Ph., Ph.D. | | | √ | | |
| 13 | Shervette III, Robert E., M.D. | | | √ | | |
| 14 | White, Sandra L., M.D., MBA, FACR | √ | | √ | | |
| | | | TOTAL | 14 | 0 | 0 |

| | Board Members - Absent (Highlight, when present) |
|---|---|
| 1 | Fowler, M. Celeste, Pharm.D. |
| 2 | Greeson, John D., M.D., MBA |
| 3 | Yates, Mary Virginia "Ginny", Pharm.D. |

## Dermatologics, Corticosteroids - Medium

**Motion: No PDL status change for the drugs in this class**

| | Board Members - Present (Strike out, when absent) | Motion Maker (√) | Seconded By (√) | VOTES YES (√) | NO (√) | ABSTAIN (√) |
|---|---|---|---|---|---|---|
| 1 | Avery, Mia, Pharm.D. | | | √ | | |
| 2 | Bona, Joseph R. M.D. - **Chair** | | | √ | | |
| 3 | Damon, Ann R., Pharm.D. | | | √ | | |
| 4 | Doad, Gurinder J.S., M.D. | | | √ | | |
| 5 | Fincher, Deborah W., M.S., R.Ph. | | | √ | | |
| 6 | Gore, Thomas B., M.D. | | | √ | | |
| 7 | Jones, Edwina L., Pharm.D., MBA | | | √ | | |
| 8 | Lorys, Robyn Pharm.D. | | | √ | | |
| 9 | May, J. Russell (Rusty) | √ | | √ | | |
| 10 | Miller, Osgood (Drew) A. R.Ph. - **Vice** | | √ | √ | | |
| 11 | Paul, Donald A., M.D. | | | √ | | |
| 12 | Rollins, Brent L., R.Ph., Ph.D. | | | √ | | |
| 13 | Shervette III, Robert E., M.D. | | | √ | | |
| 14 | White, Sandra L., M.D., MBA, FACR | | | √ | | |
| | | | TOTAL | 14 | 0 | 0 |

| | Board Members - Absent (Highlight, when present) |
|---|---|
| 1 | Fowler, M. Celeste, Pharm.D. |
| 2 | Greeson, John D., M.D., MBA |
| 3 | Yates, Mary Virginia "Ginny", Pharm.D. |

## Dermatologics, Corticosteroids - High

**Motion: No PDL status change for the drugs in this class**

| | Board Members - Present (Strike out, when absent) | Motion Maker (√) | Seconded By (√) | VOTES YES (√) | NO (√) | ABSTAIN (√) |
|---|---|---|---|---|---|---|
| 1 | Avery, Mia, Pharm.D. | | | √ | | |
| 2 | Bona, Joseph R. M.D. - **Chair** | | | √ | | |
| 3 | Damon, Ann R., Pharm.D. | | | √ | | |
| 4 | Doad, Gurinder J.S., M.D. | | | √ | | |
| 5 | Fincher, Deborah W., M.S., R.Ph. | | | √ | | |
| 6 | Gore, Thomas B., M.D. | | | √ | | |
| 7 | Jones, Edwina L., Pharm.D., MBA | | | √ | | |
| 8 | Lorys, Robyn Pharm.D. | | | √ | | |
| 9 | May, J. Russell (Rusty) | √ | | √ | | |
| 10 | Miller, Osgood (Drew) A. R.Ph. - **Vice** | | √ | √ | | |
| 11 | Paul, Donald A., M.D. | | | √ | | |
| 12 | Rollins, Brent L., R.Ph., Ph.D. | | | √ | | |
| 13 | Shervette III, Robert E., M.D. | | | √ | | |
| 14 | White, Sandra L., M.D., MBA, FACR | | | √ | | |
| | | | TOTAL | 14 | 0 | 0 |

| | Board Members - Absent (Highlight, when present) |
|---|---|
| 1 | Fowler, M. Celeste, Pharm.D. |
| 2 | Greeson, John D., M.D., MBA |
| 3 | Yates, Mary Virginia "Ginny", Pharm.D. |

## Dermatologics, Scabicides-Pediculocides

**Motion:**

| Drug | PDL Status |
|---|---|
| *Natroba (Topical) Suspension* | NP/PA |

| | Board Members - Present (Strike out, when absent) | Motion: Maker (√) | Seconded: By (√) | VOTES: YES (√) | NO (√) | ABSTAIN (√) |
|---|---|---|---|---|---|---|
| 1 | Avery, Mia, Pharm.D. | | | √ | | |
| 2 | Bona, Joseph R. M.D. - **Chair** | | | √ | | |
| 3 | Damon, Ann R., Pharm.D. | | | √ | | |
| 4 | Doad, Gurinder J.S., M.D. | | | √ | | |
| 5 | Fincher, Deborah W., M.S., R.Ph. | | | √ | | |
| 6 | Gore, Thomas B., M.D. | | | √ | | |
| 7 | Jones, Edwina L., Pharm.D., MBA | | √ | √ | | |
| 8 | Lorys, Robyn Pharm.D. | | | √ | | |
| 9 | May, J. Russell (Rusty) | | | √ | | |
| 10 | Miller, Osgood (Drew) A. R.Ph. - **Vice** | | | √ | | |
| 11 | Paul, Donald A., M.D. | √ | | √ | | |
| 12 | Rollins, Brent L., R.Ph., Ph.D. | | | √ | | |
| 13 | Shervette III, Robert E., M.D. | | | √ | | |
| 14 | White, Sandra L., M.D., MBA, FACR | | | √ | | |
| | | | TOTAL | 14 | 0 | 0 |

| | Board Members - Absent (Highlight, when present) |
|---|---|
| 1 | Fowler, M. Celeste, Pharm.D. |
| 2 | Greeson, John D., M.D., MBA |
| 3 | Yates, Mary Virginia "Ginny", Pharm.D. |

## Growth Hormones

**Motion: No PDL status change for the drugs in this class**

| | Board Members - Present (Strike out, when absent) | Motion Maker (√) | Seconded By (√) | VOTES YES (√) | NO (√) | ABSTAIN (√) |
|---|---|---|---|---|---|---|
| 1 | Avery, Mia, Pharm.D. | | √ | √ | | |
| 2 | Bona, Joseph R. M.D. - **Chair** | | | √ | | |
| 3 | Damon, Ann R., Pharm.D. | | | √ | | |
| 4 | Doad, Gurinder J.S., M.D. | | | √ | | |
| 5 | Fincher, Deborah W., M.S., R.Ph. | | | √ | | |
| 6 | Gore, Thomas B., M.D. | | | √ | | |
| 7 | Greeson, John D., M.D., MBA | | | √ | | |
| 8 | Jones, Edwina L., Pharm.D., MBA | | | √ | | |
| 9 | Lorys, Robyn Pharm.D. | | | √ | | |
| 10 | May, J. Russell (Rusty) | √ | | √ | | |
| 11 | Miller, Osgood (Drew) A. R.Ph. - **Vice** | | | √ | | |
| 12 | Paul, Donald A., M.D. | | | √ | | |
| 13 | Rollins, Brent L., R.Ph., Ph.D. | | | √ | | |
| 14 | Shervette III, Robert E., M.D. | | | √ | | |
| 15 | White, Sandra L., M.D., MBA, FACR | | | √ | | |
| 16 | Yates, Mary Virginia "Ginny", Pharm.D. | | | √ | | |
| | | | TOTAL | 14 | 0 | 0 |

| | Board Members - Absent (Highlight, when present) |
|---|---|
| 1 | Fowler, M. Celeste, Pharm.D. |
| 2 | Greeson, John D., M.D., MBA |
| 3 | Yates, Mary Virginia "Ginny", Pharm.D. |

## Multiple Sclerosis (MS) Agents

**Motion:**

| Drug | PDL Status |
|---|---|
| *Betaseron (Sub-Q) Kit* | NP/PA |
| *Extavia (Sub-Q) Kit* | P |

| | Board Members - Present (Strike out, when absent) | Motion Maker (√) | Seconded By (√) | VOTES YES (√) | NO (√) | ABSTAIN (√) |
|---|---|---|---|---|---|---|
| 1 | Avery, Mia, Pharm.D. | | | √ | | |
| 2 | Bona, Joseph R. M.D. - **Chair** | | | √ | | |
| 3 | Damon, Ann R., Pharm.D. | | | √ | | |
| 4 | Doad, Gurinder J.S., M.D. | | | √ | | |
| 5 | Fincher, Deborah W., M.S., R.Ph. | | | √ | | |
| 6 | Gore, Thomas B., M.D. | | | √ | | |
| 7 | Jones, Edwina L., Pharm.D., MBA | √ | | √ | | |
| 8 | Lorys, Robyn Pharm.D. | | √ | √ | | |
| 9 | May, J. Russell (Rusty) | | | √ | | |
| 10 | Miller, Osgood (Drew) A. R.Ph. - **Vice** | | | √ | | |
| 11 | Paul, Donald A., M.D. | | | √ | | |
| 12 | Rollins, Brent L., R.Ph., Ph.D. | | | √ | | |
| 13 | Shervette III, Robert E., M.D. | | | √ | | |
| 14 | White, Sandra L., M.D., MBA, FACR | | | √ | | |
| | | | TOTAL | 14 | 0 | 0 |

| | Board Members - Absent (Highlight, when present) |
|---|---|
| 1 | Fowler, M. Celeste, Pharm.D. |
| 2 | Greeson, John D., M.D., MBA |
| 3 | Yates, Mary Virginia "Ginny", Pharm.D. |

## Multivitamins, Prenatal

**Motion:** The Department is to consider a Maximum Allowable Cost (MAC) for these agents

| | Board Members - Present (Strike out, when absent) | Motion Maker (√) | Seconded By (√) | VOTES YES (√) | NO (√) | ABSTAIN (√) |
|---|---|---|---|---|---|---|
| 1 | Avery, Mia, Pharm.D. | | | √ | | |
| 2 | Bona, Joseph R. M.D. - **Chair** | | | √ | | |
| 3 | Damon, Ann R., Pharm.D. | | | √ | | |
| 4 | Doad, Gurinder J.S., M.D. | | | √ | | |
| 5 | Fincher, Deborah W., M.S., R.Ph. | | | √ | | |
| 6 | Gore, Thomas B., M.D. | | | √ | | |
| 7 | Jones, Edwina L., Pharm.D., MBA | | √ | √ | | |
| 8 | Lorys, Robyn Pharm.D. | | | √ | | |
| 9 | May, J. Russell (Rusty) | | | √ | | |
| 10 | Miller, Osgood (Drew) A. R.Ph. - **Vice** | √ | | √ | | |
| 11 | Paul, Donald A., M.D. | | | √ | | |
| 12 | Rollins, Brent L., R.Ph., Ph.D. | | | √ | | |
| 13 | Shervette III, Robert E., M.D. | | | √ | | |
| 14 | White, Sandra L., M.D., MBA, FACR | | | √ | | |
| | | | TOTAL | 14 | 0 | 0 |

| | Board Members - Absent (Highlight, when present) |
|---|---|
| 1 | Fowler, M. Celeste, Pharm.D. |
| 2 | Greeson, John D., M.D., MBA |
| 3 | Yates, Mary Virginia "Ginny", Pharm.D. |

## Nasal Antiallergics

**Motion: No PDL status change for the drugs in this class**

| | Board Members - Present (Strike out, when absent) | Motion Maker (√) | Seconded By (√) | VOTES YES (√) | NO (√) | ABSTAIN (√) |
|---|---|---|---|---|---|---|
| 1 | Avery, Mia, Pharm.D. | | | √ | | |
| 2 | Bona, Joseph R. M.D. - **Chair** | | | √ | | |
| 3 | Damon, Ann R., Pharm.D. | | | √ | | |
| 4 | Doad, Gurinder J.S., M.D. | | | √ | | |
| 5 | Fincher, Deborah W., M.S., R.Ph. | | | √ | | |
| 6 | Gore, Thomas B., M.D. | | | √ | | |
| 7 | Jones, Edwina L., Pharm.D., MBA | | | √ | | |
| 8 | Lorys, Robyn Pharm.D. | | | √ | | |
| 9 | May, J. Russell (Rusty) | √ | | √ | | |
| 10 | Miller, Osgood (Drew) A. R.Ph. - **Vice** | | | √ | | |
| 11 | Paul, Donald A., M.D. | | √ | √ | | |
| 12 | Rollins, Brent L., R.Ph., Ph.D. | | | √ | | |
| 13 | Shervette III, Robert E., M.D. | | | √ | | |
| 14 | Yates, Mary Virginia "Ginny", Pharm.D. | | | √ | | |
| | | | TOTAL | 14 | 0 | 0 |

| | Board Members - Absent (Highlight, when present) |
|---|---|
| 1 | Fowler, M. Celeste, Pharm.D. |
| 2 | Greeson, John D., M.D., MBA |
| 3 | Yates, Mary Virginia "Ginny", Pharm.D. |

## Nasal Steroids

**Motion:**

| Drug | PDL Status |
|---|---|
| *Nasacort AQ (Nasal) Spray* | NP/PA |
| *Qnasl (Nasal) HFA Aer AD* | P |

| | Board Members - Present (Strike out, when absent) | Motion Maker (√) | Seconded By (√) | VOTES YES (√) | NO (√) | ABSTAIN (√) |
|---|---|---|---|---|---|---|
| 1 | Avery, Mia, Pharm.D. | | √ | √ | | |
| 2 | Bona, Joseph R. M.D. - **Chair** | | | √ | | |
| 3 | Damon, Ann R., Pharm.D. | | | √ | | |
| 4 | Doad, Gurinder J.S., M.D. | | | √ | | |
| 5 | Fincher, Deborah W., M.S., R.Ph. | | | √ | | |
| 6 | Gore, Thomas B., M.D. | | | √ | | |
| 7 | Jones, Edwina L., Pharm.D., MBA | √ | | √ | | |
| 8 | Lorys, Robyn Pharm.D. | | | √ | | |
| 9 | May, J. Russell (Rusty) | | | √ | | |
| 10 | Miller, Osgood (Drew) A. R.Ph. - **Vice** | | | √ | | |
| 11 | Paul, Donald A., M.D. | | | | | √ |
| 12 | Rollins, Brent L., R.Ph., Ph.D. | | | √ | | |
| 13 | Shervette III, Robert E., M.D. | | | √ | | |
| 14 | White, Sandra L., M.D., MBA, FACR | | | √ | | |
| | | | TOTAL | 13 | 0 | 1 |

| | Board Members - Absent (Highlight, when present) |
|---|---|
| 1 | Fowler, M. Celeste, Pharm.D. |
| 2 | Greeson, John D., M.D., MBA |
| 3 | Yates, Mary Virginia "Ginny", Pharm.D. |

## Ophthalmic, Adrenergics

**Motion:**

| Drug | PDL Status |
|---|---|
| *Iopidine (Opthalmic) Drops* | P |
| *Simbrinza (Opthalmic) Drops Susp* | P |

| | Board Members - Present (Strike out, when absent) | Motion Maker (√) | Seconded By (√) | VOTES YES (√) | NO (√) | ABSTAIN (√) |
|---|---|---|---|---|---|---|
| 1 | Avery, Mia, Pharm.D. | | | √ | | |
| 2 | Bona, Joseph R. M.D. - **Chair** | | | √ | | |
| 3 | Damon, Ann R., Pharm.D. | | √ | √ | | |
| 4 | Doad, Gurinder J.S., M.D. | | | √ | | |
| 5 | Fincher, Deborah W., M.S., R.Ph. | | | √ | | |
| 6 | Gore, Thomas B., M.D. | | | √ | | |
| 7 | Jones, Edwina L., Pharm.D., MBA | | | √ | | |
| 8 | Lorys, Robyn Pharm.D. | √ | | √ | | |
| 9 | May, J. Russell (Rusty) | | | √ | | |
| 10 | Miller, Osgood (Drew) A. R.Ph. - **Vice** | | | √ | | |
| 11 | Paul, Donald A., M.D. | | | √ | | |
| 12 | Rollins, Brent L., R.Ph., Ph.D. | | | √ | | |
| 13 | Shervette III, Robert E., M.D. | | | √ | | |
| 14 | White, Sandra L., M.D., MBA, FACR | | | √ | | |
| | | | TOTAL | 14 | 0 | 0 |

| | Board Members - Absent (Highlight, when present) |
|---|---|
| 1 | Fowler, M. Celeste, Pharm.D. |
| 2 | Greeson, John D., M.D., MBA |
| 3 | Yates, Mary Virginia "Ginny", Pharm.D. |

## Ophthalmic - Antiallergics

**Motion: No PDL status change for the drugs in this class**

| | Board Members - Present (Strike out, when absent) | Motion Maker (√) | Seconded By (√) | VOTES YES (√) | NO (√) | ABSTAIN (√) |
|---|---|---|---|---|---|---|
| 1 | Avery, Mia, Pharm.D. | | | √ | | |
| 2 | Bona, Joseph R. M.D. - **Chair** | | | √ | | |
| 3 | Damon, Ann R., Pharm.D. | | | √ | | |
| 4 | Doad, Gurinder J.S., M.D. | | | √ | | |
| 5 | Fincher, Deborah W., M.S., R.Ph. | | | √ | | |
| 6 | Gore, Thomas B., M.D. | | | √ | | |
| 7 | Jones, Edwina L., Pharm.D., MBA | | √ | √ | | |
| 8 | Lorys, Robyn Pharm.D. | | | √ | | |
| 9 | May, J. Russell (Rusty) | √ | | √ | | |
| 10 | Miller, Osgood (Drew) A. R.Ph. - **Vice** | | | √ | | |
| 11 | Paul, Donald A., M.D. | | | | | √ |
| 12 | Rollins, Brent L., R.Ph., Ph.D. | | | √ | | |
| 13 | Shervette III, Robert E., M.D. | | | √ | | |
| 14 | White, Sandra L., M.D., MBA, FACR | | | √ | | |
| | | | TOTAL | 13 | 0 | 1 |

| | Board Members - Absent (Highlight, when present) |
|---|---|
| 1 | Fowler, M. Celeste, Pharm.D. |
| 2 | Greeson, John D., M.D., MBA |
| 3 | Yates, Mary Virginia "Ginny", Pharm.D. |

## Ophthalmic - Anti-Infectives

**Motion:**

| Drug | PDL Status |
|---|---|
| *Bleph-10 (Ophthalmic) Drops* | NP/PA |
| *Ilotycin (Opthalmic) Oint* | NP/PA |
| *Trifluridine (Opthalmic) Drops* | P |
| *Viroptic (Opthalmic) Drops* | NP/PA |

| | Board Members - Present (Strike out, when absent) | Motion Maker (√) | Seconded By (√) | VOTES YES (√) | NO (√) | ABSTAIN (√) |
|---|---|---|---|---|---|---|
| 1 | Avery, Mia, Pharm.D. | | | √ | | |
| 2 | Bona, Joseph R. M.D. - **Chair** | | | √ | | |
| 3 | Damon, Ann R., Pharm.D. | √ | | √ | | |
| 4 | Doad, Gurinder J.S., M.D. | | | √ | | |
| 5 | Fincher, Deborah W., M.S., R.Ph. | | | √ | | |
| 6 | Gore, Thomas B., M.D. | | | √ | | |
| 7 | Jones, Edwina L., Pharm.D., MBA | | | √ | | |
| 8 | Lorys, Robyn Pharm.D. | | | √ | | |
| 9 | May, J. Russell (Rusty) | | | √ | | |
| 10 | Miller, Osgood (Drew) A. R.Ph. - **Vice** | | √ | √ | | |
| 11 | Paul, Donald A., M.D. | | | | | √ |
| 12 | Rollins, Brent L., R.Ph., Ph.D. | | | √ | | |
| 13 | Shervette III, Robert E., M.D. | | | √ | | |
| 14 | White, Sandra L., M.D., MBA, FACR | | | √ | | |
| | | | TOTAL | 13 | 0 | 1 |

| | Board Members - Absent (Highlight, when present) |
|---|---|
| 1 | Fowler, M. Celeste, Pharm.D. |
| 2 | Greeson, John D., M.D., MBA |
| 3 | Yates, Mary Virginia "Ginny", Pharm.D. |

## Ophthalmic - Beta Blockers

**Motion: No PDL status change for the drugs in this class**

| | Board Members - Present (Strike out, when absent) | Motion Maker (√) | Seconded By (√) | VOTES YES (√) | NO (√) | ABSTAIN (√) |
|---|---|---|---|---|---|---|
| 1 | Avery, Mia, Pharm.D. | | | √ | | |
| 2 | Bona, Joseph R. M.D. - **Chair** | | | √ | | |
| 3 | Damon, Ann R., Pharm.D. | | | √ | | |
| 4 | Doad, Gurinder J.S., M.D. | | | √ | | |
| 5 | Fincher, Deborah W., M.S., R.Ph. | | | √ | | |
| 6 | Gore, Thomas B., M.D. | | | √ | | |
| 7 | Jones, Edwina L., Pharm.D., MBA | | √ | √ | | |
| 8 | Lorys, Robyn Pharm.D. | | | √ | | |
| 9 | May, J. Russell (Rusty) | √ | | √ | | |
| 10 | Miller, Osgood (Drew) A. R.Ph. - **Vice** | | | √ | | |
| 11 | Paul, Donald A., M.D. | | | | | √ |
| 12 | Rollins, Brent L., R.Ph., Ph.D. | | | √ | | |
| 13 | Shervette III, Robert E., M.D. | | | √ | | |
| 14 | White, Sandra L., M.D., MBA, FACR | | | √ | | |
| | | | TOTAL | 13 | 0 | 1 |

| | Board Members - Absent (Highlight, when present) |
|---|---|
| 1 | Fowler, M. Celeste, Pharm.D. |
| 2 | Greeson, John D., M.D., MBA |
| 3 | Yates, Mary Virginia "Ginny", Pharm.D. |

## Ophthalmic Nonsteroidal Antiinflammatory Drugs (NSAIDs)

**Motion:**

| Drug | PDL Status |
|---|---|
| *Ilevro (Opthalmic) Drops Susp 0.3%* | P |

| | Board Members - Present (Strike out, when absent) | Motion Maker (√) | Seconded By (√) | VOTES YES (√) | NO (√) | ABSTAIN (√) |
|---|---|---|---|---|---|---|
| 1 | Avery, Mia, Pharm.D. | | | √ | | |
| 2 | Bona, Joseph R. M.D. - **Chair** | | | √ | | |
| 3 | Damon, Ann R., Pharm.D. | | | √ | | |
| 4 | Doad, Gurinder J.S., M.D. | | | √ | | |
| 5 | Fincher, Deborah W., M.S., R.Ph. | | √ | √ | | |
| 6 | Gore, Thomas B., M.D. | | | √ | | |
| 7 | Jones, Edwina L., Pharm.D., MBA | √ | | √ | | |
| 8 | Lorys, Robyn Pharm.D. | | | √ | | |
| 9 | May, J. Russell (Rusty) | | | √ | | |
| 10 | Miller, Osgood (Drew) A. R.Ph. - **Vice** | | | √ | | |
| 11 | Paul, Donald A., M.D. | | | √ | | |
| 12 | Rollins, Brent L., R.Ph., Ph.D. | | | √ | | |
| 13 | Shervette III, Robert E., M.D. | | | √ | | |
| 14 | White, Sandra L., M.D., MBA, FACR | | | √ | | |
| | | | TOTAL | 14 | 0 | 0 |

| | Board Members - Absent (Highlight, when present) |
|---|---|
| 1 | Fowler, M. Celeste, Pharm.D. |
| 2 | Greeson, John D., M.D., MBA |
| 3 | Yates, Mary Virginia "Ginny", Pharm.D. |

## Ophthalmic - Prostaglandins

**Motion: No PDL status change for the drugs in this class**

| | Board Members - Present (Strike out, when absent) | Motion Maker (√) | Seconded By (√) | VOTES YES (√) | NO (√) | ABSTAIN (√) |
|---|---|---|---|---|---|---|
| 1 | Avery, Mia, Pharm.D. | | | √ | | |
| 2 | Bona, Joseph R. M.D. - **Chair** | | | √ | | |
| 3 | Damon, Ann R., Pharm.D. | | | √ | | |
| 4 | Doad, Gurinder J.S., M.D. | | | √ | | |
| 5 | Fincher, Deborah W., M.S., R.Ph. | | | √ | | |
| 6 | Gore, Thomas B., M.D. | | | √ | | |
| 7 | Jones, Edwina L., Pharm.D., MBA | | √ | √ | | |
| 8 | Lorys, Robyn Pharm.D. | | | √ | | |
| 9 | May, J. Russell (Rusty) | √ | | √ | | |
| 10 | Miller, Osgood (Drew) A. R.Ph. - **Vice** | | | √ | | |
| 11 | Paul, Donald A., M.D. | | | | | √ |
| 12 | Rollins, Brent L., R.Ph., Ph.D. | | | √ | | |
| 13 | Shervette III, Robert E., M.D. | | | √ | | |
| 14 | White, Sandra L., M.D., MBA, FACR | | | √ | | |
| | | | TOTAL | 13 | 0 | 1 |

| | Board Members - Absent (Highlight, when present) |
|---|---|
| 1 | Fowler, M. Celeste, Pharm.D. |
| 2 | Greeson, John D., M.D., MBA |
| 3 | Yates, Mary Virginia "Ginny", Pharm.D. |

## Ophthalmic Steroids

**Motion:**

| Drug | PDL Status |
|---|---|
| *Durezol (Opthalmic) Drops* | P |

| | Board Members - Present (Strike out, when absent) | Motion: Maker (√) | Motion: Seconded By (√) | VOTES: YES (√) | NO (√) | ABSTAIN (√) |
|---|---|---|---|---|---|---|
| 1 | Avery, Mia, Pharm.D. | | | √ | | |
| 2 | Bona, Joseph R. M.D. - **Chair** | | | √ | | |
| 3 | Damon, Ann R., Pharm.D. | | | √ | | |
| 4 | Doad, Gurinder J.S., M.D. | | | √ | | |
| 5 | Fincher, Deborah W., M.S., R.Ph. | | | √ | | |
| 6 | Gore, Thomas B., M.D. | | | √ | | |
| 7 | Jones, Edwina L., Pharm.D., MBA | √ | | √ | | |
| 8 | Lorys, Robyn Pharm.D. | | | √ | | |
| 9 | May, J. Russell (Rusty) | | | √ | | |
| 10 | Miller, Osgood (Drew) A. R.Ph. - **Vice** | | | √ | | |
| 11 | Paul, Donald A., M.D. | | | √ | | |
| 12 | Rollins, Brent L., R.Ph., Ph.D. | | √ | √ | | |
| 13 | Shervette III, Robert E., M.D. | | | √ | | |
| 14 | White, Sandra L., M.D., MBA, FACR | | | √ | | |
| | | | TOTAL | 14 | 0 | 0 |

| | Board Members - Absent (Highlight, when present) |
|---|---|
| 1 | Fowler, M. Celeste, Pharm.D. |
| 2 | Greeson, John D., M.D., MBA |
| 3 | Yates, Mary Virginia "Ginny", Pharm.D. |

## Otic Anti-Infectives

**Motion: No PDL status change for the drugs in this class**

| | Board Members - Present (Strike out, when absent) | Motion Maker (√) | Seconded By (√) | VOTES YES (√) | NO (√) | ABSTAIN (√) |
|---|---|---|---|---|---|---|
| 1 | Avery, Mia, Pharm.D. | | | √ | | |
| 2 | Bona, Joseph R. M.D. - **Chair** | | | √ | | |
| 3 | Damon, Ann R., Pharm.D. | | | √ | | |
| 4 | Doad, Gurinder J.S., M.D. | | | √ | | |
| 5 | Fincher, Deborah W., M.S., R.Ph. | | | √ | | |
| 6 | Gore, Thomas B., M.D. | | | √ | | |
| 7 | Jones, Edwina L., Pharm.D., MBA | | | √ | | |
| 8 | Lorys, Robyn Pharm.D. | | | √ | | |
| 9 | May, J. Russell (Rusty) | √ | | √ | | |
| 10 | Miller, Osgood (Drew) A. R.Ph. - **Vice** | | | √ | | |
| 11 | Paul, Donald A., M.D. | | √ | √ | | |
| 12 | Rollins, Brent L., R.Ph., Ph.D. | | | √ | | |
| 13 | Shervette III, Robert E., M.D. | | | √ | | |
| 14 | White, Sandra L., M.D., MBA, FACR | | | √ | | |
| | | | TOTAL | 14 | 0 | 0 |

| | Board Members - Absent (Highlight, when present) |
|---|---|
| 1 | Fowler, M. Celeste, Pharm.D. |
| 2 | Greeson, John D., M.D., MBA |
| 3 | Yates, Mary Virginia "Ginny", Pharm.D. |

## Phosphate Binder Agents

**Motion:**

| Drug | PDL Status |
|---|---|
| *Calcium Acetate (Oral) Capsule* | P |
| *Calcium Acetate (Oral) Tablet* | P |
| *Phoslyra (Oral) Solution* | P |

| | Board Members - Present (Strike out, when absent) | Motion Maker (√) | Seconded By (√) | VOTES YES (√) | NO (√) | ABSTAIN (√) |
|---|---|---|---|---|---|---|
| 1 | Avery, Mia, Pharm.D. | | | √ | | |
| 2 | Bona, Joseph R. M.D. - **Chair** | | | √ | | |
| 3 | Damon, Ann R., Pharm.D. | | √ | √ | | |
| 4 | Doad, Gurinder J.S., M.D. | | | √ | | |
| 5 | Fincher, Deborah W., M.S., R.Ph. | | | √ | | |
| 6 | Gore, Thomas B., M.D. | | | √ | | |
| 7 | Jones, Edwina L., Pharm.D., MBA | | | √ | | |
| 8 | Lorys, Robyn Pharm.D. | √ | | √ | | |
| 9 | May, J. Russell (Rusty) | | | √ | | |
| 10 | Miller, Osgood (Drew) A. R.Ph. - **Vice** | | | √ | | |
| 11 | Paul, Donald A., M.D. | | | √ | | |
| 12 | Rollins, Brent L., R.Ph., Ph.D. | | | √ | | |
| 13 | Shervette III, Robert E., M.D. | | | √ | | |
| 14 | White, Sandra L., M.D., MBA, FACR | | | √ | | |
| | | | TOTAL | 14 | 0 | 0 |

| | Board Members - Absent (Highlight, when present) |
|---|---|
| 1 | Fowler, M. Celeste, Pharm.D. |
| 2 | Greeson, John D., M.D., MBA |
| 3 | Yates, Mary Virginia "Ginny", Pharm.D. |

## Smoking Deterrents

**Motion: No PDL status change for the drugs in this class**

| | Board Members - Present (Strike out, when absent) | Motion Maker (√) | Seconded By (√) | VOTES YES (√) | NO (√) | ABSTAIN (√) |
|---|---|---|---|---|---|---|
| 1 | Avery, Mia, Pharm.D. | | | √ | | |
| 2 | Bona, Joseph R. M.D. - **Chair** | | | √ | | |
| 3 | Damon, Ann R., Pharm.D. | | | √ | | |
| 4 | Doad, Gurinder J.S., M.D. | | | √ | | |
| 5 | Fincher, Deborah W., M.S., R.Ph. | | | √ | | |
| 6 | Gore, Thomas B., M.D. | | | √ | | |
| 7 | Jones, Edwina L., Pharm.D., MBA | | | √ | | |
| 8 | Lorys, Robyn Pharm.D. | | | √ | | |
| 9 | May, J. Russell (Rusty) | √ | | √ | | |
| 10 | Miller, Osgood (Drew) A. R.Ph. - **Vice** | | | √ | | |
| 11 | Paul, Donald A., M.D. | | | √ | | |
| 12 | Rollins, Brent L., R.Ph., Ph.D. | | | √ | | |
| 13 | Shervette III, Robert E., M.D. | | | √ | | |
| 14 | White, Sandra L., M.D., MBA, FACR | | √ | √ | | |
| | | | TOTAL | 14 | 0 | 0 |

| | Board Members - Absent (Highlight, when present) |
|---|---|
| 1 | Fowler, M. Celeste, Pharm.D. |
| 2 | Greeson, John D., M.D., MBA |
| 3 | Yates, Mary Virginia "Ginny", Pharm.D. |

## Urinary Anti-Infectives

***See Attachment ___ for drug list***

**Motion:**

| Drug | PDL Status |
|---|---|
| *Hiprex (Oral) Tablet* | NP/PA |
| *Methenamine Hippurate (Oral) Tablet* | NP/PA |
| *Ur N-C (Oral) Tablet* | NP/PA |
| *Urimar-T (Oral) Tablet* | NP/PA |
| *Urogesic-Blue (Oral) Tablet* | NP/PA |

| | Board Members - Present (Strike out, when absent) | Motion Maker (√) | Seconded By (√) | VOTES YES (√) | NO (√) | ABSTAIN (√) |
|---|---|---|---|---|---|---|
| 1 | Avery, Mia, Pharm.D. | | √ | √ | | |
| 2 | Bona, Joseph R. M.D. - **Chair** | | | √ | | |
| 3 | Damon, Ann R., Pharm.D. | | | √ | | |
| 4 | Doad, Gurinder J.S., M.D. | | | √ | | |
| 5 | Fincher, Deborah W., M.S., R.Ph. | | | √ | | |
| 6 | Gore, Thomas B., M.D. | | | √ | | |
| 7 | Jones, Edwina L., Pharm.D., MBA | √ | | √ | | |
| 8 | Lorys, Robyn Pharm.D. | | | √ | | |
| 9 | May, J. Russell (Rusty) | | | √ | | |
| 10 | Miller, Osgood (Drew) A. R.Ph. - **Vice** | | | √ | | |
| 11 | Paul, Donald A., M.D. | | | √ | | |
| 12 | Rollins, Brent L., R.Ph., Ph.D. | | | √ | | |
| 13 | Shervette III, Robert E., M.D. | | | √ | | |
| 14 | White, Sandra L., M.D., MBA, FACR | | | √ | | |
| | | | TOTAL | 14 | 0 | 0 |

| | Board Members - Absent (Highlight, when present) |
|---|---|
| 1 | Fowler, M. Celeste, Pharm.D. |
| 2 | Greeson, John D., M.D., MBA |
| 3 | Yates, Mary Virginia "Ginny", Pharm.D. |

## Urinary Antispasmodics

**Motion: No PDL status change for the drugs in this class**

| | Board Members - Present (Strike out, when absent) | Motion Maker (√) | Seconded By (√) | VOTES YES (√) | NO (√) | ABSTAIN (√) |
|---|---|---|---|---|---|---|
| 1 | Avery, Mia, Pharm.D. | | | √ | | |
| 2 | Bona, Joseph R. M.D. - **Chair** | | | √ | | |
| 3 | Damon, Ann R., Pharm.D. | | | √ | | |
| 4 | Doad, Gurinder J.S., M.D. | | | √ | | |
| 5 | Fincher, Deborah W., M.S., R.Ph. | | | √ | | |
| 6 | Gore, Thomas B., M.D. | | | √ | | |
| 7 | Jones, Edwina L., Pharm.D., MBA | | | √ | | |
| 8 | Lorys, Robyn Pharm.D. | | √ | √ | | |
| 9 | May, J. Russell (Rusty) | √ | | √ | | |
| 10 | Miller, Osgood (Drew) A. R.Ph. - **Vice** | | | √ | | |
| 11 | Paul, Donald A., M.D. | | | | | √ |
| 12 | Rollins, Brent L., R.Ph., Ph.D. | | | √ | | |
| 13 | Shervette III, Robert E., M.D. | | | √ | | |
| 14 | White, Sandra L., M.D., MBA, FACR | | | √ | | |
| | | | TOTAL | 13 | 0 | 1 |

| | Board Members - Absent (Highlight, when present) |
|---|---|
| 1 | Fowler, M. Celeste, Pharm.D. |
| 2 | Greeson, John D., M.D., MBA |
| 3 | Yates, Mary Virginia "Ginny", Pharm.D. |

## Urinary Prostatic Hypertrophy

**Motion: No PDL status change for the drugs in this class**

| | Board Members - Present (Strike out, when absent) | Motion Maker (√) | Seconded By (√) | VOTES YES (√) | NO (√) | ABSTAIN (√) |
|---|---|---|---|---|---|---|
| 1 | Avery, Mia, Pharm.D. | | | √ | | |
| 2 | Bona, Joseph R. M.D. - **Chair** | | | √ | | |
| 3 | Damon, Ann R., Pharm.D. | | | √ | | |
| 4 | Doad, Gurinder J.S., M.D. | | | √ | | |
| 5 | Fincher, Deborah W., M.S., R.Ph. | | | √ | | |
| 6 | Gore, Thomas B., M.D. | | | √ | | |
| 7 | Jones, Edwina L., Pharm.D., MBA | | | √ | | |
| 8 | Lorys, Robyn Pharm.D. | | √ | √ | | |
| 9 | May, J. Russell (Rusty) | √ | | √ | | |
| 10 | Miller, Osgood (Drew) A. R.Ph. - **Vice** | | | √ | | |
| 11 | Paul, Donald A., M.D. | | | | | √ |
| 12 | Rollins, Brent L., R.Ph., Ph.D. | | | √ | | |
| 13 | Shervette III, Robert E., M.D. | | | √ | | |
| 14 | White, Sandra L., M.D., MBA, FACR | | | √ | | |
| | | | TOTAL | 13 | 0 | 1 |

| | Board Members - Absent (Highlight, when present) |
|---|---|
| 1 | Fowler, M. Celeste, Pharm.D. |
| 2 | Greeson, John D., M.D., MBA |
| 3 | Yates, Mary Virginia "Ginny", Pharm.D. |

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# Manufacturers' Forum
# Manufacturer Presentations

**Dates:** May 1, 2014

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

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

*Catamaran Health Solutions*
Talmahjia "Tami" Sweat, PharmD, Director, Clinical Management, Public Sector

**Drug Summary Documents**
Please note that relevant, electronic materials that were provided by manufacturers were forwarded to the Drug Utilization Review Board (DURB). For the drugs presented at the February 2014 Forum, May 2014 Forum or that manufacturers provided a summary on that are being reviewed at the June 5, 2014 DURB meeting, 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. Boehringer Ingelheim**
Patricia Grossman, PharmD, MBA, Associate Director, Health Economics and Outcomes Research
Jay Moore, Manager, Access, Reimbursement and Distribution

**Pradaxa® (dabigatran)**
PRADAXA (dabigatran etexilate mesylate) capsules is indicated to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation (NVAF).

**WARNING: DISCONTINUING PRADAXA IN PATIENTS WITHOUT ADEQUATE CONTINUOUS ANTICOAGULATION INCREASES RISK OF STROKE. Discontinuing PRADAXA places patients at an increased risk of thrombotic events. If anticoagulation with PRADAXA must be discontinued for a reason other than pathological bleeding, consider coverage with another anticoagulant.**

**Statement of PRADAXA Efficacy and Safety**
- In the RE-LY pivotal, phase 3 trial, PRADAXA 150 mg BID demonstrated a superior 35% risk reduction of stroke/systemic embolism versus warfarin (primary efficacy endpoint; 134 vs 202 events, HR: 0.65, 95% CI [0.52, 0.81], *P*=0.0001)
    - Superior 25% reduction of ischemic stroke versus warfarin (component of primary endpoint; 103 vs 134 events, HR: 0.75, 95% CI [0.58, 0.97], P=0.0296)
    - Superior 74% reduction of hemorrhagic stroke versus warfarin (component of primary endpoint; 12 vs 45 events, HR: 0.26, 95% CI [0.14, 0.49], P<0.0001)

- Similar rate of major bleeds versus warfarin (primary safety endpoint; 399 [3.3%] vs 421 [3.6%] events, HR: 0.93, 95% CI [0.81, 1.07])
- Higher rate of major GI bleeds versus warfarin (186 [1.6%] vs 125 [1.1%] events, HR: 1.50, 95% CI [1.2-1.9])
- Higher rate of total GI bleeds versus warfarin (681 [6.1%] vs 452 [4.0%] events, HR: 1.52, 95% CI [1.35-1.72])
- Lower rate of total bleeding events versus warfarin (1993 [16.6%] vs 2166 [18.4%] events, HR: 0.91, 95% CI [0.85, 0.96])
- Lower rate of intracranial bleeds versus warfarin (38 [0.3%] vs 90 [0.8%] events, HR: 0.41, 95% CI [0.28-0.60])
- Lower rate of all-cause mortality vs warfarin (438 [3.6%/year] vs 487 [4.1%/year], HR: 0.88, 95% CI [0.77, 1.00], *P*=0.052)
- On November 2, 2012, the US Food and Drug Administration (FDA) announced the results of a Mini-Sentinel assessment evaluating new information about the risk of serious bleeding associated with use of the anticoagulants PRADAXA and warfarin:
    - Bleeding rates associated with new use of PRADAXA do not appear higher vs new use of warfarin
    - Results are consistent with observations from the pivotal RE-LY Trial
- The FDA investigated the actual rates of gastrointestinal and intracranial bleeding for new users of PRADAXA compared with new users of warfarin. This assessment was done using insurance claims and administrative data from the FDA's Mini-Sentinel pilot of the Sentinel Initiative.
- As a result of this assessment, the FDA has not changed its recommendations regarding PRADAXA. PRADAXA provides an important health benefit when used as directed.5 Healthcare professionals who prescribe PRADAXA should carefully follow the dosing recommendations in the drug label, especially for patients with renal impairment, to reduce the risk of bleeding.
- In the RELY-ABLE long-term safety extension trial over 2 additional years, bleed rates were similar to those seen during the RE-LY trial.
    - Rates of total bleeding, life-threatening bleeding, and major bleeding were similar to those seen during RE-LY® (There was no adjudication of outcome events in RELY-ABLE)
- PRADAXA has over 4 years of clinical trial experience in patients with NVAF.

**CONTRAINDICATIONS**

PRADAXA is contraindicated in patients with:

- active pathological bleeding;
- known serious hypersensitivity reaction (e.g., anaphylactic reaction or anaphylactic shock) to PRADAXA;
- mechanical prosthetic heart valve

**WARNINGS & PRECAUTIONS**

- Increased Risk of Stroke with Discontinuation of PRADAXA
- Risk of Bleeding
- Thromboembolic and Bleeding Events in Patients with Prosthetic Heart Valves
- Thromboembolic and Bleeding Events in Patients with Prosthetic Heart Valves (Continued)
- Effect of P-gp Inducers & Inhibitors on Dabigatran Exposure

**Other Measures Evaluated**

In the pivotal trial, a higher rate of clinical myocardial infarction was reported in patients who received PRADAXA (0.7 per 100 patient-years for 150 mg dose) than in those who received warfarin (0.6).

**Questions and Answers**

Q: What is considered the advantage of Pradaxa?
A: Only oral anticoagulant that is superior to warfarin in hemorrhagic and ischemic strokes.

## II. Cornerstone

Archie Stone, PhD, Senior Director, Medical Affairs
Gary Golby, Senior National Account Manager
Lee Stout, National Account Executive

**Pertzye® (pancrelipase)**

**BACKGROUND**

Exocrine pancreatic insufficiency (EPI) is common in persons with cystic fibrosis (CF) and requires the use of pancreatic enzyme replacement therapy (PERT) administered orally with meals (Davis, 1996; CFF, 2012). Available PERT formulations utilize enteric-coated (EC) pancreatic enzymes contained within microcapsules or microspheres to prevent gastric acid inactivation of the enzymes in the stomach. To enable digestion of food, the acidic contents of the gastric contents must be neutralized on arrival in the duodenum. In EPI, the failure of the pancreas to secrete bicarbonate inhibits the neutralization step (Dutta, 1979). The enzymes (lipases) responsible for lipid digestion in the small bowel are inactivated below a pH of 5.5 (Go, 1970). The mean postprandial intraluminal pH in the distal duodenum of people with CF-associated EPI has been reported to be below 5.0, with individual values frequently less than 4.0 (Dutta, 1988). Given that the optimal pH for maximal lipase activity is in the range of 8 to 9, it has been suggested that the acidic environment may result in reduced release of enzymes as well as irreversible inactivation of lipase from enteric-coated PERT products.

**PERTZYE® Product Information**

- PERTZYE® (pancrelipase) is a pancreatic enzyme preparation consisting of a combination of porcine-derived lipases, proteases, and amylases indicated for the treatment of exocrine pancreatic insufficiency due to cystic fibrosis or other conditions. Please note the following limitation of use: PERTZYE® is not interchangeable with any other pancrelipase product.
- PERTZYE® is a unique EC-bicarbonate-buffered PERT formulation developed to optimize the pH in the microenvironment surrounding the microspheres. The buffering capacity is preserved by the EC until the release of the enzymes in the upper intestine.
- PERTZYE® is an orally administered delayed-release capsule that is dosed according to the number of daily lipase units required for individual patients. PERTZYE® is available in 2 color-coded capsule strengths of 8,000 and 16,000 USP units of lipase. Therapy should be initiated at the lowest recommended dose and gradually increased. The dosage of PERTZYE® should be individualized based on clinical symptoms, the degree of steatorrhea present, and the fat content of the diet. Dosage recommendations for pancreatic enzyme replacement therapy were published following the Cystic Fibrosis Foundation Consensus Conferences. PERTZYE® should be administered in a manner consistent with the recommendations of the Conferences and the Prescribing Information. Patients may be dosed on a fat ingestion-based or actual body weight-based dosing scheme.

**PERTZYE® CLINICAL TRIALS**

The short-term safety and efficacy of PERTZYE® was evaluated in a randomized, double-blind, placebo-controlled, cross-over study in 24 children and adults (ages 8 to 43 years) with exocrine pancreatic insufficiency due to cystic fibrosis. During two treatment periods, subjects were randomized to receive PERTZYE® or placebo for 6 to 8 days of treatment with 72-hour stool collection during each blinded treatment phase. Mean coefficient of fat absorption with PERTZYE® was 83% compared with 46% with placebo ($p < 0.001$). There was also significant improvement in nitrogen absorption and a decrease in stool weight and stool frequency with PERTZYE® treatment. The possible contribution of the bicarbonate buffer in PERTZYE® to the efficacy observed cannot be determined since no comparison with a non-buffered PERT formulation was performed. Adverse event type and frequency were not significantly different between treatments; however, diarrhea, dyspepsia and cough occurred at a higher rate with PERTZYE® (10%) than with placebo (4%).

**Important Safety Information**

- Fibrosing colonopathy is associated with high-dose use of pancreatic enzyme replacement.
- Exercise caution when doses of PERTZYE® exceed 2,500 lipase units/kg body weight per meal (or greater than 10,000 lipase units/kg body weight per day).
- To avoid irritation of oral mucosa, do not chew PERTZYE® or retain in the mouth.
- Hyperuricemia may develop. Consider monitoring uric acid levels in patients with hyperuricemia, gout, or renal impairment.
- There is theoretical risk of viral transmission with all pancreatic enzyme products including PERTZYE®.
- Exercise caution when administering pancrelipase to a patient with a known allergy to proteins of porcine origin.
- The most common adverse reactions (≥ 10% of patients treated with PERTZYE®) are diarrhea, dyspepsia, and cough.

**Questions and Answers**

Q: What are considered the advantages of Pertzye?

A: Does not require acid-suppressing drugs and unique formulated to stimulate normal pancreatic function.

**III. Forest**

Alex Bennett, PhD, Associate Director, Scientific Communications
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**Bystolic® (nebivolol)**

Pronunciation: Generic Name: nebivolol (ne-BIV-oh-lol); Brand Name: Bystolic (bi-STOL-ik)

**INDICATION AND USAGE**

**BYSTOLIC (nebivolol)** is a beta-adrenergic blocking agent indicated for the treatment of hypertension, to lower blood pressure. BYSTOLIC may be used alone or in combination with other antihypertensive agents. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. There are no controlled trials demonstrating risk reduction with BYSTOLIC, but at least one pharmacologically similar drug has demonstrated such benefits.

**CLINICAL PHARMACOLOGY**

In extensive metabolizers and at doses ≤10 mg, BYSTOLIC is preferentially β1 selective. BYSTOLIC lacks intrinsic sympathomimetic and membrane stabilizing activity. At clinically relevant doses, BYSTOLIC does not demonstrate α1 - adrenergic receptor blocking activity. The mechanism of action of BYSTOLIC has not been definitively established. Possible factors may include decreased heart rate, decreased myocardial contractility, diminution of tonic sympathetic outflow to the periphery from cerebral vasomotor centers, suppression of renin activity, vasodilation and decreased peripheral vascular resistance.

**PHARMACOKINETICS AND DRUG INTERACTIONS**

Mean peak plasma concentrations occur 1.5 to 4 hours after oral dosing and food does not alter the pharmacokinetics. BYSTOLIC is 98% protein-bound and is metabolized mainly via glucuronidation and hepatic CYP2D6 enzymes. The half-life is 12 to 19 hours. Drugs that inhibit CYP2D6 (quinidine, fluoxetine, etc.) can be expected to increase plasma levels of BYSTOLIC. When co-administered with inhibitors or inducers of CYP2D6, patients should be closely monitored and the BYSTOLIC dose adjusted according to BP response. Reserpine or clonidine may produce excessive reduction of sympathetic activity. Do not use BYSTOLIC with other β-blockers. Both digitalis glycosides and β-blockers slow atrioventricular conduction and decrease heart rate; concomitant use can increase the risk of bradycardia. BYSTOLIC can exacerbate the effects of myocardial depressants or inhibitors of AV conduction, such as certain calcium antagonists (particularly of the phenylalkylamine [verapamil] and benzothiazepine [diltiazem] classes), or antiarrhythmic agents, such as disopyramide.

**EFFICACY**

The antihypertensive effectiveness of BYSTOLIC monotherapy was demonstrated in three, 12-week randomized, double-blind, placebo-controlled trials in patients with mild to moderate hypertension. Two of these trials (Studies 1 and 2) included 1716 patients from the general population (mean age 54; male 55%; non-Caucasian 26%; diabetic 7%). The third trial (Study 3) included 300 Black patients (mean age 51; male 45%; diabetic 14%). BYSTOLIC significantly decreased sitting systolic/diastolic blood pressures (SiSBP/SiDBP) in most groups studied with BP-lowering effects evident within 2 weeks of treatment and maintained over the 24-hour dosing interval. The antihypertensive effect was similar in subgroups analyzed by age or sex. Efficacy of monotherapy was established in Black patients, although the magnitude of effect was somewhat less than in Caucasians. A fourth trial (Study 4) that enrolled 669 patients (mean age 54; male 55%; non-Caucasian 46%, diabetic 14%) with inadequate BP control demonstrated that BYSTOLIC, at doses of 5-20 mg, administered once daily concomitantly with up to two other agents (ACEIs, ARBs and/or thiazide diuretics), resulted in significant additional BP reduction over placebo vs. baseline.

**Placebo-subtracted least-square mean reductions in trough SiSBP/SiDBP**

| | **Bystolic 1.25mg** | **Bystolic 2.5mg** | **Bystolic 5mg** | **Bystolic 10mg** | **Bystolic 20mg** | **Bystolic 30-40mg** |
|---|---|---|---|---|---|---|
| **Study 1** | -6.6*/-5.1* | -8.5*/-5.6* | -8.1*/-5.5* | -9.2*/-6.3* | -8.7*/-6.9* | -11.7*/-8.3* |
| **Study 2** | -3.8/-3.2* | -3.1/-3.9* | -6.3*/-4.5* | | | |
| **Study 3†** | -1.5/-2.9 | -2.6/-4.9* | -6.0*/-6.1* | -7.2*/-6.1* | -6.8*/-5.5* | |
| **Study 4‡** | -5.7*/-3.3* | -3.7*-3.5* | -6.2*/-4.6* | | | |

*p<0.05 based on pair-wise comparison vs. placebo; †Study enrolled only Black patients; ‡Added to one or two other antihypertensives

**CONTRAINDICATIONS**
BYSTOLIC is contraindicated in patients with severe bradycardia, heart block greater than first degree, cardiogenic shock, decompensated cardiac failure, sick sinus syndrome (unless permanent pacemaker is in place), severe hepatic impairment (Child-Pugh >B), and in patients who are hypersensitive to any component of this product.

**WARNINGS AND PRECAUTIONS**
Do not abruptly discontinue BYSTOLIC therapy in patients with coronary artery disease. Severe exacerbation of angina, myocardial infarction and ventricular arrhythmias have been reported following the abrupt discontinuation of therapy with β-blockers. BYSTOLIC was not studied in patients with angina pectoris or who had a recent myocardial infarction (MI). In general, patients with bronchospastic diseases should not receive β-blockers. Because β-blocker withdrawal has been associated with an increased risk of MI and chest pain, patients undergoing major surgery should generally continue treatment throughout the perioperative period, but should be closely monitored when anesthetic agents which depress myocardial function are used. β-blockers may mask some of the manifestations of hypoglycemia and hyperthyroidism, particularly tachycardia. Nonselective β-blockers may potentiate insulin-induced hypoglycemia. β-blockers can precipitate or aggravate symptoms of arterial insufficiency in patients with peripheral vascular disease. Because of significant negative inotropic and chronotropic effects in patients treated with β-blockers and calcium channel blockers of the verapamil and diltiazem type, monitor ECG and blood pressure in patients treated concomitantly with these agents. When co-administered with CYP2D6 inhibitors, the BYSTOLIC dose may need to be reduced. Renal and hepatic clearance of BYSTOLIC is decreased in patients with severe renal and moderate hepatic impairment, respectively. BYSTOLIC has not been studied in patients receiving dialysis, or in patients with severe hepatic impairment. While taking β-blockers, patients with a history of severe anaphylactic reactions to a variety of allergens may be more reactive to repeated challenge, and may be unresponsive to the usual doses of epinephrine. In patients with known or suspected pheochromocytoma, initiate an α-blocker prior to the use of any β-blocker.

**Questions and Answers**
Q: What are considered the advantages of Bystolic?
A: Cardioselective, unique mechanism of action in producing vasodilation to decrease blood pressure, improved adverse events, efficacy in African Americans, Hispanics and younger adults, efficacy as add-on therapy, metabolic neutral and erectile dysfunction is not a concern.

**Linzess® (linaclotide)**
Pronunciation: Generic Name: linaclotide (lin-AK-loe-tide), Brand Name: Linzess (lin-ZESS)

**INDICATION**
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.

**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 a decrease in 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.

**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.

**Questions and Answers**
Q: What are considered the advantages of Linzess?
A: New mechanism of action, improves IBS-C in men and women and improves pain.

Q: How are other Medicaid plans covering?
A: Some plans are still reviewing; Alabama and South Carolina do not manage the class.

## IV. Johnson & Johnson

Megan L. Jones, PharmD, MPA, Senior Liaison, Health Economics & Outcomes Research
J. Leigh Faircloth, Strategic Market Director
Samantha Ramos, Strategic Market Director

**Xarelto® (rivaroxaban)**
Pronunciation: XARELTO® (zah-REL-toe), rivaroxaban (ri-va-rox'-a-ban)

Rivaroxaban is indicated for the treatment of deep vein thrombosis (DVT) and treatment of pulmonary embolism (PE). Rivaroxaban is indicated for the reduction in the risk of recurrence of DVT and of PE. Rivaroxaban is indicated to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation (AF). Rivaroxaban is indicated for the prophylaxis of DVT, which may lead to PE in patients undergoing hip replacement surgery or knee replacement surgery.

**New Clinical Information**
*Prins MH, et al. Oral rivaroxaban versus standard therapy for the treatment of symptomatic venous thromboembolism: a pooled analysis of the EINSTEIN-DVT and PE randomized studies*. A pre-specified pooled analysis of the EINSTEIN-DVT and EINSTEIN-PE studies was conducted to provide more precise estimates of the safety and efficacy of rivaroxaban, as well as a more detailed analysis of the efficacy and safety of rivaroxaban in key clinical subgroups including patients with cancer, patients with previous DVT/PE, patients presenting with a large clot burden and those defined as fragile patients [patients meeting one or more of the following criteria: age > 75 years, calculated creatinine clearance < 50ml/min, or low body weight (less than or equal to 50kg)]. Both studies used the same protocol which compared rivaroxaban (15mg twice-daily for 21 days, followed by 20mg once daily) with standard therapy (enoxaparin 1.0mg/kg (twice-daily and warfarin or acenocoumarol) to ascertain outcomes. The primary efficacy outcome was symptomatic recurrent VTE, which was defined as a composite of fatal or nonfatal PE or DVT. The principal safety outcome was clinically relevant bleeding, which was defined as a composite of major and clinically relevant nonmajor bleeding. Recurrent VTE occurred in 2.1% and 2.3% of rivaroxaban and standard therapy patients, respectively (HR, 0.89 (95% CI, 0.66-1.19); one-sided P <0.001 for the noninferiority margin of 1.75 and two-sided P=0.41 for superiority; absolute risk reduction of 0.2% in favor of rivaroxaban (95% CI, -0.4% to 0.9%). A first major or nonmajor clinically relevant bleeding event occurred in 9.4% of patients treated with rivaroxaban and 10.0% of patients in the standard therapy group (HR, 0.93; 95% CI, 0.81-1.06; absolute risk reduction, 0.6%; 95% CI, -0.7 to 1.9%; P=0.27). A first major bleeding event was observed in 1.0% of rivaroxaban-treated patients and 1.7% of standard therapy patients (HR, 0.54; 95% CI, 0.37-0.79; P=0.002; absolute risk reduction, 0.8% in favor of rivaroxaban; 95% CI, 0.3% to 1.3%; P=0.002)

**Questions and Answers**
Q: What are considered advantages of Xarelto?
A: Range of indications, uptake in hospitals and phase 3 trials for reversal under way.

## V. AstraZeneca

Tim A. Briscoe, PharmD, CDE, Senior Regional Scientific Manager
Anabelle Keohane, PharmD, RPh, Senior Medical Science Liaison
Negelle Y. Green, LCSW, Account Director

**Brilinta® (ticagrelor)**
Pronunciation: BRILINTA (brih-LIN-tah); Ticagrelor (tye-KA-grel-or)

**Overview**
The clinical evidence for the efficacy and safety of BRILINTA is derived from the PLATO (PLATelet inhibition and patient Outcomes) trial. BRILINTA, as compared to clopidogrel, reduced the rate of the combined endpoint of cardiovascular (CV) death, myocardial infarction (MI), or stroke in patients with acute coronary syndrome (ACS) by 16% (relative risk reduction [RRR]; p<0.001), with an absolute risk reduction (ARR) of 1.9%. The difference between treatments was driven by CV death and MI, with no difference in stroke. BRILINTA is the first and only oral antiplatelet agent Food Drug Administration (FDA) approved to demonstrate significant reductions in CV death versus clopidogrel (1.1% ARR; 21% RRR; p=0.001). Maintenance doses of aspirin (ASA) above 100 mg reduce the effectiveness of BRILINTA and should be avoided. The overall rate of PLATO-defined total major bleeding was similar between the BRILINTA and clopidogrel groups; there was a higher rate of non-coronary artery bypass graft (CABG)-related bleeding with ticagrelor.

**Indications**
- BRILINTA is a P2Y12 platelet inhibitor indicated to reduce the rate of thrombotic CV events in patients with ACS (unstable angina [UA], nonST elevation myocardial infarction [NSTEMI], or ST elevation myocardial infarction [STEMI]). BRILINTA has been shown to reduce the rate of a combined endpoint of CV death, MI or stroke compared to clopidogrel. The difference between treatments was driven by CV death and MI with no difference in stroke. In patients treated with percutaneous coronary intervention (PCI), it also reduces the rate of stent thrombosis.
- BRILINTA has been studied in ACS in combination with ASA. Maintenance doses of ASA above 100 mg decreased the effectiveness of
- BRILINTA. Avoid maintenance doses of ASA above 100 mg daily.

**Boxed Warnings**
Please refer to the BRILINTA Prescribing Information for Boxed Warnings related to increased risk of bleeding and reduced effectiveness with maintenance doses of ASA greater than 100 mg per day.

**Contraindications**
BRILINTA is contraindicated in patients with a history of intracranial hemorrhage, active pathological bleeding, severe hepatic impairment, and hypersensitivity to ticagrelor or any component of the product.

**Select Subgroup Publications**
- Invasive: A prespecified analysis from the PLATO study in 13,408 patients with intent for an invasive treatment strategy showed that treatment with ticagrelor resulted in a significant reduction in the composite endpoint of CV death, MI, and stroke vs clopidogrel (9.0% vs 10.7%; HR, 0.84; 95% CI, 0.75-0.94; p=0.0025) respectively, without any additional risks of PLATO-defined total major bleeding (11.5% vs 11.6%; HR, 0.99; 95% CI, 0.89-1.10; p=0.8803), respectively. The rate of non-CABG major bleeding with ticagrelor vs clopidogrel was 4.7% vs. 4.0% (HR, 1.16; 95% CI, 0.97–1.38; p=0.104).
- Medically Managed: In a prespecified analysis of the PLATO trial 5216 patients were planned for noninvasive treatment (medical management) at randomization. Ticagrelor significantly reduced the incidence of the composite endpoint of CV death, MI, or stroke, when compared to clopidogrel (12% vs 14.3%; HR, 0.85; 95% CI, 0.73-1.00; p=0.045). No statistically significant difference in the rate of PLATO-defined major bleeding was observed with ticagrelor vs clopidogrel (11.9% vs 10.3%; HR, 1.17; 95% CI, 0.98-1.39; p=0.079). The rate of non-CABG major bleeding with ticagrelor vs clopidogrel was 4.0% vs. 3.1% (HR, 1.30; 95% CI, 0.95 to 1.77; p=0.103).
- Elderly: A prespecified analysis assessed the clinical outcomes in elderly patients (≥75 years) versus younger patients (<75 years) treated with ticagrelor versus clopidogrel. In elderly patients (≥75 years), the primary composite outcome occurred in 17.2% of patients receiving ticagrelor and 18.3% of patients receiving clopidogrel (HR, 0.89; 95% CI, 0.74–1.08). When considering patients ≥75 years of age and <75 years of age the treatment effect was independent of age (p-value interaction=0.56). In patients ≥75 years, PLATO defined total major bleeding occurred in 14.2% on ticagrelor and 13.5% of on clopidogrel (HR, 1.02; 95% CI, 0.82–1.27), was similar in both treatment groups and independent of age (<75 vs. ≥75 years; p-value interaction of 0.89). The rate of non-CABG major bleeding in patients ≥75 years was 8.3% on ticagrelor and 7.1% on clopidogrel (HR, 1.18; 95% CI, 0.87-1.59).

- Patients with a History of Stroke or Transient Ischemic Attack (TIA): A prespecified analysis of the PLATO trial evaluated the effect of a past medical history of TIA or nonhemorrhagic stroke on the efficacy and safety endpoints for ticagrelor at 1 year. The rates of the primary efficacy and safety endpoints were consistent with the overall PLATO trial results. The relative reduction of the composite endpoint with ticagrelor vs clopidogrel was 13% and 16% for patients with and without a prior TIA or stroke, respectively. There was no significant treatment-by-stroke or TIA history interaction for the primary endpoint after multivariable adjustment (p-value interaction=0.39). PLATO-defined total major bleeding and non-CABG major bleeding, were not significantly affected by a history of TIA or nonhemorrhagic stroke (p-value interaction=0.77 and 0.24, respectively).
- Effect on Recurrent Events: An analysis of the PLATO trial evaluated the effect of ticagrelor versus clopidogrel on recurrent CV and ischemic events. Treatment with ticagrelor was more effective than clopidogrel in reducing the time from randomization to the second event/death for the composite endpoint of CV Death, MI, or stroke (HR, 0.80; 95% CI, 0.70-0.90; p<0.001). Recurrent PLATO major or Thrombolysis in Myocardial Infarction (TIMI) major non-CABG bleeding events were not different between the two treatment groups (p=0.96 and 0.38, respectively).
- The PLATO trial was not designed or powered to demonstrate the efficacy or safety of ticagrelor compared with clopidogrel in specific subgroups. Subgroup analyses were performed to confirm consistency of results in different cohorts.

**Adverse Reactions**
The most common adverse reactions are bleeding and dyspnea.

**Questions and Answers**
No questions followed.

**Symbicort® (budesonide and formoterol fumarate dihydrate)**
Pronunciation: SYMBICORT (sim-buh-cort), budesonide / formoterol fumarate dihydrate (bue-DES-oh-nide / for-MOE-ter-ol FUE-ma-rate DYE-hye-drate)

**Indications**
Asthma: SYMBICORT is indicated for the treatment of asthma in patients 12 years of age and older. The SYMBICORT PI contains a boxed warning stating, LABAs, such as formoterol (one of the active ingredients in SYMBICORT), increase the risk of asthma-related death.
COPD: SYMBICORT 160/4.5 is indicated for the BID maintenance treatment of airflow obstruction in patients with COPD including chronic bronchitis and emphysema. SYMBICORT 160/4.5 is the only approved dosage for the treatment of airflow obstruction in COPD.

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

**Asthma Specific Population Data**
- In a 12-week, randomized, double-blind, multicenter clinical trial of 311 Black patients aged ≥ 12 years with moderate-to-severe asthma, improvement in predose forced expiratory volume in one second (FEV1) from baseline to the treatment average (primary variable) was significantly greater with SYMBICORT 160/4.5 mcg versus budesonide DPI 180 mcg (0.16 L vs. 0.07 L; p = 0.008); this effect was also observed at weeks 2, 6, and end of treatment (p ≤ 0.032).2,3 2 Reductions in daily asthma symptom score (p = 0.039), total daily rescue medication use (p = 0.029), and nighttime rescue medication use (p = 0.007) were significantly greater in patients treated with SYMBICORT compared to those treated with budesonide. In a 12-week, randomized, double-blind, multicenter, clinical trial of 250 Hispanic patients, SYMBICORT 160/4.5 mcg improved lung function vs. budesonide pMDI 160 mcg, although the differences were not statistically significant. In both studies, the overall adverse event (AE) profile was similar between treatment groups, with most AEs being mild-to-moderate in intensity.
- In a 52-week, randomized, double-blind, multicenter study, the safety and efficacy of SYMBICORT 160/4.5 mcg was compared to budesonide pMDI 160 mcg in African American patients aged ≥ 12 years (n = 742) with moderate-to-severe asthma. There were a total of 36 and 61 asthma exacerbations (defined as oral/systemic corticosteroid use and/or an asthma-related hospitalization, emergency room visit, or urgent care visit) in the SYMBICORT 160/4.5 mcg (n = 377) and budesonide pMDI 160 mcg (n = 364) groups, respectively. The time to first asthma exacerbation was longer in the SYMBICORT versus budesonide group (p = 0.018). The rate of asthma exacerbations was reduced by 38.5% with SYMBICORT versus budesonide (rate ratio, 0.615; p = 0.002). Patients treated with SYMBICORT showed significant improvements in pulmonary function (predose FEV1, forced

vital capacity and morning peak expiratory flow) compared to those treated with budesonide ($p \leq 0.013$). No substantial or unexpected patterns of abnormalities were observed in laboratory, electrocardiographic, or Holter monitoring assessments.

**COPD Exacerbations Study**

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

**Additional Safety**

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

**Questions and Answers**

Q: Did any new safety issues result from studies in other ethnic groups?
A: Safety is comparable to previous studies conducted.

## VI. Pharmacyclics

Shannon Hill, PA, MMSE, Medical Science Liaison
Cathy Consolo, National Account Executive

**Imbruvica® (ibrutinib)**

Pronunciation: imbruvica ((im-BRU-vih-kuh)/ibrutinib (eye broo' ti nib)

- Mantle Cell Lymphoma (MCL), an aggressive B-cell Non-Hodgkins Lymphoma (NHL), is a therapeutic challenge to manage, as responses to second- and third-line therapies are often incomplete and not durable due to the progressive nature of MCL and the development of drug resistance. MCL is an uncommon subtype of NHL which represents about 6% of all NHL cases, resulting in an incidence of approximately 4,000 cases/year.
- Chronic Lymphocytic Leukemia (CLL) is a lymphoproliferative disorder characterized by progressive expansion of monoclonal B lymphocytes.4 The American Cancer Society's statistics estimate that about 15,680 new cases of CLL will be diagnosed in 2013 and that 4,580 men and women will die from this cancer.3
- FDA granted Breakthrough Therapy Designation Status to ibrutinib based upon the potential to treat patients with relapsed and refractory MCL and patients with del 17p CLL. A breakthrough therapy program is for a drug that treats a serious or life-threatening condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement on a clinically significant endpoint(s) over available therapies.

**Indications**

IMBRUVICA is a kinase inhibitor indicated for the treatment of patients with MCL who have received at least one

prior therapy. It is also indicated for the treatment of patients with CLL who have received at least one prior therapy. These indications are based on overall response rate. Improvements in survival or disease-related symptoms have not been established.

**Dosing and Administration**
For MCL, the recommended dosage is 560 mg (four 140 mg capsules) taken orally once daily. For CLL, the recommended dosage is 420 mg (three 140 mg capsules) taken orally once daily.

**Warnings/Precautions**
- Hemorrhage: Monitor for bleeding.
- Infections: Monitor patients for fever and infections and evaluate promptly.
- Myelosuppression: Check complete blood counts monthly.
- Renal Toxicity: Monitor renal function and maintain hydration.
- Second Primary Malignancies: Other malignancies have occurred in patients, including skin cancers, and other carcinomas.
- Embryo-Fetal Toxicity: Can cause fetal harm. Advise women of the potential risk to a fetus and to avoid pregnancy while taking the drug.

**Clinical Studies**
- The safety and efficacy of IMBRUVICA in patients with MCL who have received at least one prior therapy were evaluated in an open-label, multi-center, single-arm trial of 111 previously-treated patients. The investigator assessed overall response rate (ORR), the primary endpoint, was 65.8% (95% CI: 56.2%, 74.5%), including 48.6% partial responses and 17.1% complete responses. The median duration of response (DOR) was 17.5 months (95% CI: 15.8%, Not Reached). An Independent Review Committee (IRC) performed independent reading and interpretation of imaging scans, demonstrating an ORR of 69%. The median time to response was 1.9 months.
- The safety and efficacy of IMBRUVICA in patients with CLL who have received at least one prior therapy were evaluated in an open-label, multi-center trial of 48 previously treated patients. The IRC ORR was 58.3% (95% CI: 43.2%, 72.4%), all partial responses. The median DOR was not reached (range: 5.6 to 24.2+ months).

**Adverse Reactions**
The most common adverse reactions (≥20%) in patients with MCL were thrombocytopenia, diarrhea, neutropenia, anemia, fatigue, musculoskeletal pain, peripheral edema, upper respiratory tract infection, nausea, bruising, dyspnea, constipation, rash, abdominal pain, vomiting and decreased appetite. The most common adverse reactions (≥20%) in patients with CLL were thrombocytopenia, diarrhea, bruising, neutropenia, anemia, upper respiratory tract infection, fatigue, musculoskeletal pain, rash, pyrexia, constipation, peripheral edema, arthralgia, nausea, stomatitis, sinusitis, and dizziness.

**Drug Interactions**
Avoid co-administration with strong and moderate CYP3A inhibitors. If a moderate CYP3A inhibitor must be used, reduce IMBRUVICA dose. Avoid co-administration with strong CYP3A inducers.

**Use in Specific Populations**
Avoid use of IMBRUVICA in patients with baseline hepatic impairment.

**Questions and Answers**
Q: Are there any phase 3 studies being conducted?
A: Yes, a phase 3 confirmatory trial is being conducted.

Q: Is there any data available yet on overall survival?
A: The data is forthcoming.

Q: What was the average duration of treatment in clinical trials?
A: For CLL, 21 months; for MCL, 17.5 months.

Q: Is the distribution limited?
A: Yes, limited to 5 specialty pharmacies.

## VII. Actelion

Sonja Grooms-Smith, PhD, Medical Science Liaison
Brad Burris, MBA/MHA, National Account Executive

**Opsumit® (macitentan)**

Pronunciation**:** Opsumit (OṔ-sum-it); macitentan (ma-sē-TEN-tan)

### Introduction

Opsumit® (macitentan) 10 mg is an orally active, dual ERA (endothelin receptor antagonist) that prevents ET-1 (endothelin-1) receptor binding.[1,2] In addition to being a potent vasoconstrictor, ET-1 is a key mediator of pathologic changes that lead to pulmonary vascular remodeling in PAH, including fibrosis, hypertrophy, and inflammation.[3] The clinical development program for Opsumit included the SERAPHIN trail, the largest study of all FDA approved pulmonary arterial hypertension (PAH) therapies.[1,4] SERAPHIN was an event driven study, with 742 PAH patients randomized 1:1:1 to placebo, macitentan 3mg, or Opsumit for a mean treatment duration of 115 weeks.

### FDA Indication

Opsumit is indicated for the treatment of PAH (WHO Group I) to delay disease progression.[1] Disease progression included death, initiation of intravenous (IV) or subcutaneous prostanoids, or clinical worsening of PAH (decreased 6-minute walk distance, worsened PAH symptoms and need for additional PAH treatment). Opsumit also reduced hospitalization for PAH.

### Efficacy and Clinical Benefits

- Opsumit significantly reduced the risk of morbidity & mortality events by 45% vs. placebo ($p<0.0001$).[1] The treatment effect with Opsumit was consistent, regardless if patients were on background PAH therapy at baseline.
- Opsumit also significantly improved clinically important secondary endpoints, including mortality due to PAH or hospitalization for PAH, 6-minute walk distance (6MWD), and WHO functional class.
- Opsumit is administered as a single 10 mg oral tablet once daily, with or without food. No dose adjustment is required in patients with hepatic or renal impairment.
- In vivo drug interaction studies in humans have shown no clinically relevant interactions between Opsumit and cyclosporine, sildenafil, or warfarin.
- In vitro, Opsumit has no relevant inhibitory or inducing effects on CYP enzymes, is neither a substrate nor an inhibitor of the multi-drug resistance protein (P-gp, MDR-1), nor is it a substrate or inhibitor of the organic anion transport pump, and does not interact with proteins involved in hepatic bile salt transport.

### Safety and Tolerability

Opsumit, like other approved endothelin receptor antagonists, has a box warning for embryo-fetal toxicity, for which there is a Risk Evaluation and Mitigation Strategy program for females.[1,2]

In the pivotal study, 3.4% and 2.1% of patients treated with Opsumit had aminotransferase elevations three and eight times above normal limits compared to 4.5% and 0.4% of placebo patients, respectively.[1] Obtain baseline liver enzymes and monitor as clinically indicated.

Decreases in hemoglobin concentration and hematocrit have occurred following administration of other ERAs and were observed in clinical studies with Opsumit.[1,2] Initiation of Opsumit is not recommended in patients with severe anemia. Measure hemoglobin prior to initiation of treatment and repeat during treatment as clinically indicated.

Strong inducers and inhibitors of the CYP3A4 isoenzyme system should be avoided in combination with Opsumit.[1]

In the pivotal study, adverse events occurring in ≥3% of patients and more frequently in patients taking Opsumit included anemia, nasopharyngitis/pharyngitis, bronchitis, headache, influenza, and urinary tract infection.[1] The incidence of serious adverse events was 45% (109/242) for Opsumit and 55% (137/249) for placebo. The incidence of serious adverse events other than those related to PAH was similar for Opsumit (27%) and placebo (25%).

### Conclusions

- FDA approval of Opsumit is based on the clinical evidence from the largest completed randomized controlled study conducted in patients with PAH.
- Opsumit is an ERA that is indicated for PAH WHO Group I and has been shown to delay disease progression and reduce hospitalization for PAH. The treatment effect with Opsumit was consistent, regardless of whether patients were on background PAH therapy at baseline.
- Due to the box warning for embryo-fetal toxicity, Opsumit is available to females through a restricted program.

**Questions and Answers**
Q: What are considered the advantages of other ERAs?
A: Dual action on receptors, impact on safety and efficacy, once daily dosing and does not affect transaminases.

Q: When does the patent on Tracleer expire?
A: November 2015.

## VIII. Bristol-Myers Squibb

David Reed, MD, FACP, Senior Director, Regional Medical & Research Specialist
Manan Shah, PharmD, PhD, Director, Health Services & Outcomes Research
Greg Ives, State Access Manager

**Eliquis® (apixaban)**
Pronunciation: ELIQUIS (ELL eh kwiss) (apixaban (a PIX a ban))

**INDICATION:** ELIQUIS is a Factor Xa inhibitor indicated to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation (NVAF).
**NEW INDICATION:** ELIQUIS is indicated for the prophylaxis of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE), in patients who have undergone hip or knee replacement surgery.

**Prophylaxis of DVT Following Hip or Knee Replacement Surgery:**
**ADVANCE-3** was a phase 3, randomized, double-blind, double-dummy study that evaluated apixaban 2.5 mg orally twice daily versus enoxaparin 40 mg subcutaneously once daily for DVT prophylaxis in patients undergoing total hip replacement (THR) surgery. The primary efficacy outcome was a composite of adjudicated asymptomatic and symptomatic DVT, nonfatal PE, and death from any cause. The primary safety outcome was bleeding during the treatment period or until 2 days after the last dose of study medication was administered. Safety outcomes included major, major + clinically relevant non-major (CRNM) and all bleeding.

- Apixaban was superior to enoxaparin 40 mg once daily for DVT prophylaxis after THR (events n/N (%): apixaban 27/1949 (1.4%) vs enoxaparin 74/1917 (3.9%); relative risk (RR) with apixaban, 0.36; 95% CI, 0.22-0.54; one-sided $P < .001$ for noninferiority and two-sided $P < .001$ for superiority).
- Major bleeding was reported in 22 of the 2673 patients who received apixaban (0.8%) and 18 of the 2659 patients who received enoxaparin (0.7%) (absolute difference in risk, 0.1%; 95% CI, – 0.3 to 0.6; $P = .54$).
- Major + CRNM bleeding was reported in 129 of the 2673 patients who received apixaban (4.8%) and 134 of the 2659 patients who received enoxaparin (5.0%) (absolute difference in risk, -0.2%; 95% CI, – 1.4 to 1.0; $P = .72$).
- All bleeding was reported in 313 of the 2673 patients who received apixaban (11.7%) and 334 of the 2659 patients who received enoxaparin (12.6%) (absolute difference in risk, -0.9%; 95% CI, – 2.6 to 0.9; $P = .34$).

**ADVANCE-2** trial was a phase 3, double-blind, double-dummy, randomized study of apixaban 2.5 mg twice daily versus enoxaparin 40 mg subcutaneously once daily for in patients undergoing total knee replacement (TKR). The primary efficacy outcome was a composite of adjudicated asymptomatic and symptomatic DVT, nonfatal PE, and death from any cause. The primary safety outcome was bleeding reported during treatment. Safety outcomes included major, major + CRNM and all bleeding.

- Apixaban was superior to enoxaparin 40 mg once daily for DVT prophylaxis after TKR (events n/N (%): apixaban 147/976 (15.06%) vs enoxaparin 243/997 (24.37%); relative risk (RR) 0.62; 95% CI 0.51-0.74; one-sided $P < .0001$ when tested for noninferiority and for superiority).
- Major bleeding events occurred in 9 of 1501 patients (0.6%) who received apixaban and in 14 of 1508 patients (0.9%) who received enoxaparin (absolute risk difference (95% CI), – 0.33% (– 0.95 to 0.29%); $P = .3014$).
- Major + CRNM bleeding was reported in 53 of the 1501 patients who received apixaban (3.5%) and 72 of the 1508 patients who received enoxaparin (4.8%) (absolute difference in risk, -1.24%; 95% CI, – 2.66 to 0.18; $P = .0881$).
- All bleeding was reported in 104 of the 1501 patients who received apixaban (6.9%) and 126 of the 1508 patients who received enoxaparin (8.4%) (absolute difference in risk, -1.39%; 95% CI, – 3.29 to 0.51; $P = .1412$).

**ADVANCE-1** trial was a phase 3, double-blind, double-dummy, randomized study of apixaban 2.5 mg twice daily versus enoxaparin 30 mg subcutaneously every 12 hours in patients undergoing TKR. The primary efficacy outcome was a composite of adjudicated asymptomatic and symptomatic DVT, nonfatal PE, and death from any cause. The

primary safety outcome was bleeding during the treatment period or until 2 days after the last dose of study medication. Safety outcomes included major, major + CRNM and all bleeding.

- Apixaban did not meet its primary efficacy endpoint for noninferiority to enoxaparin 30 mg every 12 hours for DVT prophylaxis after TKR (events n/N (%): apixaban 104/1157 (9.0%) vs enoxaparin 100/1130 (8.8%); relative risk [RR] 1.02; 95% CI, 0.78-1.32; *P* = .06 for noninferiority)
- Major bleeding events occurred in 11 of 1596 patients (0.7%) who received apixaban and in 22 of 1588 patients (1.4%) who received enoxaparin (difference in risk [95% CI], – 0.81%[ – 1.49 to 0.14%]; *P* = .05).
- Major + CRNM bleeding was reported in 46 of the 1596 patients who received apixaban (2.9%) and 68 of the 1588 patients who received enoxaparin (4.3%) (absolute difference in risk, -1.46%; 95% CI, – 2.75 to 0.17; *P* = .03).
- All bleeding was reported in 85 of the 1596 patients who received apixaban (5.3%) and 108 of the 1588 patients who received enoxaparin (6.8%) (absolute difference in risk, -1.52%; 95% CI, – 3.18 to 0.13; *P* = .08).

**ECONOMIC BURDEN**

Both stroke and bleeding are major events that may increase healthcare expenditure in NVAF. A Medicare claims study assessed the costs of stroke (ischemic or hemorrhagic) and major bleeding specifically in NVAF patients. Ischemic stroke, hemorrhagic stroke and major bleeding substantially increased incremental annualized medical costs ($34,201, $44,716, and $29,965, respectively), with major bleeding being the most common event (16% vs. 8% for ischemic stroke and 1% for hemorrhagic stroke) and hemorrhagic strokes producing the largest incremental annualized per person cost ($44,716). Main limitations of this study were: Medicare 5% sample did not contain prescription information, therefore warfarin exposure was inferred from claims for INR testing; aspirin or other therapies to prevent stroke or estimate the impact of medications that might interact with warfarin were also unavailable. Another weakness of this analysis is the lack of any measurement of the quality of anticoagulation and finally, only the first outcome of interest that occurred was considered in this study.

**PHARMACOECONOMICS**

**Medical Cost Avoidance Analyses:**

- A medical cost avoidance analysis, based on data from the RE-LY, ROCKET-AF and ARISTOTLE trials, evaluated the medical cost reductions associated with the use of each novel oral anticoagulant (dabigatran, rivaroxaban, and apixaban) instead of warfarin from the US payer perspective. The costs were adjusted to 2010 dollars. Acquisition costs of drugs and costs of monitoring were not included in the model. In a patient year, the medical cost reductions for dabigatran, rivaroxaban and apixaban vs. warfarin, were estimated to be -$179, -$89 and -$485, respectively. When clinical event rates and costs were varied simultaneously, medical cost reductions > $0 were associated with 92.6%, 79.8% and 100.0% of the 10,000 iterations tested in sensitivity analysis for dabigatran, rivaroxaban and apixaban vs. warfarin, respectively. Main limitations of this study were: not including INR monitoring and drug costs, long-term burden of events were not considered, when the relative risk was not reported in a trial, the relative risk of the endpoint containing the event was used instead, patient mortality was not included, although studies with similar design and patients populations were chosen, differences still exist between the trials.
- A medical cost avoidance analysis based on a real world setting, to estimate the difference in medical costs associated with use of apixaban instead of warfarin in real world NVAF patients. Patients with NVAF diagnosed during 2007–2010 from a Medco population of U.S. commercial and Medicare health plans with stroke and major bleeding excluding intracranial hemorrhage (MBEIH) were identified using diagnosis codes. To estimate the absolute risk reduction (ARR) between warfarin and apixaban in real world, the relative risk reductions (RRR) from ARISTOTLE were multiplied by the event rates observed in real world during warfarin exposure. Medical cost reductions associated with apixaban vs. warfarin were calculated by applying the ARR to the one-year incremental cost for each event. Stroke and MBEIH costs were obtained from the literature and adjusted to 2011 dollars. During a patient year, the use of apixaban instead of warfarin resulted in medical cost reductions of $493 for stroke and $752 for MBEIH and $1,245 for the combined outcome of both events. The medical costs avoided were greater as baseline stroke risk increased. Main limitations of this study were: identification of clinical events using administrative codes rather than confirmatory clinical data, inability to evaluate the level of international normalized ratio (INR) control, and not including INR monitoring and drug costs

**Cost Effectiveness Analyses:**

- Two cost-effectiveness analyses (CEAs) have compared apixaban with warfarin for the prevention of stroke, and systemic embolism in patients with NVAF. The analyses found that in primary prevention apixaban was the dominant strategy (less costly, more effective).

- For secondary prevention, apixaban was cost-effective. Apixaban provided an incremental cost-effectiveness ratio (ICER) of $11,400 per quality-adjusted life year (QALY).
- The only CEA to compare apixaban with aspirin found that apixaban was inferior at 1 year, cost-effective at approximately 3 years and dominant at 6 years.

**Questions and Answers**
Q: Are there any head to head studies vs. other oral anticoagulants indicated in DVT prophylaxis?
A: No.

Q: Is there any patient satisfaction data?
A: There is a survey that assessing patient's satisfaction with anticoagulant therapy.

**IX. Pfizer**
Tom Heard, PharmD, CGP, Associate Director, Medical Outcomes
Brian K. Gillespie, Account Manager

**Lyrica® (pregabalin)**
Pronunciation: LEER-i-kah) (pregabalin) (pre GAB a lin) Capsules, C-V

**Painful Diabetic Peripheral Neuropathy (pDPN)**
- *Pregabalin in Patients with Inadequately Treated Painful DPN Patients:* In a randomized, double-blind, placebo-controlled, withdrawal trial conducted to evaluate the efficacy of pregabalin in patients with painful DPN who were not adequately treated by other pharmacotherapy, from weeks 7-18 of the double-blind phase, the pain scores were significantly different for pregabalin versus placebo, however, at study endpoint (week 19), the mean difference in change from baseline using the last observation carried forward (LOCF) analysis (primary endpoint) for pregabalin compared with placebo was not statistically significant. However, when the primary analysis was repeated using a baseline observation carried forward (BOCF) analysis, the treatment difference for pregabalin compared with placebo was statistically significant.
- *Drug-Drug Interactions (DDI) and Drug-Condition Interactions (DCI) and Cost-Effectiveness in pDPN patients initiating either pregabalin or duloxetine:* A retrospective cohort study was performed to quantify the prevalence of potential DDI and DCI in pDPN patients initiating either pregabalin (N=2499) or duloxetine (N=1354). The cost effectiveness of each drug despite potential DDI/DCI was assessed as a secondary endpoint. Data were derived from inpatients medical, outpatient medical, and outpatient prescription administrative claims in the Truven Health MarketScan Commercial and Medicare Supplemental Databases. The primary endpoint was defined as the prevalence of potential DDI/DCI in painful DPN members newly initiating either pregabalin or duloxetine. There were 2% of pregabalin members with a potential pregabalin DDI/DCI compared to 71% of duloxetine members with a potential duloxetine DDI/DCI. Members initiating pregabalin, despite potential DDI/DCI, had significantly lower health care costs.
- *Burden of Illness Associated with Painful Diabetic Peripheral Neuropathy Among Adults Seeking Treatment in the U.S.: Results From a Retrospective Chart Review and Cross-sectional Survey:* This observational study recruited 112 subjects with pDPN during routine visits from general practitioner and specialist sites. Subjects completed a one-time questionnaire and investigators completed a case report form based on a 6-month retrospective chart review to capture clinical information, pDPN-related treatments, and other pDPN-related health care resource use over the past 6 months. Annualized costs were extrapolated based on reported 6-month health care resource use. Subjects with pDPN exhibited high pain levels, which were associated with poor sleep, function, and productivity. Health care resource utilization in pDPN was prevalent and costs increased with greater pain severity. The burden of pDPN was greater among subjects with greater pain severity. In total, 81.3% were prescribed at least one medication for their pDPN; 50.9% reported taking at least one nonprescription medication.

**Fibromyalgia (FM)**
- *Pregabalin in FM Pain in Patients Taking a Selective Serotonin Reuptake Inhibitor (SSRI) or serotonin norepinephrine reuptake inhibitor (SNRI) for Comorbid Depression:* In a 14-week, randomized, 2-way crossover, double-blind, placebo-controlled study in 197 patients with FM pain taking a SSRI or a SNRI for comorbid depression, pregabalin (300-450 mg/day) significantly reduced mean pain score (25% reduction) versus placebo (16% reduction) ($p<0.01$). A significant improvement in FM pain was maintained at each week through study endpoint in an analysis of data pooled across both crossover periods. Additionally, pregabalin significantly

improved function by 30% versus 20% compared to placebo as measured by the secondary endpoint on the FIQ ($p<0.0001$).

- *Estimating the Economic Benefits of Positive Shifts in FM Severity:* Data from 3 clinical trials of pregabalin in patients with FM were modeled; efficacy results were extrapolated. Mean annual costs (direct and indirect) were assigned based on FM severity levels. FM severity levels were defined using established cut-points on the Fibromyalgia Impact Questionnaire (FIQ). Mean annualized costs at end-point were estimated for all patients within each cohort and the mean differences in costs were compared using a regression model. The difference in mean annual costs was $2059 lower for pregabalin 450 mg ($p=0.003$) and $441 lower for pregabalin 300 mg ($p=0.52$). Improvements in FM severity were associated with overall reductions in cost. Reductions in indirect costs may offset the costs of treatment with pregabalin.

**Painful Diabetic Peripheral Neuropathy (pDPN), Peripheral Herpetic Neuralgia (PHN), and FM**

- *Impact of Step-Therapy (ST) Protocol for Pregabalin on Healthcare Utilization and Expenditures in a Commercial Population.* Retrospective study of outcomes associated with implementation of a pregabalin step-therapy protocol using claims data from Humana ('restricted' cohort) and Thomson Reuters MarketScan ('unrestricted' cohort). Members aged 18–65 years receiving treatment for pDPN, PHN, or FM during 2008 or 2009 were identified; cohorts were matched on diagnosis and geographic region. Baseline to follow-up changes in healthcare resource utilization and costs were determined using difference-in-differences (DID) analysis. Statistical models adjusting for covariates explored relationships between restricted access and outcomes. Implementation of a pregabalin step-therapy protocol resulted in lower pregabalin utilization, but this restriction was not associated with reductions in total healthcare costs, medical costs, or pharmacy costs. After adjusting for baseline compositional differences between cohorts, restricted plan membership was associated with a net increase in all-cause medical ($1222; $p = 0.016$) and disease-related healthcare costs ($859; $p = 0.002$).
- *Impact of a Pregabalin Step-Therapy policy Among Medicare Advantage Beneficiaries.* Pharmacy and medical claims data from Humana (restricted cohort; ST policy implemented 01/01/2009) and Thomson Reuters MarketScan_ (unrestricted cohort) were analyzed for Medicare Advantage Prescription Drug members aged 65 to 89 years receiving treatment for pDPN, PHN, or FM. DID was used to examine year-over-year changes in disease-related and all-cause utilization and costs. Regression analyses examined medication utilization and healthcare expenditures after controlling for between-group compositional differences. After controlling for differences in age and comorbidity burden between the groups, implementation of a pregabalin ST restriction was associated with increased disease-related pharmacy costs and decreased total medical costs; however, there was no net difference in total healthcare cost or total pharmacy cost.

**Questions and Answers**

Q: When does the patent expire?
A: 2019.

**Quillivant XR® (methylphenidate extended-release)**

Pronunciation: Brand: Quillivant XR (kwil-ə-vant), Generic: methylphenidate (METH il FEN i date)

**PRODUCT VALUE**

- Quillivant XR is intended to address the unmet need for an oral extended-release (ER) stimulant formulation that can be taken by patients who prefer a liquid dosage form. ER stimulant tablet and capsule formulations cannot be crushed. Those that can be sprinkled on applesauce or dissolved in water may be cumbersome to administer, rejected by patients who find that food does not mask the unpleasant taste or texture, and not completely consumed (thereby potentially resulting in exposure to less than the full prescribed dose).
- Quillivant XR is the first once-daily, ER oral suspension methylphenidate (MPH) formulation approved for the treatment of ADHD. This formulation contains approximately 20% immediate-release (IR) and 80% ER MPH, which contributes to rapid initial absorption of MPH followed by a continuous release and avoids the frequent peak and trough fluctuations seen with short-acting, IR stimulants. Importantly, Quillivant XR was specifically designed to have the desired features of both IR (rapid onset of effect) and ER (long duration of efficacy) as a liquid MPH formulation.

**INDICATIONS AND USAGE**

- Quillivant XR is a central nervous stimulant indicated for the treatment of ADHD. The efficacy of Quillivant XR was established in a 2-week, placebo-controlled trial in children aged 6 to 12 years with a diagnosis of ADHD. Patients in the trial met DSM-IV® criteria for ADHD. Accumulated efficacy data from other MPH products were also considered.

- Quillivant XR is a powder that, after reconstitution with water at the pharmacy, forms an ER oral suspension formulation of MPH HCl intended for once daily oral administration in the morning with or without food. After reconstitution, Quillivant XR is available in a 25 mg per 5 mL (5 mg per mL) ER oral suspension. The dose should be individualized according to the needs and responses of the patient. The recommended starting dose of Quillivant XR for patients 6 years and above is 20 mg once daily in the morning. The dose may be titrated weekly in increments of 10 mg to 20 mg. Daily doses above 60 mg have not been studied and are not recommended. Before administering the dose, vigorously shake the bottle of Quillivant XR for at least 10 seconds, to ensure that the proper dose is administered.

**PHARMACOKINETICS**
Two studies evaluated the pharmacokinetics (PKs) of Quillivant XR. One study was an open-label, randomized, crossover study in 28 healthy adults aged 18-68 years that compared the PKs of a single 60-mg dose of Quillivant XR administered at Hour 0 and IR liquid MPH (Methylin Oral Solution) administered as a 30-mg dose at Hour 0 and Hour 6. Under fasting conditions, *d*-MPH mean (± SD) peak plasma concentration occurred at a median time of 5.0 hours after Quillivant XR dosing. The relative bioavailability of Quillivant XR 60 mg dosed at Hour 0 compared to 30 mg IR liquid MPH dosed at Hour 0 and Hour 6 was 95%. The second study was an open-label, single-dose study of Quillivant XR in 14 children and adolescents with ADHD. The PKs of Quillivant XR were linear and dose proportional over the dose range studied. Mean drug concentrations were similar for the children and adolescent age groups after a 20 mg dose, but higher concentrations were observed for children than adolescents after a 60 mg dose. These differences appeared to be explained by body weight differences. When corrected for dose and body weight, mean $C_{max}$ and AUC values were similar among all age groups.

**CLINICAL EFFICACY AND SAFETY**
- The efficacy and safety of Quillivant XR was evaluated in a single, randomized, double-blind, placebo-controlled, crossover, multicenter, laboratory classroom study of 45 children aged 6 to 12 years with ADHD. Subjects completed an open-label dose optimization period (4 to 6 weeks) followed by a 2-week, double-blind, crossover treatment of the individually optimized dose of Quillivant XR (20-60 mg/day) or placebo. At the end of each week of the double-blind treatment phase, trained observers evaluated the attention and behavior of subjects in a laboratory classroom using the Swanson, Kotkin, Agler, M-Flynn and Pelham (SKAMP) rating scale. At 4 hours post-dose (primary efficacy endpoint), SKAMP-Combined scores were statistically significantly lower (i.e., more improved) during treatment with Quillivant XR than during treatment with placebo. Results indicated that Quillivant XR provided a rapid onset of effect (45 minutes) that was maintained throughout the entire 12-hour study period.
- Based on accumulated data from other MPH products, the most common (≥5% and twice the rate of placebo) adverse reactions are appetite decreased, insomnia, nausea, vomiting, dyspepsia, abdominal pain, weight decreased, anxiety, dizziness, irritability, affect lability, tachycardia, and blood pressure increased. Based on limited experience with Quillivant XR in controlled trials, the adverse reaction profile of Quillivant XR appears similar to those of other ER MPH products.

**Questions and Answers**
Q: What is the stability after pharmacist mixes?
A: 4 months and does not need to be refrigerated.

Q: What is the average dose?
A: 40 mg/day.

## X. Takeda

Faisal Riaz, MD, Senior Manager, Clinical Sciences and Health Outcomes
Jennifer Hooks, Regional Account Manager

**Brintellix® (vortioxetine)**

| | |
|---|---|
| Pronunciation | Brin'–tel–ix (vor–tee–OX–uh–teen) |
| Indication | Brintellix is indicated for the treatment of major depressive disorder (MDD) |
| Approved Doses | **5, 10, 15, and 20 mg immediate release tablets** |

| | |
|---|---|
| **Dosage and Administration** | Recommended starting dose is 10 mg once daily without regard to meals. Dose should then be increased to<br>20 mg/day, as tolerated. Consider 5 mg/day for patients who do not tolerate higher doses. Brintellix can be discontinued abruptly; however, it is recommended that doses of 15 or 20 mg/day be reduced to 10 mg/day for 1 week prior to full discontinuation if possible. Maximum recommended dose is 10 mg/day in known CYP2D6 poor metabolizers. Reduce dose by ½ in patients on concomitant strong CYP2D6 inhibitor. Consider increasing Brintellix dose when a strong CYP inducer is coadministered for > 14 days; maximum recommended dose should not exceed 3 times the original dose. No dose adjustment on the basis of age, race, gender, ethnicity, renal function, or mild to moderate hepatic impairment; not recommended in severe hepatic impairment. |
| **Safety** | Brintellix was evaluated for safety in 4746 patients aged 18-88 years with MDD in clinical studies; 2616 were exposed to Brintellix 5-20 mg/day in 6- to 8-week studies and 204 patients to 5-10 mg/day in a 24- to 64-week maintenance study. A total of 2586 patients were exposed to ≥ 1 dose in open-label studies; 1727 for 6 months and 885 for ≥ 1 year. Most commonly observed adverse reactions (incidence ≥ 5% and at least twice the rate of placebo) were nausea (frequency dose-related), constipation, and vomiting. Nausea was usually mild or moderate; median duration was 2 weeks. As measured by the Arizona Sexual Experiences Scale, the incidence of treatment emergent sexual dysfunction was 22-34% with Brintellix vs 20% with placebo in females, and 16-29% with Brintellix vs 14% with placebo in males. |

**Efficacy**

- Efficacy was established in six 6- to 8-week randomized, double-blind, placebo-controlled, fixed-dose studies (5 studies in adults aged 18-75 years [Table, Studies 1-5] and 1 study in elderly aged 64-88 years [Study 6]) and 1 maintenance study in adult inpatients and outpatients who met the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV-TR) criteria for MDD.
- Primary efficacy measures were Hamilton Depression Scale (HAMD-24) total score in Study 2 and 6 and Montgomery-Asberg Depression Rating Scale (MADRS) total score in all others. In each of these studies, ≥ 1 dose group of Brintellix was superior to placebo in improvement of depressive symptoms as measured by mean change from baseline to endpoint visit on the primary efficacy measurement. Two studies of 5 mg in the US failed to show effectiveness.
- The effect of Brintellix based on the primary efficacy measure was generally observed starting at week 2 and increased in subsequent weeks with the full antidepressant effect generally not seen until week 4 or later.
- In the 24- to 64-week maintenance study, patients in remission (MADRS total score ≤ 10; n = 396/639) after an initial 12 weeks of open-label Brintellix 5-10 mg (about 75% were on 10 mg/day) experienced a significantly longer time to recurrence of depressive episodes (MADRS total score ≥ 22 or lack of efficacy as judged by the investigator) than patients on placebo.

**Boxed Warning: Suicidal Thoughts and Behaviors**

Increased risk of suicidal thinking and behavior in children, adolescents, and young adults taking antidepressants; monitor for worsening and emergence of suicidal thoughts and behaviors; Brintellix has not been evaluated for use in pediatric patients.

**Contraindications, Warnings and Precautions**

- Do not use monoamine oxidase inhibitors (MAOIs) intended to treat psychiatric disorders with or within 21 days of stopping Brintellix. Do not use Brintellix within 14 days of stopping an MAOI intended to treat psychiatric disorders. Do not start in a patient being treated with linezolid or intravenous methylene blue.
- Serotonin syndrome can occur with Brintellix alone but especially during concomitant administration with other serotonergic agents. If such symptoms occur, discontinue Brintellix and initiate supportive treatment. If concomitant use, inform patients of a potential increased risk for serotonin syndrome, particularly during treatment initiation and dose increases.
- Treatment with serotonergic antidepressants may increase the risk of abnormal bleeding. Caution about the increased risk of bleeding when coadministered with NSAIDs, aspirin, or other drugs that affect coagulation.
- Activation of mania/hypomania can occur with antidepressant treatment. Screen patients for bipolar disorder.
- Hyponatremia can occur in association with the syndrome of inappropriate antidiuretic hormone secretion (SIADH).

**Questions and Answers**

Q: What are considered the advantages of Brintellix?

A: Efficacy and safety demonstrated in trials, works in elderly, works in patients that fail 1-2 therapies and good safety profile.

**XI. Jazz**

Parris Pope, PharmD, RPh, Medical Scientist
Kenneth Ley, MBA, Government Account Manager

**Versacloz® (clozapine oral suspension)**

Pronunciations: VER sa kloz, KLOE-za-peen.

*Background*

- The incidence of schizophrenia is about 0.3 per 1,000 people.
- There is a 2- to 3-fold increased risk of mortality in patients with schizophrenia, with suicide being a major cause of this excess mortality,2 and patients with schizophrenia have a shorter life expectancy than the general population.
- 10–30% of patients with schizophrenia have little or no response to treatment.
- Many patients fulfill the criteria for having treatment-resistant schizophrenia, defined by the American Psychiatric Association (APA) guidelines as little or no symptomatic response to at least 2 antipsychotic trials of at least 6 weeks with dosing in the therapeutic range.
- APA and PORT guidelines recommend treatment with clozapine for these treatment-resistant patients.

*Data related to VERSACLOZ*

- VERSACLOZ is bioequivalent to marketed clozapine tablets (eg, Clozaril) and is the first and only approved antipsychotic oral suspension indicated for treatment-resistant schizophrenia. Oral formulations have the following features:
    - Single vehicle formulation
    - Dosing flexibility by eliminating the use of different tablet strengths
    - Consistent dosing formulation and appearance over time for a patient population that is sensitive to change
- VERSACLOZ is indicated for the treatment of severely ill patients with schizophrenia who fail to respond adequately to standard antipsychotic treatment. Because of the significant risk of agranulocytosis and seizure associated with its use, VERSACLOZ should be used only in patients who have failed to respond adequately to standard antipsychotic treatment.
- In a prospective, single-blind trial of haloperidol (mean dosage, 61 ±14 mg/d) for 6 weeks, patients whose condition remained unimproved were then randomly assigned, in a double-blind manner, to clozapine (up to 900 mg/d) or chlorpromazine (up to 1800 mg/d) for 6 weeks
    - 286 patients were evaluated
    - 30% of clozapine-treated patients were categorized as treatment responders* vs 4% of chlorpromazine-treated patients
    - Clozapine demonstrated efficacy in patients with treatment-resistant schizophrenia on the Brief Psychiatric Rating and Clinical Global Impression Scales
- VERSACLOZ is also indicated for reducing the risk of recurrent suicidal behavior in patients with schizophrenia or schizoaffective disorder who are judged to be at chronic risk for re-experiencing suicidal behavior, based on history and recent clinical state.
- The effectiveness of clozapine in reducing the risk of recurrent suicidal behavior was assessed in a prospective, randomized, open-label, active-controlled, multicenter, international, parallel-group comparison of clozapine versus olanzapine in 956 patients with schizophrenia or schizoaffective disorder (DSM-IV) who were judged to be at risk of recurrent suicidal behavior.
    - During this study, fewer clozapine-treated patients attempted suicide (P=0.03), required hospitalizations (P=0.05) or rescue interventions (P=0.01), or required concomitant treatment with antidepressants (P=0.01) or anxiolytics/soporifics (P=0.03) when compared to olanzapine.
    - This result should be interpreted only as evidence of the effectiveness of clozapine in delaying time to recurrent suicidal behavior and not a demonstration of the superior efficacy of clozapine over olanzapine
- The most commonly reported adverse reactions (≥5%) across clozapine clinical trials were: CNS reactions (sedation, dizziness/vertigo, headache, and tremor); cardiovascular reactions (tachycardia, hypotension, and

syncope); autonomic nervous system reactions (hypersalivation, sweating, dry mouth, and visual disturbances); gastrointestinal reactions (constipation and nausea); and fever.
- Because of the risk of agranulocytosis, VERSACLOZ is available only through a restricted program called the VERSACLOZ Patient Registry. Prescribers, patients, pharmacies, and distributors must enroll in the program at www.versaclozregistry.com.
- The full prescribing information for VERSACLOZ contains a BOXED warning regarding agranulocytosis; orthostatic hypotension, bradycardia and syncope; seizure; myocarditis and cardiomyopathy; and increased mortality in elderly patients with dementia-related psychosis

*Treatment response was predefined as a decrease in BPRS score of at least 20% and either (1) a CGI-S score of ≤ 3 (mildly ill), or (2) a BPRS score of ≤ 35, at the end of 6 weeks of treatment.

**Questions and Answers**
Q: What are considered the advantages of Versacloz over the sublingual tablets?
A: Versatility of dosing, improved taste and can assist patients having difficulty swallowing.

## XII. GlaxoSmithKline

Brian Streng, PharmD, MBA, Scientific Account Liaison
Vivian Lee Ryan, Regional Account Manager

**Breo Ellipta® (fluticasone furoate/vilanterol)**
Pronunciation: (BREE-oh ee-LIP-ta) (floo-TIK-a-sone FURE-oh-ate / vye-LAN-ter-ol)

**INDICATION**
- Breo® Ellipta® is a combination ICS/LABA indicated for the long-term, once-daily, maintenance treatment of airflow obstruction in patients with COPD, including chronic bronchitis and/or emphysema. Breo® Ellipta® is also indicated to reduce exacerbations of COPD in patients with a history of exacerbations.
- Important Limitations of Use: Breo® Ellipta® is NOT indicated for the relief of acute bronchospasmor for the treatment of asthma.

**EFFICACY DATA**
- Two24–week, randomized, double-blind, placebo-controlled trials (N=2,254) assessed different strengths of fluticasone furoate/vilanterol (FF/VI) in improving lung function as measured by weighted mean forced expiratory volume in one second (FEV ) (0-4 hour) on day 168 and change from baseline in trough FEV on day 169.
- In the first trial the FF/VI doses tested were 100/25 mcg and 200/25 mcg. The difference in the weighted mean FEV1 (0-4 hours) between FF/VI 100/25 mcg and placebo was 214 mL (95% CI: 161, 266) and between FF/VI 100/25 mcg and FF 100 mcg was 168 mL (95% CI: 116, 220). The difference between FF/VI 100/25 mcg and VI 25 mcg for the change from baseline in trough FEV1 was 45 mL (95% CI: -8, 97). In this trial, the statistical significance of the primary endpoints for FF/VI 100/25 mcg could not be inferred because of the pre-specified statistical hierarchy that was imposed to account for the multiple statistical tests that were conducted across treatment comparisons and endpoints.
- In the second trial, the FF/VI doses tested were 100/25 mcg and 50/25 mcg. FF/VI 100/25 mcg significantly improved weighted mean FEV1 (0-4 hours) compared to placebo (difference of 173 mL [95% CI: 123, 224 mL], P < 0.001) and compared with FF 100 mcg (difference of 120 ml [95% CI: 70, 170], P < 0.001); however no significant difference was seen between FF/VI 100/25 mcg and VI 25 mcg in trough FEV1 (48 mL [95% CI: -6, 102 mL], P = 0.082).
- Two 52–week, randomized, double-blind, controlled trials assessed the efficacy of 3 different strengths of FF/VI (50/25 mcg, 100/25 mcg, and 200/25 mcg) measured by the annual rate of moderate/severe exacerbations in 3,255 patients with COPD.4 The difference in annual rate of moderate/severe exacerbations in FF/VI 100/25 mcg compared to VI 25 mcg was statistically significant in the first trial (21% reduction, [95% CI: 3, 36], P =0.024), but statistical significance in the second trial (34% reduction [95% CI: 19, 46]) could not be inferred because of the pre-specified statistical hierarchy that was imposed to account for the multiple statistical tests that were conducted across treatment comparisons and endpoints.
- The most common adverse reactions (≥3% and more common than placebo) reported in two 6-month clinical trials with Breo® Ellipta® (and placebo) were nasopharyngitis, 9% (8%); upper respiratory tract infection, 7% (3%); headache, 7% (5%); and oral candidiasis, 5% (2%).

**COMPARATIVE EFFICACY DATA WITH Advair Diskus® (FLUTICASONEPROPIONATE/SALMETEROL) IN COPD**

- Four randomized clinical studies (HZC113109,HZC112352,RLV116974andHZC113107) evaluated the FEV1 of FF/VI once daily compared with fluticasone propionate/salmeterol (FP/SAL) powder twice daily over a 12-week treatment period in patients with COPD. Three replicate studies compared FF/VI 100/25 to FP/SAL 250/50 mcg (Studies HZC113109, HZC112352 and RLV116974)5-7, and a fourth study compared FF/VI 100/25 to FP/SAL 500/50 mcg (StudyHZC113107).
- In replicate studies HZC113109, HZC112352 and RLV116974, FF/VI 100/25 given once daily in the morning was compared to FP/SAL 250/50 mcg given twice daily.5-7 In studyHZC113109 FF/VI 100/25 once daily demonstrated a statistically significant greater improvement in the primary endpoint, 24–hour weighted mean FEV1, at 12 weeks compared to FP/SAL 250/50 mcg twice daily. There was no statistically significant difference in the primary endpoint between FF/VI 100/25 and FP/SAL 250/50 mcg in studies HZC112352 or RLV116974.
- StudyHZC113107 compared treatment with FF/VI 100/25 once daily and FP/SAL 500/50 mcg twice daily. The results did not show a statistically significant improvement in 24-hour weighted-mean FEV1 between the treatment groups.
- Headache was the most common adverse event (AE) observed with either FF/VI 100/25 (5%to 6%) or FP/SAL 250/50 mcg (4%) during studies HZC113109 and HZC112352. Nasopharyngitis was the most common AE reported during study RLV116974 (FF/VI 100/25 7%; FP/SAL 250/50 mcg 6%). Other commonly reported AEs reported for either FF/VI 100/25 or FP/SAL 250/50 mcg during all three studies were oral or oropharyngeal candidiasis, cough, pyrexia, back pain, and muscle spasm, each of which occurred in no more 3% of patients in either treatment group. In study HZC113107, the most common on-treatment AEs were (FF/VI 100/25, FP/SAL500/50): headache (8%, 7%), back pain (4%, 1%), nasopharyngitis (3%, 5%), cough (1%, 3%), and oral candidiasis (<1%, 2%).

**Questions and Answers**

Q: What is the difference in the Ellipta inhaler?
A: The inhaler counts and turns red when patient needs to refill.

Q: When does Advair patent expire?
A: 2016.

Q: What is the place in therapy?
A: Fits in GOLD COPD guidelines for patients that need ICS/LABA.

Q: What are considered the advantages of Breo Ellipta?
A: Once daily dosing, improved device, improved FEV vs. Advair and vilanterol alone.

Q: Is there any adherence data?
A: Real-world data is being examined.

Q: Is an asthma indication being sought?
A: Have not yet filed but there is an active program investigating use in asthma.

## XIII. Teva

Contessa Fincher, PhD, MPH, Medical Science Liaison

**Granix® (tbo-filgrastim)**

Pronunciation: tbo fil-**gras**-tim

GRANIX or tbo-filgrastim was approved in 2012 by the FDA and is a short-acting granulocyte colony stimulating factor or G-CSF indicated for reducing the duration of severe neutropenia in patients with nonmyeloid malignancies who are receiving myelosuppressive anticancer drugs associated with a clinically significant incidence of febrile neutropenia.

GRANIX is a nonglycosylated methionyl human G-CSF manufactured by recombinant DNA technology in *E. coli*. GRANIX is supplied as a pre-filled syringe for subcutaneous injection and should be administered by a healthcare professional. GRANIX binds to G-CSF receptors and stimulates the proliferation of neutrophils. G-CSF is known to stimulate differentiation, commitment, and some end cell activation which increases neutrophil counts and activity.

The primary concern for patients with cancer and severe chemotherapy-induced neutropenia is the increased risk of potentially fatal infections. The degree and duration of neutropenia determines the risk of infection. A 2004 study by Crawford et al. found that an ANC nadir <1.0x$10^9$/L is associated with a 30% risk of serious infection if neutropenia lasts 2 weeks and 45% chance of serious infection if neutropenia lasts 3 weeks. The typical mortality rate associated with episodes of febrile neutropenia in various studies has ranged from 5% to 13.7%, although the risk may approach or exceed 50% in some high-risk populations. Therefore, current oncology guidelines published by the major oncology organizations throughout the world consistently advocate for routine G-CSF support in patients with solid tumors and lymphoma in whom the risk of neutropenia is ≥20%.

The efficacy and safety of GRANIX was evaluated in 3 phase 3 head-to-head randomized, controlled, clinical studies comparing tbo-filgrastim and a non-US-approved filgrastim product as controls. Efficacy endpoints assessed in the clinical trials included the duration of severe neutropenia, defined as the number of days with Grade 4 neutropenia; incidence of febrile neutropenia, defined as body temperature of >38.5°C for >1 hour and ANC<0.5x$10^9$/L, both measured on the same day; and incidence of protocol-defined febrile neutropenia, defined as the administration of systemic antibiotics.

Trial 1 compared the efficacy and safety of GRANIX, filgrastim, and placebo in 348 patients with breast cancer. Patients randomized to placebo in cycle 1 were switched to GRANIX for subsequent cycles. The primary endpoint was the duration of severe neutropenia in cycle 1, defined as the number of days with grade 4 neutropenia with an ANC <0.5 x $10^9$/L. Trial 1, authored by del Giglio et al, is the clinical trial that supported the FDA-approved label. Additional clinical trials, Trials 2 and 3, were conducted that support the published evidence base for clinical trial experience of tbo-filgrastim.

Trial 2 compared the safety and efficacy of GRANIX and filgrastim in 240 patients receiving platinum-based chemotherapy for lung cancer. Those patients randomized to filgrastim in cycle 1 switched to GRANIX in subsequent cycles. The primary aim of the study was to demonstrate safety and efficacy of tbo-filgrastim when administered for up to a maximum of 6 chemotherapy cycles in patients with lung cancer.

Trial 3 compared the safety and efficacy of GRANIX and filgrastim in 92 patients with non-Hodgkin's lymphoma. Again those patients randomized to filgrastim in cycle 1 were switched to GRANIX in subsequent cycles.[12] The primary aim of this study was to demonstrate the safety and efficacy of tbo-filgrastim when administered for up to 6 chemotherapy cycles in patients with NHL.

GRANIX demonstrated superiority over placebo in trial 1, cycle 1 for duration of severe neutropenia and incidence of febrile neutropenia while demonstrating non-inferiority of GRANIX and filgrastim for cycle 1 which was the primary endpoint of the study. Additional non-inferiority was established for additionally evaluated efficacy endpoints assessed across the 3 phase 3 studies including the duration of severe neutropenia and incidence of febrile neutropenia.

The most common adverse reaction attributed to study drug in controlled clinical studies of GRANIX was bone pain. Warnings and precautions include splenic rupture, acute respiratory distress syndrome, allergic reactions, use in patients with sickle cell disease, and potential for tumor growth stimulatory effects on malignant cells. All warnings and precautions associated with tbo-filgrastim have previously been identified and experienced with the utilization of short-acting GCSF agents.

**Questions and Answers**
Q: Is Granix considered a biosimilar to Neupogen?
A: No, was not approved by the FDA as a biosimilar.

Q: Will Teva seek additional indications?
A: Most likely not.

Q: What are considered the advantages of Granix compared to Neupogen?
A: Can be out of refrigerated for 5 days vs. 3 days with Neupogen and lower WAC pricing than Neupogen.

Q: Who can administer?
A: Any healthcare practitioner.

Q: Is the distribution limited?

A: No.

## XIV. Supernus

Welton O'Neil, Jr, PharmD, Senior Director, Medical Affairs
Adriana Sanchez, Director of Corporate Accounts

**Oxtellar XR® (oxcarbazepine extended-release)**

- **Oxtellar XR®** (ahks-TEH-lahr eks ahr) is a novel once-daily extended-release formulation of oxcarbazepine (ox car baz˙ e peen) for adjunctive treatment of partial-onset seizures in adults and children 6 to 17 years of age.
- Oxcarbazepine immediate-release (Trileptal® OXC-IR) has limited tolerance and adherence, limiting the maximum effective dose.
- In a steady-state crossover study in healthy volunteers (Oxtellar XR 1200mg daily vs. OXC-IR 1200mg given as 600mg twice daily), AUC was ~ 19% lower and Cmin ~16% lower on Oxtellar XR compared to OXC-IR. These products are **not bioequivalent.**
- A randomized crossover study showed very few AEs on Oxtellar XR (using Solutrol®, Supernus' novel proprietary technology) vs. OXC-IR.
- Oxtellar XR AUC and Cmax are lower, adverse event frequency is impressively low, while overall efficacy in the phase 3 pivotal trial (PROSPER) was robust, well within the range observed with other oxcarbazepine products.
- Efficacy and safety of Oxtellar XR were established in the pivotal trial (PROSPER).
  - The median percent reductions in seizure frequency, (primary endpoint):
    - 29% (placebo)
    - 38% (Oxtellar XR 1200mg)
    - 43% (Oxtellar XR 2400mg, statistically significant)
- Responder rates (50% or more seizure frequency reduction) :
    - 28% (placebo)
    - 36% (Oxtellar XR 1200mg)
    - 41% (Oxtellar XR 2400mg)
- Seizure free rates:
    - 3% (placebo)
    - 5% (Oxtellar XR 1200mg)
    - 11% (Oxtellar XR 2400mg, statistically significant, one of the highest rates observed)
- In the North American cohort analysis, median percent seizure reductions were:
    - 13% (placebo)
    - 35% (Oxtellar XR 1200mg, statistically significant)
    - 53% (Oxtellar XR 2400mg, statistically significant)
- Approval of the 1200 mg dose by the FDA was reached through: 1) concentration-response Cmin breakpoint analysis (10 mcg/ml) showing 66% of patients receiving 1200mg daily above 10 mcg/ml, 2) FDA analysis of the exposure-response of OXC-IR vs. OXC-XR showed similar slopes, 3) NA cohort analysis5
- There are no head-to-head clinical trials comparing Oxtellar XR to OXC-IR. While no direct comparisons can be made, however:
    - The primary efficacy endpoints in both pivotal trials appear to be similar
    - The tolerability profiles differ:
      - Discontinuations due to AEs in the OXC-IR pivotal trial:
        - 9% (placebo)
        - 36% (1200mg per day/600mg bid)
        - 67% (2400mg per day/1200mg bid)
      - Discontinuations due to AEs in the Oxtellar XR pivotal trial:
        - 12% (placebo)
        - 16% (1200mg daily)
        - 30% (2400mg daily)

**SUMMARY**

- Oxtellar XR is the first and only FDA-approved, once daily extended-release formulation of oxcarbazepine
- Pivotal study confirmed efficacy:
    - Reduced seizure frequency, improved responder rate, and a very high rate of seizure freedom
- Oxtellar XR therapy:

    - Provides a smoother PK profile with once-daily dosing
    - Consistent plasma levels over 24 hours
    - Allows effective use of higher doses of OXC
    - Once-daily dosing with 3 available dosage strengths
- In conclusion, we respectfully request the Georgia Medicaid P&T Committee to consider removing the current PA requirement for Oxtellar XR and include it as a Non-Preferred product on the GA Medicaid Drug List.

**Trokendi XR® (topiramate extended-release)**

- Trokendi XR™ (tro-Ken-dee eks ahr) is a novel once-daily extended-release formulation of topiramate (toe pyreˈa mate) approved for the treatment of epilepsy without a phase 3 trial (see basis for FDA approval below)
- Indicated for initial monotherapy in partial onset or primary generalized tonic-clonic seizures 10 years and older; adjunctive therapy in partial onset or primary generalized tonic-clonic seizures 6 years and older; adjunctive therapy in Lennox-Gastaut Syndrome 6 years and older.
- The goal for Trokendi XR was once-daily bioequivalence to topiramate immediate-release (TPM-IR, Topamax®) with improved tolerability and adherence.
- Simplified dosing and improved tolerability of once-daily Trokendi XR may facilitate patient adherence and may also positively impact health and economic outcomes.
- Topiramate immediate-release is a highly effective broad spectrum antiepileptic drug with poor tolerability:
    - Associated with a distinctive profile of negative neurocognitive effects including word-finding difficulty, mental slowing and confusion / difficulty thinking / disorientation
    - Negative cognitive effects may be sensitive to dose, plasma concentrations, and rate of input Dose-management strategies help improve topiramate tolerability for many patients
    - Clinical usefulness of TPM-IR remains limited by intolerable cognitive effects, even at low doses
- The basis for FDA approval of Trokendi XR included:
    - Pharmacokinetic data proving **bioequivalence** between once-daily Trokendi XR (using Microtrol®, Supernus' novel technology ) and twice-daily TPM-IR (Topamax) over 24 hours
    - Safety and efficacy data from studies previously conducted with TPM-IR
    - Drug safety and pharmacokinetic data generated in patients with epilepsy
    - Direct safety and efficacy evaluations of Trokendi XR were not required
    - While bioequivalent at steady state, Trokendi XR has a slower absorption profile (Tmax 6 hrs v. 1 hr) and a 35% lower peak-to-trough fluctuation (FL: Trokendi XR 26% v. Topamax 40%)
    - Trokendi XR produced fewer cognitive deficits than TPM-IR (single blind healthy volunteer study), as measured by the Controlled Oral Word Association (COWA) test of verbal fluency
    - In subjects completing both treatment arms of Trokendi XR vs Topamax, COWA change scores significantly favored Trokendi XR over the entire treatment period and at the 100mg/day dosage
    - Bioequivalence allows patients with epilepsy on TPM-IR to be converted mg-to-mg overnight to once-daily Trokendi XR
    - Switching TPM-IR twice daily to Trokendi XR once daily at identical dosages showed no deterioration of seizure control
    - 93% of patients with epilepsy surveyed in a crossover study preferred Trokendi XR over TPM-IR, and 92% believed once-daily dosing facilitated adherence
    - Population pharmacokinetic dosing simulations show Trokendi XR offers the convenience of once-daily dosing without increasing patient risk from missed, delayed, or doubled doses relative to twice-daily TPM IR 13
    - Dose recommendations for Trokendi XR in elderly patients are the same for TPM-IR: adjusted for renal function status (one-half the adult dose if CrCl <70mL/min/1.73m2)

**SUMMARY:**

- Trokendi XR is the first FDA-approved once-daily extended-release formulation of topiramate indicated for the full spectrum of epilepsy
- Trokendi XR :
    - Bioequivalent to twice-daily Topamax
    - Reduces cognitive impairment (COWA test of verbal fluency)
    - Once-daily dosing with 4 available dosage strengths
- Converting to Trokendi XR from twice-daily Topamax:
    - Proceed with mg-to-mg overnight conversion
    - Patients on Trokendi XR indicate that once-daily dosing increases their adherence

- In conclusion, we respectfully request the Georgia Medicaid P&T Committee to consider removing the current PA requirement for Oxtellar XR and include it as a Non-Preferred product on the GA Medicaid Drug List.

**Questions and Answers**
Q: Have adherence studies been conducted?
A: Studies are ongoing and data may be available at the end of 2014.

Q: How are other Medicaid plans covering these agents?
A: Some states do not manage the class, some states manage with PA

Q: Are other indications being sought?
A: Not at this time.

## XV. Otsuka

Kelly Stein-Marcus, PhD, Senior Medical Science Liaison
Dianna Sedgwick, CMR, Senior Account Executive

**Abilify Maintena® (aripiprazole long-acting injection)**

**Introduction**
- Abilify Maintena indication: for treatment of schizophrenia. Efficacy was demonstrated in a placebo-controlled, randomized-withdrawal maintenance trial in patients with schizophrenia and additional support for efficacy was derived from oral aripiprazole trials.
- Boxed Warning: Increased mortality in elderly patients with dementia-related psychosis

**Study Reference**
Kane JM, Sanchez R, Zhao J, Duca AR, Johnson BR, McQuade RD, Eramo A, Baker RA, Peters-Strickland T. Hospitalization rates in patients switched from oral anti-psychotics to aripiprazole once-monthly for the management of schizophrenia. J Med Econ. 2013;16(7):917-925.

**Objective**
To assess total psychiatric hospitalization rates in patients diagnosed with schizophrenia previously treated with oral standard-of-care (SOC) antipsychotics, before and after prospective treatment with aripiprazole once monthly, using a mirror-image study design.

**Methods**
- Patients: included aged 18-65 years with current diagnosis of schizophrenia; ≥1 psychiatric hospitalization within 48 months but managed as outpatients for 4 weeks prior to signed consent
- Study Design: Phase IIIb, multicenter, open-label, mirror-image study to assess hospitalization rates in patients with schizophrenia treated retrospectively with oral SOC antipsychotics (6 months) followed by prospective treatment with aripiprazole once-monthly (6 months) in a naturalistic community setting in North America
    - Prospective arms included oral conversion to aripiprazole (Phase A) followed by 24-week, open label treatment with 400mg IM aripiprazole once-monthly (Phase B)
- Outcomes Measures
    - Total psychiatric hospitalization rates were assessed between the retrospective oral SOC treatment period (Months –4 to –1) and the prospective aripiprazole once-monthly treatment period (Months 4 to 6) in patients treated with aripiprazole once-monthly for ≥3 months during Phase B
    - Total psychiatric hospitalization rates were also assessed between the retrospective SOC period (Months –6 to –1) and the prospective aripiprazole once-monthly treatment period (Months 1 to 6) for all patients entering Phase B
    - Safety and tolerability were also assessed
- Statistical Analysis: Differences in total psychiatric hospitalization rates in the retrospective and prospective periods in this preliminary analysis were assessed using a statistical test of significance at alpha level 0.0148

**Results**
- 183 patients entered prospective phase
- After switching to aripiprazole once monthly, total psychiatric hospitalization rates for the 3-month prospective

period were significantly lower (p<0.0001, Exact McNemar's test) compared with the retrospective 3-month period when the same patients received SOC anti-psychotics (6.6% [n=8/121] vs 28.1% [n=34/121]
- Total psychiatric hospitalization rates for all patients who entered the prospective treatment phase were significantly lower (p<0.0001, Exact McNemar's test) for the prospective 6 months following switch to aripiprazole once-monthly, compared with the retrospective 6-month SOC period (14.2% [n=26/183] vs 41.5% [n=76/183]), respectively; rate ratio=0.34)
- The most common treatment-emergent adverse events (occurring in ≥5% of patients) were psychotic disorder (7.7%), akathesia (7.2%), insomnia (7.2%), paranoid schizophrenia (5.5%), back pain (5%), and schizophrenia (5%).
- Discontinuation (all causes) during the prospective phase was 44.8% (n=82/183)

**Questions and Answers**
Q: What are considered the advantages of Ability Maintena?
A: No prolaction elevation warning, every 4 week dosing, not in oil base so easier to absorb and decreased injection

**XVI. Eisai**
Kimberly Phelps-Webber, PharmD, Medical Science Liaison
Tony Lanza, MD, Regional Account Manager
Anthony Duca, National Account Manager

**Fycompa™ (perampanel)**
Pronunciation: FYCOMPA (fy-COMP-uh), generic name - perampanel (per-AM-pan-el)

FYCOMPA (perampanel) is a noncompetitive AMPA-type glutamate receptor antagonist indicated as adjunctive therapy for the treatment of partial onset seizures with or without secondarily generalized seizures in patients with epilepsy aged 12 years and older. FYCOMPA was FDA approved in October 2012 and will be available following DEA scheduling. Eisai recommends FYCOMPA be available to beneficiaries with Preferred Drug status in the Georgia Medicaid program as it helps address an unmet need in partial onset seizures.

Epilepsy is the fourth most common neurological disorder in the US. Epilepsy and seizures affect 2 to almost 3 million Americans, regardless of age. The estimated annual cost of epilepsy and seizures is $17.6 billion in direct and indirect costs. A retrospective claims database analysis showed that non-epilepsy related healthcare resource utilization and medical costs dominated healthcare resource utilization costs and direct medical costs in Medicaid patients with epilepsy, indicating that substantial comorbidities are associated with epilepsy patients in the Medicaid population.

Patients with uncontrolled epilepsy have been shown to utilize more healthcare services and have higher healthcare costs compared to epilepsy patients on a stable AED regimen. Uncontrolled epilepsy patients, on average, have significantly more chronic conditions compared to stable patients ($p < 0.001$) and a significantly higher proportion of uncontrolled patients have a head injury, brain tumor, cerebrovascular disease/stroke, and depression and other mood disorders than stable patients ($p < 0.02$).

FYCOMPA was evaluated in 3 phase III clinical trials. Patients in these studies included those with partial onset seizures with or without secondary generalization and whose seizures were uncontrolled despite receiving 1-3 other AEDs.
- FYCOMPA 4-12mg significantly reduced partial onset seizure frequency in refractory patients as measured by the percent reduction in seizure frequency per 28 days.
- Up to 35% of patients achieved a greater than or equal to 50% reduction in seizure frequency.
- FYCOMPA was shown to be clinically effective across patient subpopulations, regardless of age, sex, or race.

FYCOMPA is approved and currently available in several countries in Europe. Also, more than 1600 patients have received FYCOMPA across multiple epilepsy clinical trials, where it demonstrated high retention rates.

In Phase 3 clinical trials, the most common adverse reactions in patients receiving FYCOMPA at doses of 8 or 12 mg (greater than or equal to 4% and occurring at least 1% higher than the placebo group) were dizziness, somnolence, fatigue, irritability, falls, nausea, weight gain, vertigo, ataxia, gait disturbance, and balance disorder.

**FYCOMPA has a boxed warning to alert prescribers and patients about the risk of serious and life-threatening neuropsychiatric events, including irritability, aggression, homicidal ideation and hostility**. Violent thoughts or threatening behavior were also observed in a few patients. These events occurred in patients with or without prior psychiatric history, prior aggressive behavior, or concomitant use of medications associated with hostility or aggression. Patients should be monitored for these reactions as well as for changes in mood, behavior, or personality that are not typical for the patient, particularly during the titration period and at higher doses. FYCOMPA should be reduced if these symptoms occur and should be discontinued immediately if symptoms are severe or are worsening.

FYCOMPA is dosed as a single tablet once-daily at bedtime and there are multiple dosage strengths available

- FYCOMPA is initiated at 2 mg once daily at bedtime in patients not on enzyme-inducing AEDs and 4 mg in patients on enzyme inducing AEDs.
- The dose may be increased based on clinical response and tolerability by a maximum of 2 mg once daily at bedtime in weekly increments to a dose of 4 mg to 12 mg once daily at bedtime. Dose increases should occur no more frequently than at weekly intervals.
- Dosage considerations and adjustments are recommended in specific populations.
- Available dosage strengths include 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, and 12 mg tablets.

In summary, upon final DEA scheduling, FYCOMPA will provide Payers, Providers and Patients with a new FDA-approved option for adjunctive treatment of partial onset seizures. FYCOMPA has multiple dosage strengths available and is orally administered once daily as a single tablet. Therefore, Eisai recommends FYCOMPA receive Preferred Status in the Georgia Medicaid program.

**Questions and Answers**
Q: How are other Medicaid plans covering?
A: At parity to other brand AEDs.

Q: What are considered the advantages of Fycompa?
A: Once daily dosing, favorable efficacy and safety, use in partial and complex seizures and novel mechanism of action.

**XVII.** Meda
John Karafilidis, PharmD, Senior Director, Medical Affairs
Amy Mitchell, RN, BSN, Healthcare Sales Consultant
Stephen Curry, Senior National Account Manager

**Aerospan® (flunisolide inhalation aerosol)**
BENEFITS OF AEROSPAN IN ASTHMA

- AEROSPAN Inhalation Aerosol contains the potent corticosteroid flunisolide that helps to reduce inflammation in the airways, the underlying cause of asthma
- AEROSPAN is an inhaled corticosteroid indicated for Maintenance treatment of asthma as prophylactic therapy in adult and pediatric patients 6 years of age and older
- AEROSPAN is approved for use in children 6 years of age and older with asthma.
- AEROSPAN is also indicated for patients requiring oral corticosteroid therapy for asthma. Many of these patients may be able to reduce or eliminate their requirement for oral corticosteroids over time.
- AEROSPAN™ is an HFA (hydrofluoroalkane) formulation of flunisolide, and is available as a pressurized, metered dose aerosol unit for oral inhalation that delivers 80 mcg per actuation.
- AEROSPAN is fitted with an integrated spacer that improves lung deposition, and reduces oral deposition
- AEROSPAN has 68.3% lung deposition, the highest of any inhaled product.
- AEROSPAN has an extrafine particle size, with a MMAD (mass median aerodynamic diameter) of 1.2 µm.
- AEROSPAN is dosed at one-third that required for flunisolide CFC.
    - In a 12-week, double-blind, active and placebo controlled trial in mild to moderate adults and adolescents 12 years of age and over, the 160 mcg BID and 320 mcg BID doses of AEROSPAN™ resulted in a significant improvement in lung function vs placebo (*P*<.01); efficacy of the 160 and 320 mcg BID doses were comparable to the 500 and 1000 mcg BID doses of flunisolide CFC;
    - In a 12-week, double-blind, active and placebo controlled trial in mild to moderate pediatric asthmatics 4 to 11, the following increases in percent predicted FEV1 were reported: 10.7% with flunisolide HFA 80 µg

bid (*P*=.008) and 10.1% with flunisolide HFA 160 µg BID (*P*=.018) when compared with placebo (3.37% change in $FEV_1$); efficacy with flunisolide HFA was comparable to 250 and 500 mcg BID doses of flunisolide CFC

- AEROSPAN has the shortest serum half-life (1.3 – 1.7 hours) and lowest volume of distribution of any inhaled steroid, which allows for rapid clearance of the drug from the systemic circulation.
- AEROSPAN does not cause cortisol suppression at approved doses.
- With other ICS agents, changes in growth velocity of -0.3 cm/year to -1.8 cm/year have been reported. AEROSPAN has been demonstrated in a long term (52-week), double-blind study of 242 children with asthma to not have an effect on growth velocity. Specifically, changes in growth velocity of -0.17 cm/year were seen versus placebo. This lack of growth effects is also supported by an open-label one-year study in 250 pediatric asthmatics.

**Questions and Answers**
Q: What are considered the advantages of Aerospan?
A: Only inhaler with built in spacer, small particle size, high lung deposition, efficacy in chronic asthma at 1/3 the dose of CFC flunisolide and favorable safety such as low rates of oral candidiasis, no significant effect on HPA-axis function and no significant effect on growth in children.

**XVIII. Iroko**
Alan Rosenthal, PharmD, Regional Director, Medical Affairs

**Zorvolex® (diclofenac)**
ZORVOLEX® (ZOR-vo-lex) diclofenac (dye-KLOE-fen-ak) capsules was approved by the FDA on October 18, 2013 for the treatment of mild to moderate acute pain in adults.

NSAIDs have long been recognized as an effective treatment for acute pain. NSAIDs are also associated with the potential for serious gastrointestinal, cardiovascular and renal adverse events. Large observational studies and meta-analyses have found that these risks are dose dependent and associated with both short and long term use.

These risks are of particular concern for the Medicaid population, who, according to a survey conducted by the CDC, have increased incidence of heart disease and report poorer health than the general population.

ZORVOLEX is the first NSAID to potentially address all of these dose-related serious AEs. ZORVOLEX utilizes SoluMatrix Fine Particle Technology™ that reduces the particle size, increasing the surface area and altering the pharmacokinetics of the drug. Compared to commercially available diclofenac IR 50 mg, ZORVOLEX 35 mg provides a 23% lower overall systemic exposure while still attaining similar time to peak drug plasma concentrations, and without the delay you might expect if you reduced the dose of a traditional NSAID. The 18 mg capsules of ZORVOLEX provide a 62% lower systemic exposure.

ZORVOLEX was approved by the FDA for the treatment of mild to moderate acute pain in adults based on a Phase III pivotal trial using a bunionectomy acute pain model. The 48 hour multi-dose study included 428 subjects, who were randomized to one of four treatment arms; ZORVOLEX 35mg three times daily, ZORVOLEX 18mg three times daily, placebo, and Celecoxib (400 mg loading dose followed by 200 mg twice daily).

Both, ZORVOLEX 35 mg and 18 mg dosed three times a day met the primary objective of a statistically significant increase in the Summed Pain Intensity Difference over 48 hours when compared to placebo. The study was not statistically powered to compare between active treatment groups; however, the celecoxib active control arm was numerically similar to Zorvolex 18mg three times daily. Opioid rescue medication was required by 15% fewer subjects in the ZORVOLEX 35 mg arm compared to the placebo group and, those who did use rescue medication, required on average 50% fewer rescue medication doses than those in the placebo arm.

There were no unusual adverse events noted and the most common AEs observed more often in ZORVOLEX patients were edema (or swelling), constipation, and pruritus (or itching) and were not statistically different from the placebo group.

An analytic model compared relative risks of GI, CV and renal serious adverse events to specific doses of diclofenac and was used to project the reduction in risk that might be seen with a dose reduction. The results demonstrated a consistent linear relationship between diclofenac daily dose and the risks of major GI and CV events across the range

of doses considered. The findings are consistent with other published studies that found high doses of NSAIDs to be associated with higher risks of GI, CV and renal events. Based on this model, a 20% lower dose of diclofenac (35 mg TID compared to 50 mg TID or 75 BID) has the potential to lower the risk of serious adverse GI events by 14 to 18%, serious cardiovascular adverse events by 7% and renal events by 19%. The estimated effect of these AE risk reductions that might be expected per 10,000 patients would be the prevention of 406 total AEs, with cost savings of $10,300,000 with a number needed to treat (NNT) of 24.6 to avoid one event as delineated below:

| Event | Projected Cost per Event | Events Prevented Utilizing 20% Lower Dose | Projected Costs Saved |
|---|---|---|---|
| GI | $7818 | 372 | $290,998 |
| CV | $251,431 | 30 | $7,525,000 |
| Renal (requiring dialysis) | $631,652 | 4 | $2,486,000 |

In summary, ZORVOLEX has proven efficacy for the treatment of mild to moderate acute pain in adults, and offers a low dose treatment option that supports the FDA Public Advisory recommendation to use the lowest effective dose of NSAIDs for the shortest duration of time consistent with individual treatment goals to potentially mitigate the increased risk of serious adverse events which may of particular importance to the Medicaid population.

**Questions and Answers**
Q: Are there any outcomes studies?
A: There are prospective studies looking at outcomes and surrogates.

Q: How are other plans covering?
A: A large Medicaid PBM recently added Zorvolex as a preferred option.

**XIX. Unither**
Gina Keller, PhD, Medical Science Liaison
Don Nopper, MBA, National Account Manager

**Orenitram® (oral treprostinil)**
Pronunciation: O-ren-i-tram, tray-pros-tin-il

Pulmonary arterial hypertension is a rare, orphan disease characterized by endothelial and smooth muscle cell proliferation and pulmonary vascular remodeling, resulting in progressive right heart failure and death. There are currently 12 FDA approved therapies including endothelin receptor antagonists, phosphodiesterase type 5 inhibitors, soluble guanylate cyclase stimulators and prostanoids. Decisions regarding choice of therapy depend on the patient's risk profile, physician practice, tolerability, and life style factors. Therapies from different classes commonly are used in combination. Despite the availability of many new therapies, medical treatment is not curative, and PAH remains a life-threatening disease.

The first FDA approved oral prostacyclin therapy option for PAH, Orenitram (oral treprostinil) will be discussed. Orenitram was FDA approved in December 2013. Treprostinil is a stable prostacyclin analogue, with the advantage of having a four-hour half-life, and is available in intravenous, subcutaneous, inhaled and now oral routes of administration. The major pharmacologic actions of treprostinil are direct vasodilation of pulmonary and systemic arterial vascular beds, inhibition of platelet aggregation, and inhibition of smooth muscle cell proliferation.

Orenitram is indicated for the treatment of PAH WHO Group 1 to improve exercise capacity. The study that established effectiveness included predominantly patients with WHO functional class II-III symptoms and etiologies of idiopathic or heritable PAH (75%) or PAH associated with connective tissue disease (19%). Orenitram is supplied as an extended release tablet and dosing is individualized according to a patient's clinical response. Orenitram is indicated for twice or thrice daily dosing regimens and should be taken with food. The maximum dose is determined by tolerability.

Three multi–center, randomized, double blind studies were conducted comparing Orenitram to placebo in a total of 349, 350 and 310 patients with PAH, respectively. The first study was a 12–week, monotherapy, placebo controlled study in treatment naive patients. This study demonstrated a 23 meter median improvement in 6MWD after 12 weeks. The second and third studies were 16–week, placebo controlled combination therapy studies that did not demonstrate a statistically significant increase in exercise capacity in patients on background ERA and/or PDE5 inhibitor therapies.

824 patients from these studies entered a long-term, uncontrolled open-label extension study. The average exposure to Orenitram was approximately 2 years, with a maximum exposure time of 6 years. The dose of Orenitram continued to increase over time. In the 522 patients completed the 12-month efficacy assessment, mean 6MWD improved by 24 meters when compared to baseline. In patients who remained in the study, overall survival was 92%, 87% and 82% at the end of 1, 2 and 3 years, respectively, although these data must be interpreted cautiously due to the lack of a control group. The most common adverse events for Orenitram were headache, nausea and diarrhea. In the 12-week, placebo controlled, randomized monotherapy study, approximately 91% of patients experienced an adverse reaction but only 4% discontinued therapy for an adverse reaction. In the long-term, open label extension study, approximately 70% of patients continued treatment with Orenitram for at least one year. The adverse event profile was similar to that observed in the placebo controlled trial.

**Questions and Answers**
Q: Why has an oral formulation not been available sooner?
A: Did not previously have capability of overcoming gut until technology of osmotic tablet.

Q: Will the distribution be limited?
A: Yes, will be limited to Accredo and Caremark due to an educational standpoint.

Q: What is considered place in therapy?
A: Oral treprostinil can be used in place of injection or inhaled formulations; these formulations do not need to be failed before oral therapy.

The following summaries were not presented at the Forum but were provided for the DURB's review.

**I. Amgen**
**Aranesp® (darbepoetin alfa)**
**Indications**
- Aranesp® is indicated for the treatment of anemia due to chronic kidney disease (CKD), including patients on dialysis and patients not on dialysis.
- Aranesp® is indicated for the treatment of anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy.

**Limitations of Use**
- Aranesp® has not been shown to improve quality of life, fatigue, or patient well-being.
- Aranesp® is not indicated for use:
    - In patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy
    - In patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure
    - As a substitute for red blood cell (RBC) transfusions in patients who require immediate correction of anemia

**Contraindications**
- Aranesp® is contraindicated in patients with:
    - Uncontrolled hypertension
    - Pure red cell aplasia (PRCA) that begins after treatment with Aranesp® or other erythropoietin protein drugs
    - Serious allergic reactions to Aranesp®

**Mechanism of Action**
Aranesp® is an erythropoiesis-stimulating protein containing 5 N-linked oligosccharide chains, with a longer half-life than epoetin alfa. Aranesp® stimulates erythropoiesis by the same mechanism as endogenous erythropoietin.

II. **Salix**
**Apriso® (mesalamine extended-release)**
Apriso (mesalamine) extended-release mesalamine capsules are indicated for the maintenance of remission of ulcerative colitis (UC) in patients 18 years of age and older. Apriso is dosed once daily with or without food. Apriso provides delayed and extended release delivery which begins releasing mesalamine at a pH ≥ 6, designed to gradually distribute mesalamine throughout the colon.

In 2012, Dr. Gary Lichtenstein and colleagues published a post-hoc analysis of two identically designed, prospective, randomized, double-blind, placebo-controlled, 6 month trials in patients with UC to evaluate the efficacy of 1.5g of Apriso once daily vs placebo in the maintenance of remission from UC in patients who switched from other 5-ASA formulations. A total of 487 patients received prior 5-ASA maintenance therapy at enrollment and were included in this analysis. In those patients switched from other 5-ASA formulations to Apriso or placebo, 78% of Apriso patients were relapse free at 6 months compared to 59% receiving placebo, a statistically significant difference. The adverse event profile was similar to placebo in this subpopulation of patients, with the most common adverse events in the Apriso group being reported as headache, diarrhea, abdominal pain, upper abdominal pain, nausea, and nasopharyngitis. In summary, Apriso is the first and only once-daily 5-ASA featuring delayed and extended release delivery that begins releasing mesalamine at a pH ≥ 6. Apriso has proven to maintain remission in two clinical trials over a duration of 6 months and was shown to be effective at maintaining remission when switching from other 5-ASA formulations. Apriso is safe, well-tolerated, and cost-effective in maintaining remission of patients with UC.

**III. Sunovion**

**Latuda® (lurasidone)**

Lurasidone is indicated for the treatment of schizophrenia (efficacy established in five 6-week controlled studies) and in the treatment of depressive episodes associated with bipolar disorder (bipolar depression), both as monotherapy and as adjunctive therapy with lithium or valproate (efficacy established in one 6-week controlled monotherapy and one adjunctive therapy study) in adults.

Two 6-week, double-blind, placebo-controlled, fixed-flexible dose, multicenter studies assessed the safety and effectiveness of lurasidone treatment, either as monotherapy or adjunctive to ongoing stable therapeutic levels of lithium or valproate, as compared to placebo in adult depressed bipolar I patients.

- Both studies enrolled patients with Bipolar I disorder experiencing a major depressive episode.
- Lurasidone monotherapy (D1050236) significantly improved depressive symptoms as determined by Montgomery-Asberg Rating Scale (MADRS) score reductions from baseline to end of Week 6 (primary outcome) whether dosed at 20-60 mg/day (-15.4; p<0.001) or at 80-120 mg/day group (-15.4; p<0.001) vs. placebo (-10.7); all comparisons by Mixed Model Repeated Measures (MMRM) analysis.
- Lurasidone 20-120 mg/day adjunctive to Li/VPA (D1050235) also significantly improved depressive symptoms, reflected by a mean (SE) MADRS score reduction at end of week 6 of -17.1 (0.87) vs. placebo + lithium or valproate -13.5 (0.91); p<0.01)].
- Both lurasidone mono- and adjunctive therapy also provided significantly greater improvements vs. placebo on all secondary efficacy endpoints, including the Hamilton Anxiety Scale, Sheehan Disability Scale score and Quality of Life Enjoyment and Satisfaction Questionnaire – Short Form score.
- Monotherapy trial (D1050236): Adverse events (≥5% Incidence and at least twice the rate of placebo)

| | Akathisia | Parkinsonism* |
|---|---|---|
| Lurasidone 20-60 mg/day | 8% | 5% |
| Lurasidone 80-120 mg/day | 11% | 8% |
| Placebo | 2% | 2% |

- The rates of discontinuation due to adverse events in the monotherapy study were 7% for lurasidone 20-60 mg/day and 6% for lurasidone 80-120 mg/day, respectively, vs. 6% for placebo.
- **Adjunctive trial (D1050235): Adverse events (≥5% Incidence and at least twice the rate of placebo)**

| | Somnolence** | Akathisia |
|---|---|---|
| Lurasidone 20-120 mg/day | 11% | 11% |
| Placebo | 5% | 5% |

- The rates of discontinuation due to adverse events in the adjunctive study were 6% for lurasidone and 8% for placebo.

**Indications and Usage**

- LATUDA is indicated for the treatment of major depressive episodes associated with bipolar I disorder (bipolar depression) as monotherapy and as adjunctive therapy with either lithium or valproate.
- LATUDA is indicated for the treatment of patients with schizophrenia.
- The efficacy of LATUDA as monotherapy and adjunctive therapy with lithium or valproate for the treatment of bipolar depression, were each established in a 6-week controlled study of adult patients with bipolar depression.
- The efficacy of LATUDA in schizophrenia was established in five 6-week controlled studies of adult patients with schizophrenia.
- The effectiveness of LATUDA for longer-term use, that is, for more than 6 weeks, has not been established in controlled studies. Therefore, the physician who elects to use LATUDA for extended periods should periodically

re-evaluate the long-term usefulness of the drug for the individual patient. The efficacy of LATUDA in the treatment of mania associated with bipolar disorder has not been established.

**IV. Ferring**

**Prepopik® (sodium picosulfate; magnesium oxide; anhydrous citric acid)**

1. Current colonoscopy screening rates
    a. CRC is highly preventable[1]
        i. 5-year survival rate over 90% after removal of localized polyps
    b. Colonoscopy is the gold standard for CRC screening
        i. Diagnostic AND treatment applications
        ii. Allows for visualization and removal of polyps
    c. Recommended by American College of Gastroenterology every 10 years in adults over 50
    d. Patients with family history of CRC: Every 5 years beginning at 40 years old (or 10 years younger than the youngest age of diagnosis in an affected relative)
    e. African Americans: beginning at age 45
2. Inadequate bowel prep is a persistent problem
    a. As many as 25% of patients undergoing colonoscopy are inadequately prepped, resulting in:
        i. Longer procedure times
        ii. Substantial numbers of missed lesions (among inadequately prepped patients, 34% had 1 or more missed adenoma during rescreening)
3. Prepopik product profile
    a. Dosage forms and strength: Available in a carton that contains a dosing cup and 2 packets, each holding 16.1 g of powder for oral solution. Each packet contains: 10.0 mg sodium picosulfate, 3.5 g magnesium oxide, and 12.0 g anhydrous citric acid
    b. Dual mechanism of action: sodium picosulfate is converted into an active metabolite, BHPM, to stimulate colonic peristalsis; magnesium oxide and anhydrous citric acid react in water to create magnesium citrate, which produces osmotic water retention. Offers 2 dosing options and a flexible hydration schedule.
4. SEE CLEAR I and II: Study Design
    a. Phase 3 randomized, assessor-blinded, multicenter studies, 1195 adult patients
    b. SEE CLEAR I—split-dose regimen (N=601)
    c. SEE CLEAR II—day-before dose regimen (N=594)
    d. Primary objective: To demonstrate noninferiority of PREPOPIK (sodium picosulfate, magnesium oxide, and anhydrous citric acid) to 2L PEG with electrolytes (PEG+E) plus 2x 5 mg bisacodyl tablets in overall colon cleansing in preparation for colonoscopy based on the Aronchick scale
    e. Secondary objectives: (1) To demonstrate noninferiority of PREPOPIK to 2L PEG with electrolytes (PEG+E) plus 2x 5 mg bisacodyl tablets with respect to the efficacy of ascending colon cleansing based on the Ottawa scale. (2) To determine tolerability and satisfaction of the preparation as assessed by a standardized subject questionnaire administered at the study site before colonoscopy. (3) To evaluate safety and tolerability through the collection of adverse events, clinical laboratory tests, and physical examination
5. Clinical Trial Results:
    a. Prepopik cleanses effectively across sections of the colon in SEE CLEAR I and II
    b. Prepopik demonstrates efficacy and safety in the elderly (Patients 65 or older) in both trials
    c. Treatment-Emergent Adverse Reactions Observed in at Least (>1%) of Patients Using the Split-Dose Regimen and Day-Before Regimen in were nausea headache and vomiting (3% or less for Prepopik, 5% or less for 2L PEG with electrolytes (PEG+E) plus 2x 5 mg bisacodyl tablets
    d. Contraindications: Patients with severely reduced renal function (creatinine clearance less than 30 mL/minute) which may result in accumulation of magnesium, Gastrointestinal obstruction or ileus, Bowel perforation, Toxic colitis or toxic megacolon, Gastric retention, An allergy to any of the ingredients in Prepopik
    e. Warnings and precautions include: Serious fluid and serum chemistry abnormalities, Seizures, Use in patients with renal impairment, Cardiac arrhythmias, Colonic mucosal ulceration, ischemic colitis and ulcerative colitis, Use in patients with significant gastrointestinal disease, Aspiration, Not for direct ingestion

GEORGIA DEPARTMENT OF COMMUNITY HEALTH

# Manufacturers' Forum

## ANNOUNCEMENT

## NorthStar HealthCare Consulting

## Georgia Department of Community Health

On behalf of the Georgia Department of Community Health (DCH) and in service to the Georgia Medicaid Fee-for-Service (FFS) Drug Utilization Review Board (DURB), NorthStar HealthCare Consulting (NHC), in conjunction with Catamaran, announces the next quarterly Manufacturers' Forum occurring on Thursday, August 7, 2014.

**Date:** **Thursday, August 7, 2014 from 9am-5pm EST**

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

**Appointments: The Manufacturers' Forum is by appointment only.** Appointments may be requested and will be scheduled ***after*** the Drugs Under Review are posted to the DCH website at **http://dch.georgia.gov/durb-meeting-information** approximately 30 days prior to the Forum. Manufacturers with drugs up for review at the current DURB meeting will be granted preference when seeking appointments. All requests for appointments must be made in writing to **GAMedicaid@nhc-llc.com** and include the drug name. 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.

**Guidelines for Participation:**

- To ensure equitable treatment of all manufacturers, individual manufacturer participation shall be limited to one 30-minute time segment per Forum. The presentation shall be limited to 20 minutes with 10 minutes for questions and answers.
- Manufacturer presentations may be audio-recorded for review after the Forum and the associated information shall be presented by NHC in summary fashion at regularly scheduled DURB meetings.
- For new drugs, manufacturers are highly encouraged to present all clinical information pertinent and relevant to current NHC clinical presentations to the DURB, to DCH drug benefit plan design as posted on the DCH website, and to other drugs within the class.
- For existing drugs, manufacturers are highly encouraged to present new clinical information since the drug was last reviewed by the DURB, especially clinical information related to comparisons of other drugs within the class.
- An electronic **one-page** summary (font 10, front only not including references) of the presentation should be provided one week prior to the presentation via email to **GAMedicaid@nhc-llc.com** and please include a pronunciation guide of the drug's brand and generic names. The one-page summary along with relevant questions and answers related to the presentation will be provided to the DURB as well as published in the DURB meeting handout that is provided to the public at the meetings and on the DCH website at **http://dch.georgia.gov/durb-meeting-information**.

**Comments and Inquiries:**

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

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



catamaran

NorthStar HealthCare Consulting Let Us Be Your Guide

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

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

**Presentation Opportunity:**

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

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

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

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

**Opportunity to Appeal to GDCH:**

**GDCH Review Process:** DURB recommendations are reviewed by GDCH for final decisions. Manufacturers may request an appeal meeting 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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# 2014

# Upcoming Meetings

## Drug Utilization Review Board Meeting

2 Peachtree Street, N.W.

5th Floor Board Room

Atlanta, Georgia 30303

| | |
|---|---|
| Thursday, September 18, 2014: | 9:30am – 1:30pm |
| Thursday, December 4, 2014: | 9:30am – 1:30pm |

## Manufacturers' Forum

NorthStar HealthCare Consulting

1121 Alderman Drive

Suite 112

Alpharetta, Georgia 30005

| | |
|---|---|
| Thursday, August 7, 2014: | 9:00am – 5:00pm |
| Thursday, November 6, 2014: | 9:00am – 5:00pm |