GEORGIA DEPARTMENT OF COMMUNITY HEALTH

Georgia Department of Community Health

DRUG UTILIZATION REVIEW BOARD MEETING

Department of Community Health
2 Peachtree Street – 5th Floor Board Room
Atlanta, Georgia 30303

September 24, 2015

OPTUMRx

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DRUG UTILIZATION REVIEW BOARD MEETING
AGENDA

2 Peachtree Street - 5th Floor DCH Board Room
Atlanta, Georgia 30303
Thursday, September 24, 2015
9:30 a.m. to 1:30 p.m.

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

➢ **New Drug Reviews**

- Belsomra
- Cosentyx
- Evekeo
- Ibrance
- Lenvima
- Lynparza
- Nplate
- Savaysa
- Soolantra
- Vimizim

➢ **Non-Supplemental Rebate Class Reviews**

➢ **Utilization Trends Review**

➢ **Drug Information Reviews**

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

FUTURE AGENDA ITEMS	*Chair*
ADJOURNMENT	*Chair*

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Department of Community Health
Drug Utilization Review Board (DURB)
MINUTES
Thursday, June 4, 2015

MEMBERS PRESENT

Osgood (Drew) A. Miller, R.Ph., Chair
Gurinder J.S. Doad, M.D., Vice-Chair
Mia Avery, Pharm.D.
Deborah W. Fincher, M.S., R.Ph.
M. Celeste Fowler, Pharm.D.
Robyn Lorys, Pharm.D.
J. Russell May, Pharm.D.
Brent L. Rollins, R.Ph., Ph.D.

MEMBERS ABSENT

Ann R. Damon, Pharm.D.
Thomas B. Gore, M.D.
Robert E. Shervette III, M.D.

Staff

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

NorthStar HealthCare Consulting

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

Catamaran

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

Goold Health Services

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

Call to Order

The Drug Utilization Review Board (DURB/DUR Board/Board) held its second meeting for the calendar year on June 4, 2015. The Chair, Osgood (Drew) A. Miller, R.Ph., called the meeting to order at 9:34am.

Comments from the Department

Turkesia Robertson-Jones, Pharm.D., Interim Pharmacy Director, Pharmacy Services, commented on the following items:

- New Students – A welcome was extended to the following University of Georgia students: Brian Tant, Laurie Jackson, Hulda Abaidoo and Christopher Campbell.

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

1. Budget Overview – Growth funded-$33.1 million; Twelve month eligibility reviews funded-$37 million; increase in rates for OB/GYN/Primary care funded; inpatient reimbursement change; Hepatitis C drugs-funding removed; ABD Care Coordination-funding removed.
2. Legislative Bills – Autism Bill (HB429)- autism services for children 0-6 years; Hospice legislation-expand eligibility from 6 months to up to 24 months, pay for treatment in addition to palliative care; PCP rate increase (does not apply to PeachCare for Kids); HB470-Pharmacy Audit Bill of Rights, changes how audit companies can be paid, MAC-requires more transparency, published response to changes
3. Procurements –All major contracts will have 7/1/16 start dates; CMO RFP is out, responses are in and under review; Rebate will be the next going out; Medication Management Utilization Services-will go out close to the Rebate RFP; PBM-one to two months away from posting; Integrated Eligibility System-implementation (phase rollout) in 2nd or 3rd quarter next year; Credentialing Verification Organization-7/1 start.
4. Immunizations – additional products will be added to the program

Minutes from the Previous Meeting

Chair Miller asked for corrections or changes to the minutes from the March 26, 2015 meeting. There were no corrections. A motion was made (J. Russell May, Pharm.D.), seconded (Brent L. Rollins, R.Ph., Ph.D.), and carried to approve the minutes as written.

External Comments Session

External comments were presented to the Board from the following:

- Tara Cockerham, Pharm.D., provided an overview of written comments received by the following:
  - Harold P. Katner, MD, FACP, FIDSA, Professor of Internal Medicine and Pediatrics, Chief of Infectious Diseases, Program Director of the Mercer University School of Medicine Infectious Diseases Fellowship at MCCG, Mercer School of Medicine – PA removal from Triumeq, Complera, Stribild and Intelence (Attachment A)
- Tara Cockerham, Pharm.D., acknowledged the following letters, which were received without disclosures:
  - Joseph Havlik, MD, West Georgia Infectious Disease – open access to all HIV agents
  - Preston Campbell, MD and Bruce Marshall, MD, Cystic Fibrosis Foundation – open access to all Cystic Fibrosis (CF) agents and inhaled antibiotics used for CF

Disclosure forms were completed by Dr. Harold P. Katner 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. Pharmacy students, Brian Tant (UGA), Laurie Jackson (UGA), Hulda Abaidoo (UGA), Christopher Campbell (UGA) and Andrea Douglas (PCOM) attended the closed session with Board members. A motion was made by Robyn Lorys, Pharm.D. and seconded by Deborah W. Fincher, M.S., R.Ph. to adjourn the open session and approve the closed session. There was a unanimous vote approving the closed session. The Chairman, Drew Miller, R.Ph., adjourned the open session at approximately 9:58 am, at which time members took a break then reconvened for the executive (closed) session.

Executive Session

The Executive Session was held from 10:05am to 11:02am.

Reconvening of Open Session

The DUR Board reconvened for the open session at 11:16am.

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 thirteen (13) manufacturers participated or provided information regarding the following drugs discussed at the June 2015 DURB meeting:

Manufacturers	Drugs
Genzyme	Cerdelga, Cerezyme
Shire	Vyvanse, VPRIV
Bristol-Myers Squibb	Atripla, Evotaz
Eisai	Akynzeo
Gilead	Stribild, Zydelig
Genentech	Esbriet
Keryx	Auryxia
Aegerion	Juxtapid
Pari	Kitabis Pak
Boehringer Ingelheim	Ofev
AstraZeneca	Symbicort
GlaxoSmithKline	Tivicay, Triumeq
Lundbeck	Northera

Questions and comments were received on the following:

- Cerdelga/Cerezyme – Only handful of Medicaid patients with Gaucher disease (2 patients)
- Vyvanse – Binge Eating Disorder diagnosis and specialist required in prior authorization criteria

The next forum will be held on Thursday, August 6, 2015 from 9am-5pm at the NorthStar Healthcare Consulting office: 1121 Alderman Drive, Suite 112, Alpharetta, GA 30005.

New Drug Reviews

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

Therapeutic Class	Drugs	Presenter
Antiemetics	*Akynzeo*	Afzal Mistry, Pharm.D.
Phosphate Binders	*Auryxia*	Afzal Mistry, Pharm.D.
Gaucher Disease Agents	*Cerdelga*	Afzal Mistry, Pharm.D.
Atiinfectives, Skin and Skin Structure Infections	*Dalvance, Sivextro*	Afzal Mistry, Pharm.D.
Idiopathic Pulmonary Fibrosis Agents	*Esbriet, Ofev*	Emily Baker, Pharm.D., BCPS
Antiinfectives, Antifungals	*Jublia, Kerydin*	Emily Baker, Pharm.D., BCPS
Alpha and Beta Adrenergic Agonists	*Northera*	Emily Baker, Pharm.D., BCPS
Antineoplastics, Chronic Lymphocytic Leukemia (CLL) and Non-Hodgkin's Lymphoma (NHL)	*Zydelig*	Emily Baker, Pharm.D., BCPS

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

- Ofev/Esbriet – not a lot of use anticipated, supportive care treatment, PA criteria-indication and safety
- Northera – tolerance to drug, only 8 week safety data available

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. Tara Cockerham. The following therapeutic categories had updates:

Drug Class/Name
Aminoglycosides for Cystic Fibrosis
Antidementia Agents
Antivirals, Antiretrovirals
Bronchodilators, Steroid-Sympathomimetic Combinations

There were no comments or questions from the Board.

The Board voted and made recommendations for all supplemental rebate drugs noted in the Board's Recommendations to the Department.

Guest Expert Speaker

Gregory S. Felzien, M.D., spoke about changes in the new HIV guidelines, potential side effects of new therapies, and discussed how new medications will be integrated into practice (Attachment B). He addressed questions from the Board and provided comments on the following:

- Improvement in adherence with one tab vs. multiple tabs – if still once a day, patients do ok.
- Why Stribild instead of Atripla – Stribild is superior to Atripla due to tolerance
- Copay waved for under 6 years old and will vary for under 21 years
- Cobicistat – already contained in Stribild and has everything in it, would need to add something else with Evotaz and Prezcobix
- Comparable therapy if can't use Stribild – have to look at patient variables
- Single tablet regimens
- Reasonable to PA for experienced clients
- Education
- Pharmacists stepping up
- Outcomes study on compliance
- Refill habits
- Comparable regimens of once a day (multiple pills) to once a day (one pill)
- Adherence outcomes-older data

DCH Decisions

DCH Decisions from the March 2015 DUR Board meeting were provided in the DCH Decision section of the DUR Board binder.

Utilization Trends Review

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

Drug Information Reviews

Information from the following was provided in detail in the Drug Information Reviews 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
There were no future agenda items noted.

Upcoming Meetings
The following upcoming meetings were published in the DURB binder:

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

  Thursday, September 24, 2015
  Thursday, December 15, 2015

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

  Thursday, August 6, 2015
  Thursday, November 5, 2015

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

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

New Drugs and Supplemental Rebate Classes

Antiemetics

The DUR Board recommended ***Preferred*** status with ***Prior Authorization*** for ***Dronabinol (Oral) Capsule*** and ***Non-Preferred*** status with ***Prior Authorization*** for ***Akynzeo® (Oral) Capsule and Marinol® (Oral) Capsule***.

Phosphate Binders

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

Gaucher Disease Agents

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

Antiinfectives, Skin and Skin Structure Infections

The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Dalvance® (Intravenous) Vial, Sivextro® (Intravenous) Vial and Sivextro® (Oral) Tablet***.

Idiopathic Pulmonary Fibrosis Agents

The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Esbriet® (Oral) Capsule and Ofev® (Oral) Capsule***.

Antiinfectives, Antifungals

The DUR Board recommended ***Preferred*** status for ***Griseofulvin Ultramicrosize (Oral) Tablet*** and ***Non-Preferred*** status with ***Prior Authorization*** for ***Gris-Peg® (Oral) Tablet***, ***Jublia® (Topical) Solution and Kerydin™ (Topical) Solution***.

Alpha and Beta Adrenergic Agonists

The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Northera™ (Oral) Capsule***.

Antineoplastics, Chronic Lymphocytic Leukemia (CLL) and Non-Hodgkin's Lymphoma (NHL)

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

Aminoglycosides for Cystic Fibrosis

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

Antidementia Agents

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

Antivirals, Antiretrovirals

The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Complera® (Oral) Tablet***, ***Stribild® (Oral) Tablet and Triumeq® (Oral) Tablet with grandfathering***.

Bronchodilators, Steroid-Sympathomimetic Combinations

The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Advair® HFA (Inhalation) HFA Aerosol and Dulera® (Inhalation) HFA Aerosol***.

Conclusion

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

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

_____

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

MERCER UNIVERSITY
SCHOOL OF MEDICINE
Department of Internal Medicine

January 19, 2015

DCH Pharmacy
Unit
2 Peachtree Street
Atlanta, Georgia 30303

To Whom It May Concern,

I am writing on behalf of my HIV patients as well as my fellow HIV providers throughout the state. My request is to remove prior approval for the dolutegravir-abacavir-lamivudine combination tablet, rilpivirine-emtricitabine-tenofovir combination tablet, the elvitegravir-cobicistat- emtricitabine-tenofovir combination tablet, along with etravirine. We are using more of the combination medications in managing our patients for adherence and tolerability reasons. When a patient is admitted to the hospital newly diagnosed with HIV and Pneumocystis, current guidelines are to start HAART as soon as possible. Once they are discharged, waiting for prior approval on any of the above that the patient may be on will lead to a delay in continuing therapy and put the patient at risk for developing resistant HIV. Another problem we are facing at least once or twice a month is the development of kidney failure on tenofovir based regimens. In these cases, switching them to the dolutegravir-abacavir-lamivudine regimen once we establish that the patient is HLAB5701 negative and if their GFR allows, is an option that leaves them on one pill daily. Because of delays in getting this medication on prior approval can again result in HIV resistance developing or further kidney damage, having this readily available would benefit patient care. Etravirine, because of its metabolism and clearance, is one of the medications that we can use in patients with kidney issues. It is also one of the medications that I can use to avoid using nucleoside reverse transcriptase inhibitors (RTI's). We are seeing more mitochondrial toxicity from long term use of nucleoside RTI's. Recently I tried to get a prior approval for etravirine for a patient that had severe mitochondrial toxicity but kept getting refused because he had no resistance issues. Mitochondrial toxicity can lead to a fatal outcome if not addressed. Leaving drugs on prior approval that can be used to replace the nucleoside RTI's and having to go through appeals, truly puts patients at risk for further toxicity (or resistance if we have to hold treatment).
Any assistance in this issue is most appreciated.

Sincerely,

Harold P. Kaner, MD, FACP, FIDSA
Professor of Internal Medicine and Pediatrics
Chief of Infectious Diseases
Program Director of the Mercer University School of Medicine Infectious Diseases Fellowship at MCCG
Division of Infectious Diseases
Mercer University School of Medicine
707 Pine Street
Macon, Georgia 31201
Phone: 478-301-5830
Fax: 478-301-5856

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HIV Guideline: April 8, 2015

Gregory S. Felzien, M.D., AAHIVS
Diplomat: Internal Medicine and Infectious Disease
Georgia Department of Public Health
Medical Advisor
Division of Health Protection/IDI-HIV

http://aidsinfo.nih.gov/guidelines

June 4, 2015

Disclosure

I have **no** vested interests that relate to this presentation

Nor do I have any relationships with;

pharmaceutical companies

biomedical device manufacturers

and/or other corporations

Whose products or services are related to pertinent therapeutic areas

Learning Objectives

- Discuss changes in the new HIV guidelines
- Discuss potential side effects of new therapies
- Discuss how new medications will be integrated into practice

Immune Boosters - Beware

Chiropractic Acupuncture

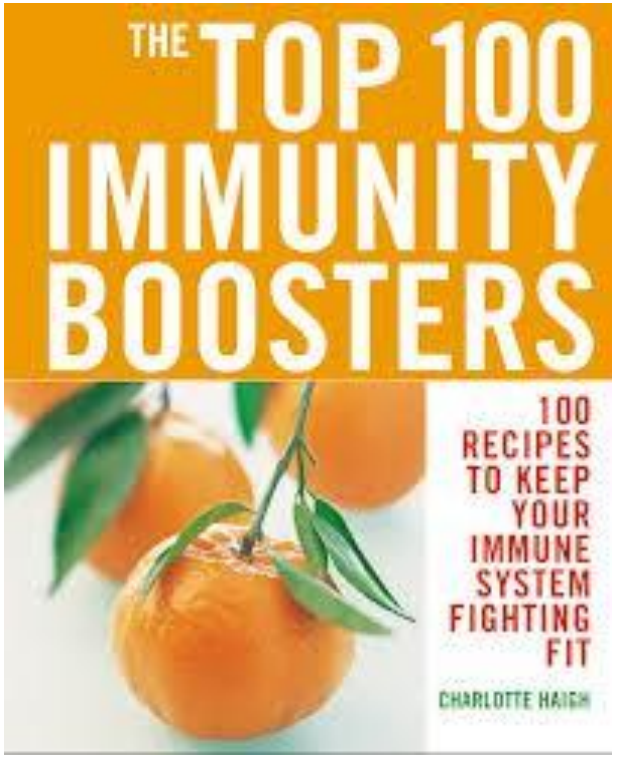
Ayurvedics: body uses three doshas:

- *vata,* the energy of movement
- *pitta,* the energy of digestion and metabolism
- *kapha*, the energy of lubrication

Herbal:

- ma huang, cat's claw, echinacea
- astragalus, bee pollen

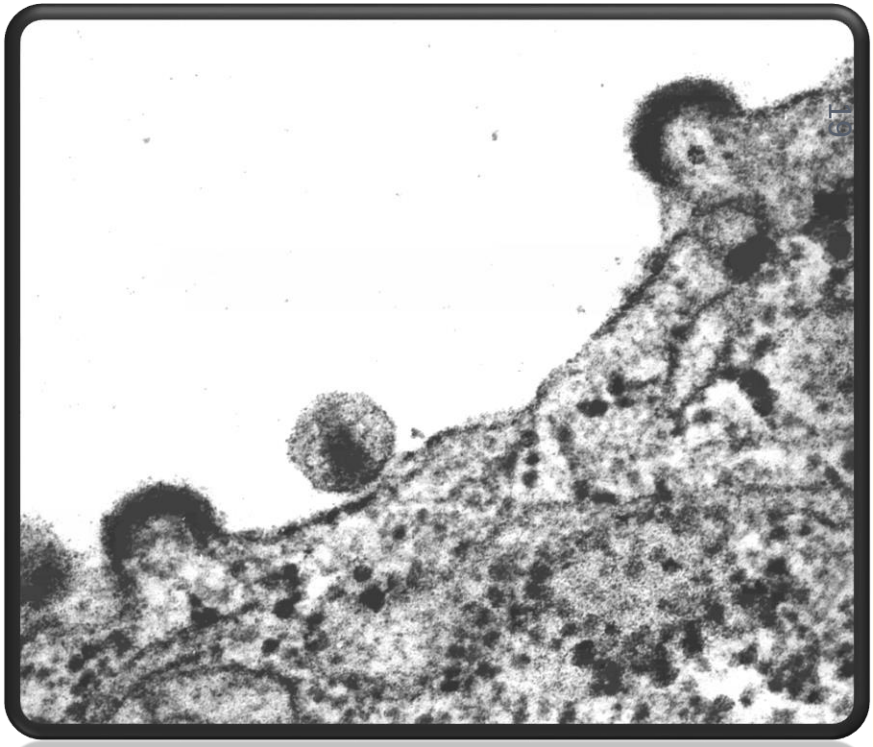
Hydrogen Peroxide



Classes of Medications

- NsRTIs
- NtRTIs
- NNRTIs
- Protease Inhibitors
- Entry Inhibitors
- Integrase Inhibitors

- Maturation Inhibitors



Initiation of ART

- Pregnancy
- History of an AIDS-defining Illness
- HIV-associated nephropathy
- HIV & Hepatitis B virus co-infection

What Was This Based On?

- Increased harmful impact of ongoing HIV replication
- Preventing secondary transmission (96% reduction)

BUT

- Client should be willing and able to commit to therapy
- Postponement of therapy may needed:
  - based on clinical and/or psychosocial factors

NsRTIs

AZT	Zidovudine /Retrovir
ddI	Didanosine /Videx
ddC	Zalcitabine /Hivid
d4T	Stavudine /Zerit
3TC	Lamivudine /Epivir
ABC	Abacavir /Ziagen
FTC	Emtricitabine /Emtriva

NtRTIs

TDF	Tenofovir /Viread

NNRTIs

NVP	Nevirapine /Viramune
DLV	Delavirdine /Rescriptor
EFV	Efavirenz /Sustiva
ETV	Etravirine / Intelence
RPV	Rilpivirine / Edurant

Booster

COBI	Cobicistat / Tybost

Protease Inhibitors

SQV	Saquinavir /Invirase
RTV	Ritonavir /Norvir
IDV	Indinavir /Crixivan
NFV	Nelfinavir /Viracept
APV	Amprenavir /Agenerase
LPV/r	Lopinavir /Ritonavir (Kaletra)
ATV	Atazanavir /Reyataz
FPV	Fosamprenavir /Lexiva
TPV	Tipranavir /Aptivus
DRV	Darunavir /Prezista

Entry Inhibitor

T-20	Enfuvirtide /Fuzeon
MVC	Maraviroc / Selzentry

Integrase Inhibitor

RAL	Raltegravir / Isentress
DTG	Dolutegravir / Tivicay
EVG	Elvitegravir / Vitekta

Average Monthly Wholesale Price

Routine 30 day supply

- Abacavir (gen): $602.66
- Emtricitabine: $602.27
- Lamivudine (gen): $429.66
- Tenofovir: $1,120.04
- Zidovudine (gen): $360.97

- Efavirenz: $1,011.97
- Etravirine: $1,212.29
- Rilpivirine: $996.43

- **Cobicistat** $216.00

- Atazanavir: $1,535.23
- Darunavir: $1,509.79
- Fosampenavir: $1,204.43
- Ritonavir: $308.60
- Lopinavir/Ritonavir: $977.22

- Raltegravir: $1,445.34
- Dolutegravir: $1,581.68
- **Elvitegravir** $1,352.05

- Enfuvirtide: $3,759.43
- Selzentry: $1,455.13

- Lamivudine, Zidovudine
  - Combivir (gen): $931.61
- Abacavir, Zidovudine, Lamivudine
  - Trizivir (gen): $1,738.46
- Abacavir, Lamivudine
  - Epzicom: $1,416.35
- Emtricitabine, Tenofovir
  - Truvada: $1,539.90
- Efavirenz, Emtriva, Tenofovir
  - Atripla: $2,551.99
- Edurant, Emtriva, Tenofovir
  - Complera: $2,463.37
- Elvitegravir, Cobicistat, Emtriva, Tenofovir
  - Stribild: $2,948.70
- Dolutegravir, Abacavir, Lamivudine
  - Triumeq $2,648.84

- Darunavir, Cobicistat
  - Prezcobix: $1,725.29
- Atazanavir, Cobicistat
  - EvoTaz: $1,684.44

Recommended Regimen Options: 2015

INSTI-Based Regimens:

- DTG/ABC/3TC

  Pre-treatment HLA-B*5701 negative

- DTG + TDF/FTC

- EVG/c/TDF/FTC

  Pre-treatment CrCl ≥70 mL/min

- RAL + TDF/FTC

PI-Based Regimens:

- DRV/r + TDF/FTC

TDF: Tenofovir, FTC: Emtricitabine, ABC: Abacavir, 3TC: Lamivudine, DRV: Darunavir, r: ritonavir, RAL: Raltegravir, DTG: Dolutegravir, EVG: Elvitegravir, Cobi: cobicistat

Alternative Regimen Options: 2015

NNRTI-Based Regimens:

- EFV/TDF/FTC 
- RPV/TDF/FTC 

  Pre-treatment HIV RNA <100,000 copies/mL + CD4 >200 cells/mm3

PI-Based Regimens:

- ATV/c + TDF/FTC 

  Pre-treatment CrCl ≥70 mL/min¥
- ATV/r + TDF/FTC 
- (DRV/c or DRV/r) + ABC/3TC 

  Pre-treatment HLA-B*5701 negative
- DRV/c¥ + TDF/FTC 

Other Regimen Options: 2015

INSTI-Based Regimen:

- RAL + ABC¥/3TC

  Pre-treatment HLA-B*5701 negative¥

NNRTI-Based Regimen:

- EFV + ABC¥/3TC

  Pre-treatment HIV RNA <100,000 copies/mL

PI-Based Regimens:

- (ATV/c or ATV/r) + ABC¥/3TC

  Pre-treatment HIV RNA <100K copies/mL

- LPV/r (once or twice daily) + ABC¥/3TC
- LPV/r (once or twice daily) + TDF/FTC

Other Regimens When TDF or ABC Cannot be Used:

- DRV/r + RAL

  HIV RNA <100K copies/mL and CD4 cell count >200 cells/mm3

- LPV/r (twice daily) + 3TC (twice daily)

Dosing and Side Effects

www.aids.gov/hiv-aids-basics/just-diagnosed-with-hiv-aids/treatment-options/side-effects/

Elvitegravir: VITEKTA

http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/203093s000lbl.pdf

- Dose with food (Adults ≥ 18yo : pregnancy category B)
  - 85 mg QD:
    - atazanavir/r 300/100 mg once daily
    - lopinavir/r 400/100 mg twice daily
  - 150 mg QD:
    - darunavir/r 600/100 mg twice daily
    - fosamprenavir/r 700/100 mg twice daily
    - tipranavir/r 500/200 mg twice daily

Selected Adverse Reactions Reported in ≥2% of HIV-1 Infected Treatment Experienced Adults

(week 96 Analysis)

	Elvitegravir (N=354)	Raltegravir (N=358)
Diarrhea	7%	5%
Nausea	4%	3%
Headache	3%	3%

Laboratory Abnormalities (Grade 3-4) Reported in ≥2% of HIV-1 Infected Treatment Experienced Adults (week 96 Analysis)

	Elvitegravir (N=354)	Raltegravir (N=358)
Total Bilirubin (>2.5 × ULN)	6%	9%
Hematuria (> 75 RBC/HPF)	6%	7%
Serum Amylase (> 2.0 × ULN)	6%	6%
Creatine Kinase (≥ 10.0 × ULN)	6%	4%
Total Cholesterol (> 300 mg/dL)	5%	5%
Total Triglycerides (>750 mg/dL)	5%	4%
Hyperglycemia (> 250 mg/dL)	5%	3%
Urine Glucose (4+)	4%	3%
GGT (> 5.0 × ULN)	3%	7%
Neutrophils (< 750/mm3)	3%	3%
ALT (> 5.0 × ULN)	2%	5%
AST (> 5.0 × ULN)	2%	6%

Outcomes

Virologic Outcomes of Randomized Treatment in HIV-1 Infected Treatment-Experienced Adults (Week 96 Analysis)

+ PI/r + another antiretroviral drug

mean age: 45 years (range 19–78); 82% male, 62% white, 34% black

	Elvitegravir (N=351)	Raltegravir (N=351)
HIV-1 RNA <50 copies/mL	**52%**	**53%**
HIV-1 RNA ≥50 copies/mL	36%	31%
No Virologic Data at Week 96	12%	16%
Discontinued Study Drug Due to AE or Death	3%	7%
Discontinued Study Drug Due to Other Reasons and Last Available HIV-1 RNA <50 copies/mL	8%	9%
Missing Data During Window but on Study Drug	1%	1%

EvoTaz: 

- Atazanavir 300 mg + Cobicistat 150 mg
- Cobicistat + tenofovir DF not recommended:
  - with an estimated CrCl below 70 mL/min
- Treatment-naïve or experienced adults ≥ 18yo
- Dose with food
- Pregnancy category B

Cobicistat: TYBOST

http://www.gilead.com/~/media/Files/pdfs/medicines/hiv/tybost/tybost_pi.pdf

- Cobicistat: 150mg PO Once a day <u>with food</u>
  - Atazanavir: 300mg Daily
  - Darunavir: 800mg Daily

The most common adverse reactions and reported in >10% of subjects

Cobicistat:	ocular icterus	15%
	jaundice	13%
	nausea	12%
Ritonavir:	ocular icterus	17%
	jaundice	11%
	nausea	11%
	diarrhea	11%

Selected Adverse Reactions Reported in ≥2% of HIV-1 Infected Treatment Naive Adults (week 48 pooled Analysis) given with ATV+Truvada

	Cobicistat (N=394)	Ritonavir (N=377)
Jaundice	5%	3%
Rash	5%	4%
Ocular icterus	3%	1%
Nausea	2%	2%

Laboratory Abnormalities (Grade 3-4) in ≥2% of HIV-1 Infected Treatment Naive Adults (week 48 pooled Analysis)

	Cobicistat (N=394)	Ritonavir (N=377)
Laboratory Parameter Abnormality	N=394	N=377
Total Bilirubin (>2.5 × ULN)	65%	56%
Creatine Kinase (≥10.0 × ULN)	5%	6%
Serum Amylase (>2.0 × ULN)	4%	2%
ALT (>5.0 × ULN)	3%	2%
AST (>5.0 × ULN)	3%	2%
GGT (>5.0 × ULN)	2%	1%
Urine Glucose (Glycosuria: ≥1000mg/dL)	3%	1%
Urine RBC (Hematuria) (>75 RBC/HPF)	3%	2%

Outcomes

Virologic Outcome of Randomized Treatment in HIV-1 Infected Treatment Naïve Adults at Week 48

mean age 37 years (range 19-70); 83% male, 60% white, 18% black, 12% Asian

	Cobicistat (N=344)	Ritonavir (N=348)
HIV-1 RNA <50 copies/mL	**85%**	**87%**
HIV RNA ≥50 copies/mL	6%	4%
No Virologic Data at Week 48 Window	9%	9%
Discontinued Study Drug Due to AE or Death	6%	7%
Discontinued Study Drug Due to Other Reasons and Last Available HIV-1 RNA <50 copies/mL	3%	2%

Prezcobix

http://www.janssentherapeutics.com/shared/product/prezcobix/prescribing-information.pdf

- Dose with food: Adults ≥ 18yo : pregnancy category C
  - 800 mg Darunavir + 150 mg Cobicistat: once a day
  - Cobicistat + tenofovir DF not recommended:
    - with an estimated CrCl below 70 mL/min

The most common adverse reactions to darunavir, (incidence ≥ 5%) of at least moderate severity (≥ Grade 2) were;

Diarrhea	Nausea
Rash	Headache
Abdominal pain	Vomiting

One single arm clinical trial conducted with darunavir and cobicistat administered as single entities in 313 HIV-infected subjects. Adverse reactions evaluated through Week 24 did not differ substantially from those reported in clinical trials with darunavir coadministered with ritonavir.

Grade 2 to 4 Laboratory Abnormalities Observed in Antiretroviral Treatment-Naïve HIV-1-Infected Adult Subjects

https://www.prezista.com/sites/default/files/pdf/us_package_insert.pdf

All Grade 2		Darunavir/r 800/100 mg once daily+ TDF/FTC	Lopinavir/r 800/200 mg per day + TDF/FTC
Alanine Aminotransferase	> 2.5 to ≤ 5.0 × ULN	9%	9%
Aspartate Aminotransferase	> 2.5 to ≤ 5.0 × ULN	7%	10%
Alkaline Phosphatase	> 2.5 to ≤ 5.0 × ULN	1%	1%
Hyperbilirubinemia	> 1.5 to ≤ 2.5 × ULN	< 1%	5%
Triglycerides	500–750 mg/dL	3%	10%
Total Cholesterol	240–300 mg/dL	23%	27%
Low-Density Lipoprotein Cholesterol	160–190 mg/dL	14%	12%
Elevate Glucose Level	126–250 mg/dL	11%	10%
Pancreatic Lipase	> 1.5 to ≤ 3.0 × ULN	3%	2%
Pancreatic Amylase	> 1.5 to ≤ 2.0 × ULN	5%	2%

Efficacy is based on efficacy demonstrated in clinical trials of darunavir coadministered with ritonavir

Virologic Outcome of Randomized Treatment of Treatment Naive at 192 Weeks

	Darunavir/ritonavir 800/100 mg once daily+ TDF/FTC N = 343	Lopinavir/ritonavir 800/200 mg per day+ TDF/FTC N = 346
Virologic success HIV-1 RNA < 50 copies/mL	**70%**	**61%**
Virologic failure	12%	15%
No virologic data at Week 192 window		
Reasons		
Discontinued study due to adverse event or death	5%	13%
Discontinued study for other reasons	13%	12%
Missing data during window but on study	< 1%	0%

Virologic Outcome of Randomized Treatment of Treatment Experienced at 96 Weeks

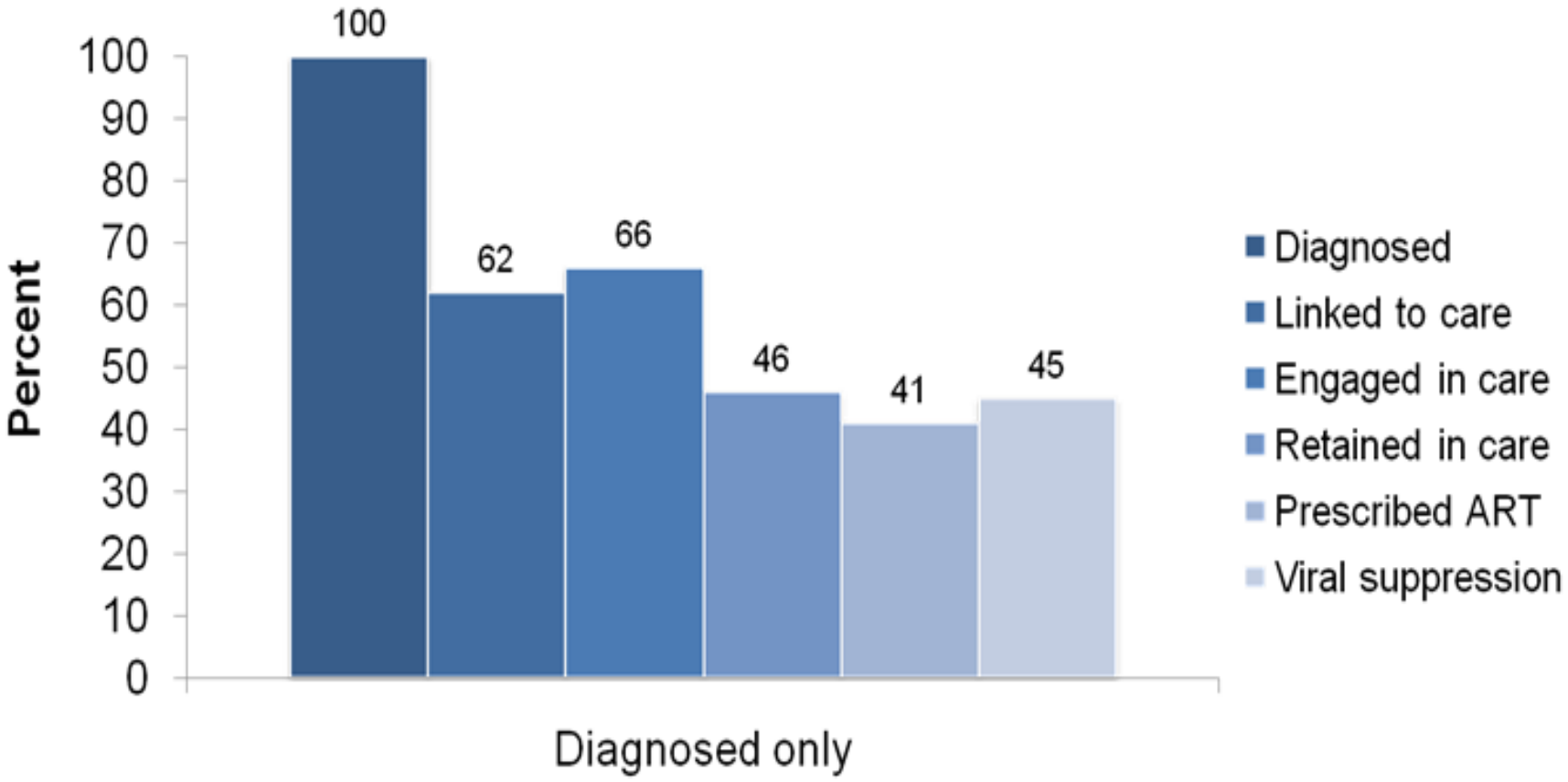
	Darunavir/ritonavir 600/100 mg twice daily+OBR N = 298	Lopinavir/ritonavir 400/100 mg twice daily + OBR N = 297
Virologic success HIV-1 RNA < 50 copies/mL	**58%**	**52%**
Virologic failure	26%	33%
No virologic data at Week 96 window		
Reasons		
Discontinued study due to adverse event or death	7%	8%
Discontinued study for other reasons	8%	7%
Missing data during window but on study	1%	< 1%

Where do these medications fit in practice

- Additional treatment options
  - Experienced and Naive
- Simplification for boosted PIs
- Issues with refrigeration
- Side effects to Ritonavir
  - Biological
  - Mental / Emotional

https://jragsdale.wordpress.com/2009/04/24/where-the-rubber-meets-the-road-putting-innovative-technology-to-work/

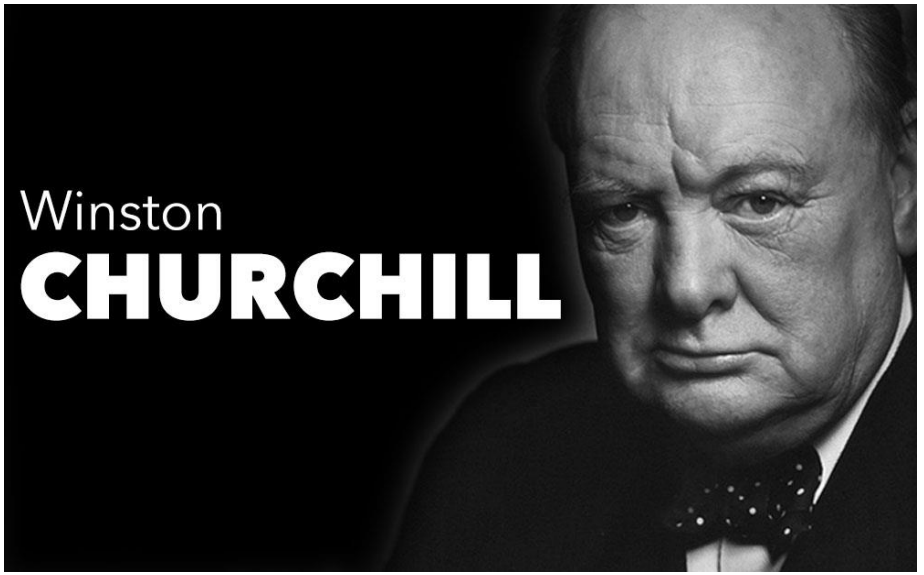
Adults and adolescents diagnosed with HIV infection, Georgia, 2011



http://dph.georgia.gov/hiv-care-continuum

Thank You

Success is not final,
failure is not fatal:
it is the courage to continue that counts.



http://ww2news.com/biographies/bio_churchill-2-2/

Drug Utilization Review Board

Motions - Votes - **New Drugs**

June 4, 2015

New Drug	Drug	PDL Status	Motion - Recommendations	Additional Comments
ANTIEMETICS	AKYNZEO (ORAL) CAPSULE	NPPA	NPPA	New Drug
	DRONABINOL (ORAL) CAPSULE	NPPA	PPA	
	MARINOL (ORAL) CAPSULE	PPA	NPPA	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.					√
2	Doad, Gurinder J.S., M.D.	√		√		
3	Fincher, Deborah W., M.S., R.Ph.			√		
4	Fowler, M. Celeste, Pharm.D.			√		
5	Lorys, Robyn Pharm.D.		√	√		
6	May, J. Russell (Rusty)			√		
7	Miller, Osgood (Drew) A. R.Ph. - **Vice**			√		
8	Rollins, Brent L., R.Ph., Ph.D.			√		
			TOTAL	7	0	1

	Board Members - Absent
1	Damon, Ann R., Pharm.D.
2	Gore, Thomas B., M.D.
3	Graham, Yolanda, M.D.
4	Shervette III, Robert E., M.D.

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Drug Utilization Review Board

Motions - Votes - **New Drugs**

June 4, 2015

New Drug	Drug	PDL Status	Motion - Recommendations	Additional Comments
PHOSPHATE BINDERS	AURYXIA (ORAL) TABLET	NPPA	NPPA	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Doad, Gurinder J.S., M.D.			√		
3	Fincher, Deborah W., M.S., R.Ph.	√		√		
4	Fowler, M. Celeste, Pharm.D.			√		
5	Lorys, Robyn Pharm.D.			√		
6	May, J. Russell (Rusty)			√		
7	Miller, Osgood (Drew) A. R.Ph. - **Vice**			√		
8	Rollins, Brent L., R.Ph., Ph.D.		√	√		
			TOTAL	8	0	0

	Board Members - Absent
1	Damon, Ann R., Pharm.D.
2	Gore, Thomas B., M.D.
3	Graham, Yolanda, M.D.
4	Shervette III, Robert E., M.D.

Drug Utilization Review Board

Motions - Votes - **New Drugs**

June 4, 2015

New Drug	Drug	PDL Status	Motion - Recommendations	Additional Comments
GAUCHER DISEASE AGENTS	CERDELGA (ORAL) CAPSULE	PPA	PPA	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.		√	√		
2	Doad, Gurinder J.S., M.D.			√		
3	Fincher, Deborah W., M.S., R.Ph.			√		
4	Fowler, M. Celeste, Pharm.D.			√		
5	Lorys, Robyn Pharm.D.	√		√		
6	May, J. Russell (Rusty)			√		
7	Miller, Osgood (Drew) A. R.Ph. - **Vice**			√		
8	Rollins, Brent L., R.Ph., Ph.D.			√		
			TOTAL	8	0	0

	Board Members - Absent
1	Damon, Ann R., Pharm.D.
2	Gore, Thomas B., M.D.
3	Graham, Yolanda, M.D.
4	Shervette III, Robert E., M.D.

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Drug Utilization Review Board

Motions - Votes - **New Drugs**

June 4, 2015

New Drug	Drug	PDL Status	Motion - Recommendations	Additional Comments
ANTI-INFECTIVE AGENTS SKIN AND SKIN STRUCTURE INFECTIONS	DALVANCE (INTRAVEN) VIAL	NPPA	NPPA	
	SIVEXTRO (INTRAVEN) VIAL	NPPA	NPPA	
	SIVEXTRO (ORAL) TABLET	NPPA	NPPA	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Doad, Gurinder J.S., M.D.			√		
3	Fincher, Deborah W., M.S., R.Ph.			√		
4	Fowler, M. Celeste, Pharm.D.		√	√		
5	Lorys, Robyn Pharm.D.			√		
6	May, J. Russell (Rusty)	√		√		
7	Miller, Osgood (Drew) A. R.Ph. - **Vice**			√		
8	Rollins, Brent L., R.Ph., Ph.D.			√		
			TOTAL	8	0	0

	Board Members - Absent
1	Damon, Ann R., Pharm.D.
2	Gore, Thomas B., M.D.
3	Graham, Yolanda, M.D.
4	Shervette III, Robert E., M.D.

Drug Utilization Review Board

Motions - Votes - **New Drugs**

June 4, 2015

New Drug	Drug	PDL Status	Motion - Recommendations	Additional Comments
IDIOPATHIC PULMONARY FIBROSIS AGENTS	ESBRIET (ORAL) CAPSULE	NPPA	NPPA	
	OFEV (ORAL) CAPSULE	NPPA	NPPA	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.	√		√		
2	Doad, Gurinder J.S., M.D.			√		
3	Fincher, Deborah W., M.S., R.Ph.		√	√		
4	Fowler, M. Celeste, Pharm.D.			√		
5	Lorys, Robyn Pharm.D.			√		
6	May, J. Russell (Rusty)			√		
7	Miller, Osgood (Drew) A. R.Ph. - **Vice**			√		
8	Rollins, Brent L., R.Ph., Ph.D.			√		
			TOTAL	8	0	0

	Board Members - Absent
1	Damon, Ann R., Pharm.D.
2	Gore, Thomas B., M.D.
3	Graham, Yolanda, M.D.
4	Shervette III, Robert E., M.D.

Drug Utilization Review Board

Motions - Votes - **New Drugs**

June 4, 2015

New Drug	Drug	PDL Status	Motion - Recommendations	Additional Comments
ANTIINFECTIVES, ANTIFUNGALS - ONYCHOMYCOSIS	GRISEOFULVIN ULTRAMICROSIZE (ORAL) TABLET	NPPA	P	
	GRIS-PEG (ORAL) TABLET	P	NPPA	
	JUBLIA (TOPICAL) SOL W/APPL	NPPA	NPPA	
	KERYDIN (TOPICAL) SOL W/APPL	NPPA	NPPA	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Doad, Gurinder J.S., M.D.			√		
3	Fincher, Deborah W., M.S., R.Ph.			√		
4	Fowler, M. Celeste, Pharm.D.			√		
5	Lorys, Robyn Pharm.D.			√		
6	May, J. Russell (Rusty)	√		√		
7	Miller, Osgood (Drew) A. R.Ph. - **Vice**			√		
8	Rollins, Brent L., R.Ph., Ph.D.		√	√		
			TOTAL	8	0	0

	Board Members - Absent
1	Damon, Ann R., Pharm.D.
2	Gore, Thomas B., M.D.
3	Graham, Yolanda, M.D.
4	Shervette III, Robert E., M.D.

Drug Utilization Review Board

Motions - Votes - **New Drugs**

June 4, 2015

New Drug	Drug	PDL Status	Motion - Recommendations	Additional Comments
ALPHA AND BETA ADRENERGIC AGONISTS	NORTHERA (ORAL) CAPSULE	NPPA	NPPA	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.		√	√		
2	Doad, Gurinder J.S., M.D.			√		
3	Fincher, Deborah W., M.S., R.Ph.			√		
4	Fowler, M. Celeste, Pharm.D.			√		
5	Lorys, Robyn Pharm.D.	√		√		
6	May, J. Russell (Rusty)			√		
7	Miller, Osgood (Drew) A. R.Ph. - **Vice**			√		
8	Rollins, Brent L., R.Ph., Ph.D.			√		
			TOTAL	8	0	0

	Board Members - Absent
1	Damon, Ann R., Pharm.D.
2	Gore, Thomas B., M.D.
3	Graham, Yolanda, M.D.
4	Shervette III, Robert E., M.D.

Drug Utilization Review Board

Motions - Votes - **New Drugs**

June 4, 2015

New Drug	Drug	PDL Status	Motion - Recommendations	Additional Comments
ANTINEOPLASTICS, CHRONIC LYMPHOCYTIC LEUKEMIA (CLL) AND NON-HODGKIN'S LYMPHOMA (NHL)	ZYDELIG (ORAL) TABLET	PPA	PPA	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.	√		√		
2	Doad, Gurinder J.S., M.D.			√		
3	Fincher, Deborah W., M.S., R.Ph.			√		
4	Fowler, M. Celeste, Pharm.D.			√		
5	Lorys, Robyn Pharm.D.		√	√		
6	May, J. Russell (Rusty)			√		
7	Miller, Osgood (Drew) A. R.Ph. - **Vice**			√		
8	Rollins, Brent L., R.Ph., Ph.D.			√		
			TOTAL	8	0	0

	Board Members - Absent
1	Damon, Ann R., Pharm.D.
2	Gore, Thomas B., M.D.
3	Graham, Yolanda, M.D.
4	Shervette III, Robert E., M.D.

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Drug Utilization Review Board

Motions - Votes - **New Drugs**

June 4, 2015

SR CLASS	Drug	PDL Status	Motion - Recommendations	Additional Comments
AMINOGLYCOSIDES FOR CYSTIC FIBROSIS	BETHKIS (INHALATION) AMPUL-NEB	P	NPPA	
	KITABIS PAK (INHALATION) AMPUL-NEB	NPPA	P	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Doad, Gurinder J.S., M.D.			√		
3	Fincher, Deborah W., M.S., R.Ph.		√	√		
4	Fowler, M. Celeste, Pharm.D.	√		√		
5	Lorys, Robyn Pharm.D.			√		
6	May, J. Russell (Rusty)			√		
7	Miller, Osgood (Drew) A. R.Ph. - **Vice**			√		
8	Rollins, Brent L., R.Ph., Ph.D.			√		
			TOTAL	8	0	0

	Board Members - Absent
1	Damon, Ann R., Pharm.D.
2	Gore, Thomas B., M.D.
3	Graham, Yolanda, M.D.
4	Shervette III, Robert E., M.D.

Drug Utilization Review Board

Motions - Votes - **New Drugs**

June 4, 2015

SR CLASS	Drug	PDL Status	Motion - Recommendations	Additional Comments
ANTIDEMENTIA AGENTS	NAMENDA XR (ORAL) CAP SPR 24	P	NPPA	WITH GRANDFATHERING

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.	√		√		
2	Doad, Gurinder J.S., M.D.			√		
3	Fincher, Deborah W., M.S., R.Ph.			√		
4	Fowler, M. Celeste, Pharm.D.		√	√		
5	Lorys, Robyn Pharm.D.			√		
6	May, J. Russell (Rusty)			√		
7	Miller, Osgood (Drew) A. R.Ph. - **Vice**			√		
8	Rollins, Brent L., R.Ph., Ph.D.			√		
			TOTAL	8	0	0

	Board Members - Absent
1	Damon, Ann R., Pharm.D.
2	Gore, Thomas B., M.D.
3	Graham, Yolanda, M.D.
4	Shervette III, Robert E., M.D.

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Drug Utilization Review Board

Motions - Votes - **New Drugs**

June 4, 2015

SR CLASS	Drug	PDL Status	Motion - Recommendations	Additional Comments
ANTIVIRALS - ANTIRETROVIRALS	COMPLERA (ORAL) TABLET 200-25-300	PPA	NPPA	GRANFATHERING FOR MEMBERS WHO ARE ALREADY ON A REGIMEN
	STRIBILD (ORAL) TABLET 150-200 MG	PPA	NPPA	
	TRIUMEQ (ORAL) TABLET 600-50-300	P	NPPA	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.		√	√		
2	Doad, Gurinder J.S., M.D.				√	
3	Fincher, Deborah W., M.S., R.Ph.				√	
4	Fowler, M. Celeste, Pharm.D.			√		
5	Lorys, Robyn Pharm.D.	√		√		
6	May, J. Russell (Rusty)			√		
7	Miller, Osgood (Drew) A. R.Ph. - **Vice**			√		
8	Rollins, Brent L., R.Ph., Ph.D.			√		
				6	2	0

	Board Members - Absent
1	Damon, Ann R., Pharm.D.
2	Gore, Thomas B., M.D.
3	Graham, Yolanda, M.D.
4	Shervette III, Robert E., M.D.

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Drug Utilization Review Board

Motions - Votes - **New Drugs**

June 4, 2015

SR CLASS	Drug	PDL Status	Motion - Recommendations	Additional Comments
BRONCHODILATORS, STEROID-SYMPATHOMIMETIC COMBINATIONS	ADVAIR HFA (INHALATION) HFA AER	P	NPPA	
	DULERA (INHALATION) HFA AER	P	NPPA	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Doad, Gurinder J.S., M.D.	√		√		
3	Fincher, Deborah W., M.S., R.Ph.			√		
4	Fowler, M. Celeste, Pharm.D.			√		
5	Lorys, Robyn Pharm.D.		√	√		
6	May, J. Russell (Rusty)			√		
7	Miller, Osgood (Drew) A. R.Ph. - **Vice**			√		
8	Rollins, Brent L., R.Ph., Ph.D.			√		
			TOTAL	8	0	0

	Board Members - Absent
1	Damon, Ann R., Pharm.D.
2	Gore, Thomas B., M.D.
3	Graham, Yolanda, M.D.
4	Shervette III, Robert E., M.D.

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Drug Utilization Review Board

Motions - Votes - **New Drugs**

June 4, 2015

SR CLASS	Drug	PDL Status	Motion - Recommendations	Additional Comments
ANTICON VULSANTS - BENZO DIAZEPINE	THE BOARD RECOMMENDED NO CHANGES 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	Doad, Gurinder J.S., M.D.			√		
3	Fincher, Deborah W., M.S., R.Ph.			√		
4	Fowler, M. Celeste, Pharm.D.			√		
5	Lorys, Robyn Pharm.D.			√		
6	May, J. Russell (Rusty)			√		
7	Miller, Osgood (Drew) A. R.Ph. - **Vice**			√		
8	Rollins, Brent L., R.Ph., Ph.D.		√	√		
			TOTAL	8	0	0

	Board Members - Absent
1	Damon, Ann R., Pharm.D.
2	Gore, Thomas B., M.D.
3	Graham, Yolanda, M.D.
4	Shervette III, Robert E., M.D.

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Important Update
DCH Decision Document

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

EFFECTIVE July 1, 2015 (see chart below)

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

ONLY DRUGS with Supplemental Rebate Offer or reviewed during the March DURB as either new to market or a change in PDL status are listed	PREFERRED AGENTS	NON-PREFERRED AGENTS
ALPHA AND BETA ADRENERGIC AGONISTS		
		NORTHERA
AMINOGLYCOSIDES FOR CYSTIC FIBROSIS		
	KITABIS	BETHKIS
		TOBI PODHALER
ANTICONVULSANTS, BENZODIAZEPINES		
	DIASTAT	
ANTIDEMENTIA AGENTS		
	EXELON TD24	NAMENDA XR
ANTIEMETICS		
	DRONABINOL	AKYNZEO
		MARINOL
ANTIINFECTIVES, ANTIFUNGALS – change effective 8.1.15		
	GRISEOFULVIN ULTRAMICROSIZE	GRIS-PEG
		JUBLIA
		KERYDIN
ANTIINFECTIVE AGENTS SKIN AND SKIN STRUCTURE INFECTIONS		
		DALVANCE
		SIVEXTRO
ANTINEOPLASTICS, CHRONIC LYMPHOCYTIC LEUKEMIA (CLL) AND NON-HODGKIN'S LYMPHOMA (NHL)		
	ZYDELIG	
ANTIVIRALS – ANTIRETROVIRALS		
	COMPLERA	
	EVOTAZ	
	NORVIR TABS 100 MG	
	STRIBILD	
	TRIUMEQ	
BRONCHODIILATORS-STEROID-SYMPATHOMIMETIC COMBINATIONS – change effective 8.1.15		
	SYMBICORT	ADVAIR HFA

ONLY DRUGS with Supplemental Rebate Offer or reviewed during the March DURB as either new to market or a change in PDL status are listed	PREFERRED AGENTS	NON-PREFERRED AGENTS
		BREO ELLIPTA
		DULERA
GAUCHER DISEASE AGENTS		
	CERDELGA	
IDIOPATHIC PULMONARY FIBROSIS AGENTS		
		ESBRIET
		OFEV
PHOSPHATE BINDERS		
	PHOSLYRA	FOSRENOL
	RENAGEL	VELPHORO
		AURYXIA

Manufacturers' Forum
Manufacturer Presentations

Dates: August 6, 2015

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

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

NorthStar HealthCare Consulting
Tara R. Cockerham, PharmD, Clinical Programs Director
Emily Baker, PharmD, BCPS, MBA, MHA, President
Afzal "Fez" Mistry, PharmD, Clinical Pharmacist

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

Drug Summary Documents
Please note that relevant, electronic materials that were provided by manufacturers were forwarded to the Drug Utilization Review Board (DURB). The manufacturers presenting at the Forum referred the audience and the readers of the materials to the prescribing information for additional information on the drug, especially in regards to safety.

Drug Presentations

I. Pfizer
Betsy Maclean, PharmD, PhD Candidate, Director, Regional Outcomes Research
Brian Gillespie, Account Director
Tom Heard, RPh, CGP, Associate Director
Cathy Preiser, Specialty Account Director

Ibrance® [EYE-brans] (palbociclib) [pal" boe sye' klib]
Indication: IBRANCE is a kinase inhibitor indicated in combination with letrozole for the treatment of postmenopausal women with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer as initial endocrine-based therapy for their metastatic disease. This indication is approved under accelerated approval based on progression-free survival (PFS). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Clinical Background and Burden of Illness: In the United States (US), breast cancer is the most common cancer affecting women, excluding skin cancer. For 2014, it was projected that there would be almost 232,670 newly diagnosed invasive cases, 62,570 new cases of carcinoma in situ, and 40,000 deaths due to this disease. It is estimated that approximately 250,000 women in the US are living with advanced breast cancer (ABC). Further, it is estimated that 30% of those initially diagnosed with early stage breast cancer will eventually progress to metastatic breast cancer (MBC). Overall, approximately 5% of new cancers in the US from 2004 to 2010 were considered ABC at diagnosis. Breast cancer is the second most common cause of cancer death in U.S. women after lung and bronchus cancers. The 5-year survival rate in patients diagnosed with ABC is 24%. Median overall survival for patients with ABC is also poor, ranging from 39.2 months in patients with de novo stage IV (metastatic) disease to 27.2 months in patients with relapsed disease.

Cost Analysis (Budget Impact Model): In a hypothetical health plan of 1,000,000 commercially insured enrollees, including palbociclib on the formulary as a first-line treatment for metastatic post-menopausal HR+/ HER2- breast cancer increases costs by $0.058 PMPM over a two-year time horizon, assuming an estimated 43 new treatment

candidates per year. The budgetary impact remained relatively modest and did not exceed $0.07 PMPM in multiple scenario and sensitivity analyses conducted.

Efficacy: The efficacy and safety/tolerability of palbociclib plus letrozole for the first-line treatment of postmenopausal women with ER+/HER2- ABC was initially established in the PALbociclib: Ongoing trials in the Management of breast cAncer (PALOMA-1) trial. This was a Phase 1/2, randomized, open-label, parallel-group, international study. The Phase I portion of the trial assessed the safety and tolerability of the combination in the target population (N=12) and established the dosing regimen of palbociclib to be used the Phase 2 portion of the trial. In the Phase 2 portion of the trial, a total of 165 postmenopausal women who had not received prior therapy for their locally advanced or metastatic ER+/HER2- breast cancer were enrolled and randomized 1:1 to treatment with the combination of palbociclib (125 mg once daily for 3 consecutive weeks of a 4 week repeating cycle) plus letrozole (2.5 mg once daily) or letrozole alone (a gold standard first-line antihormonal therapy for postmenopausal women with ER+/HER2- ABC) until disease progression, unacceptable toxicity, or withdrawal of consent. The primary study endpoint was investigator-assessed progression-free survival (PFS).
Median investigator-assessed PFS was significantly longer with the addition of palbociclib to letrozole compared to letrozole alone [20.2 vs. 10.2 months, respectively; hazard ratio (HR) 0.488, 95% CI 0.319-0.748; 1-sided p=0.0004] for the treatment of postmenopausal women with ER+/HER2- ABC in the first-line setting. There was also a positive trend in OS in favor of palbociclib plus letrozole at the time of final PFS analysis, although this analysis is not mature. (37.5 months vs 33.3 months; HR=0.813; 95% CI: 0.492-1.345; 1-sided p=0.2105).

Safety:

- Neutropenia: Neutropenia is frequently reported with IBRANCE therapy. In the randomized Phase II study, Grade 3 (57%) or 4 (5%) decreased neutrophil counts were reported in patients receiving IBRANCE plus letrozole. Febrile neutropenia can occur.
  - Monitor complete blood count prior to starting IBRANCE and at the beginning of each cycle, as well as Day 14 of the first two cycles, and as clinically indicated. For patients who experience grade 3 neutropenia, consider repeating the complete blood count monitoring one week later. Dose interruption, dose reduction or delay in starting treatment cycles is recommended for patients who develop Grade 3 or 4 neutropenia.
- Infections: Infections have been reported at a higher rate in patients treated with IBRANCE plus letrozole (55%) compared with letrozole alone (34%). Grade 3 or 4 infections occurred in 5% of patients treated with IBRANCE plus letrozole vs. no patients treated with letrozole alone. Monitor patients for signs and symptoms of infection and treat as medically appropriate.
- Pulmonary Embolism (PE): PE has been reported at a higher rate in patients treated with IBRANCE plus letrozole (5%) compared with no cases in patients treated with letrozole alone. Monitor patients for signs and symptoms of PE and treat as medically appropriate.
- Additional hematologic abnormalities: Decreases in hemoglobin (83% vs 40%), leukocytes (95% vs 26%), lymphocytes (81% vs 35%), and platelets (61% vs 16%) occurred at a higher rate in patients treated with IBRANCE plus letrozole vs letrozole alone.
- Adverse reactions: The most common all causality adverse reactions (≥10%) of any grade reported in patients treated with IBRANCE plus letrozole vs letrozole alone in the phase II study included neutropenia (75% vs 5%), leukopenia (43% vs 3%), fatigue (41% vs 23%), anemia (35% vs 7%), upper respiratory infection (31% vs 18%), nausea (25% vs 13%), stomatitis (25% vs 7%), alopecia (22% vs 3%), diarrhea (21% vs 10%), thrombocytopenia (17% vs 1%), decreased appetite (16% vs 7%), vomiting (15% vs 4%), asthenia (13% vs 4%), peripheral neuropathy (13% vs 5%), and epistaxis (11% vs 1%).
  - Grade 3/4 adverse reactions reported (≥10%) occurring at a higher incidence in the IBRANCE plus letrozole vs letrozole alone group include neutropenia (54% vs 1%) and leukopenia (19% vs 0%). The most frequently reported serious adverse events in patients receiving IBRANCE were pulmonary embolism (4%) and diarrhea (2%).

Questions and Answers
Q: When will the confirmatory trial be completed, and what is the primary endpoint in the trial?
A: In the 4th quarter of 2016; progression-free survival.

Q: Has overall survival ever been studied as the primary endpoint?
A: Not as the primary endpoint.

Q: Are any other indications being studied?

A: There are currently three ongoing studies for breast cancer in different patient populations.

Embeda® [EM-BE-DA] (morphine sulfate/naltrexone) [MORE-feen SUL-fate/nal-TREX-one HYE-droe-KLOR-ide]
Indication: EMBEDA (morphine sulfate and naltrexone hydrochloride extended release capsules) is a combination opioid agonist/opioid antagonist product indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

Societal and Economic Costs of Opioid Medication Abuse, Dependence: Total US societal and economic costs due to prescription opioid medication abuse, dependence, or misuse are substantial and are estimated to be > $50 billion annually. Several analyses have been conducted of Medicaid populations and have found that prescription opioid medication abusers, compared to non-abusers, have substantially greater annual health care costs, resource utilization, and prevalence of comorbidities. Recent data show that excess annual medical cost in Medicaid patients with diagnosed opioid abuse and dependence is ~$15,000/year.

Embeda technology and clinical data: Each EMBEDA capsule contains pellets of morphine, each with a core of sequestered naltrexone (a mu-opioid receptor antagonist). When EMBEDA is taken as directed (capsules swallowed whole or contents of the capsule sprinkled on applesauce and swallowed without chewing), the morphine is released to interact with mu-opioid receptors, and the naltrexone remains sequestered. The sequestered naltrexone is intended to have no clinical effect as it passes through the gastrointestinal (GI) tract without being absorbed. When EMBEDA is tampered with (e.g., crushing), the naltrexone is released to reduce the effects of morphine. In opioid-tolerant individuals, the absorption of naltrexone HCl may increase the risk of precipitating withdrawal.

Open-label, randomized, single-dose, 2-sequence, crossover study under fasting conditions in healthy adult volunteers (aged 19-45 years) (N=36) showed that Embeda is bioequivalent to morphine sulfate ER (Kadian®) capsules with regard to rate and extent of plasma morphine absorption. The analgesic efficacy of EMBEDA has been evaluated in one randomized, double-blind, placebo-controlled clinical trial in osteoarthritis (OA) patients with moderate to severe pain. The mean change from baseline in Brief Pain Inventory (BPI) diary average pain score (primary efficacy measure) was statistically significantly better for Embeda compared with the placebo group (-0.2 ± 1.9 vs +0.3 ± 2.1; p=0.045).

The abuse potential of EMBEDA when crushed was examined in three randomized, double-blind, single-dose, placebo- and active-controlled crossover studies in nondependent recreational opioid users when administered via oral route (Studies 1 and 2) and via intranasal route (Study 3).

Data from Study 1 showed that the oral administration of crushed Embeda was associated with significantly lower mean and median Drug Liking and Drug High scores using Visual Analog Scale (VAS) compared with immediate-release morphine (p<0.001). In this study, at least a 30% and 50% reduction in Drug Liking with crushed Embeda compared with IR morphine was observed in 72% and 56% of subjects, respectively. At least a 30% and 50% reduction in Drug High with crushed EMBEDA was observed in 56% and 31% of subjects, respectively.

In the second study (Study 2), oral administration of crushed EMBEDA resulted in significantly lower mean and median Drug Liking and Drug High (p<0.001) and Take Drug again scores (p<0.005) compared to crushed ER morphine sulfate. At least a 30% and 50% reduction in Drug Liking with crushed EMBEDA compared with crushed ER morphine was observed in 76% and 52% of subjects, respectively. At least a 30% and 50% reduction in Drug High with crushed EMBEDA was observed in 79% and 64% of subjects, respectively.

Intranasal administration of crushed EMBEDA (Study 3) was associated with statistically significantly lower mean and median Drug Liking, Drug High, and Take Drug Again scores compared with crushed ER morphine (p<0.001). In Study 3, at least a 30% and 50% reduction in Drug Liking with crushed EMBEDA compared with crushed ER morphine was observed in 63% and 59% of subjects, respectively. At least a 30% and 50% reduction in Drug High with crushed EMBEDA was observed in 59% and 37% of subjects, respectively.

A fourth study was conducted with IV administration of simulated crushed EMBEDA (Study 4). IV administration of the combination of morphine sulfate and naltrexone HCl was associated with statistically significantly lower mean and median Drug Liking and Drug High scores compared to morphine alone. However, it is unknown whether these results with simulated crushed EMBEDA predict a reduction in abuse by the IV route until additional postmarketing data are available. Abuse of EMBEDA is still possible through oral, intranasal, and intravenous routes. Data from laboratory and clinical studies may not fully predict abuse potential.

Economic Model: Economic models demonstrate that the larger costs associated with opioid abuse and dependence are driven by direct medical costs of abuse (eg, hepatitis, HIV, trauma) and related medical events such as emergency department (ED) visits, hospitalizations and substance abuse treatment. A model was developed to assess the quantitative relationship between positive subjective measures (PSM) i.e., drug liking and high from human abuse liability studies and real-world non-medical use (NMU); a PSM-NMU model. The PSM-NMU model demonstrated a significant relation between reductions in the PSM of overall drug liking and real-world NMU rates. Using this PSM-NMU model for an ER morphine ADO (i.e., EMBEDA) with a previous budget-impact model allowed an estimation of medical events avoided and cost savings based on the overall US population covered by a single payer. This analysis estimated annual reductions in NMU rates in the range of 45.1% to 98.8% and estimated health care savings in the range of $147.7 million to $323.6 million annually in the US for EMBEDA, assuming it replaced the branded non–abuse-deterrent formulation ER morphine products currently available.

Safety: EMBEDA is contraindicated in patients with significant respiratory depression, acute or severe bronchial asthma, known or suspected paralytic ileus, or hypersensitivity to morphine or naltrexone. The most common adverse reactions (> 10%) are constipation, nausea, and somnolence.

Dosage and administration: EMBEDA is available in six dosage strengths: 20 mg/0.8 mg, 30 mg/1.2 mg, 50mg/2 mg, 60 mg/2.4mg , 80 mg /3.2 mg and 100mg/4 mg. Embeda 100/4 mg capsules are only for patients in whom tolerance to an opioid of comparable potency is established. Patients considered opioid-tolerant are those taking, for 1 week or longer, at least 60 mg of morphine daily, at least 30 mg of oral oxycodone daily, at least 8 mg of oral hydromorphone daily, or an equianalgesic dose of another opioid EMBEDA is administered at a frequency of either once daily (every 24 hours) or twice daily (every 12 hours). Because steady-state plasma concentrations are approximated within 24 to 36 hours, EMBEDA dose may be adjusted every 1 to 2 days. Do not abruptly discontinue EMBEDA in a physically-dependent patient. Instruct patients to swallow EMBEDA capsules intact, or to sprinkle the capsule contents on applesauce and immediately swallow without chewing. The pellets in the capsule are not to be crushed, dissolved, or chewed. If the pellets in EMBEDA capsules are crushed, dissolved or chewed it will result in uncontrolled delivery of morphine and can lead to overdose or death. They can release sufficient naltrexone to precipitate withdrawal in opioid-dependent individuals.

Questions and Answers
Q: Why was this product taken off the market?
A: It was taken off the market due to stability issues.

II. Merck
Gelcys M. Campo, PharmD, Medical Affairs Director
Lisa Bishop, Senior Region Account Executive

Belsomra® [bell-SOM-rah] (suvorexant)
Indication: BELSOMRA is an orexin receptor antagonist indicated for the treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance.

Dosage and Administration: Use the lowest dose effective for the patient. The recommended dose for BELSOMRA is 10 mg, taken no more than once per night and within 30 minutes of going to bed, with at least 7 hours remaining before the planned time of awakening. If the 10-mg dose is well tolerated but not effective, the dose can be increased. The maximum recommended dose of BELSOMRA is 20 mg once daily.

Contraindications: BELSOMRA is contraindicated in patients with narcolepsy.

Warnings and Precautions: BELSOMRA is a CNS depressant that can impair daytime wakefulness, even when used as prescribed. BELSOMRA can impair driving skills and may increase the risk of falling asleep while driving. Coadministration with other CNS depressants (eg, benzodiazepines, opioids, tricyclic antidepressants, alcohol) increases the risk of CNS depression. Patients should be advised not to consume alcohol in combination with BELSOMRA because of additive effects. The risk of next-day impairment, including impaired driving, is increased if BELSOMRA is taken with less than a full night of sleep remaining, if a higher than the recommended dose is taken, if coadministered with other CNS depressants, or if coadministered with other drugs that increase blood levels of BELSOMRA. The failure of insomnia to remit after 7 to 10 days of treatment may indicate the presence of a primary

psychiatric and/or medical illness that should be evaluated. In clinical studies, a dose-dependent increase in suicidal ideation was observed in patients taking BELSOMRA, as assessed by questionnaire.

Controlled Substance: BELSOMRA contains suvorexant, a Schedule IV controlled substance.

Efficacy: Controlled Clinical Studies: BELSOMRA was evaluated in 3 clinical trials in patients with insomnia characterized by difficulties with sleep onset and sleep maintenance. Two similarly designed, 3-month, randomized, double-blind, placebo-controlled, parallel-group studies were conducted (Study 1 and Study 2). BELSOMRA 10 mg and 20 mg were superior to placebo for sleep latency and sleep maintenance, as assessed objectively by polysomnography. Effects on Driving: Two randomized, double-blind, placebo- and active-controlled, 4-period crossover studies evaluated the effects of nighttime administration of BELSOMRA on next-morning driving performance 9 hours after dosing in 24 healthy elderly subjects (≥65 years old, mean age 69 years; 14 men, 10 women) who received BELSOMRA 15 mg and 30 mg, and 28 non-elderly subjects (mean age 46 years; 13 men, 15 women) who received BELSOMRA 20 mg and 40 mg. Testing was conducted after 1 night and after 8 consecutive nights of treatment with BELSOMRA at these doses. The primary outcome measure was change in Standard Deviation of Lane Position (SDLP), a measure of driving performance, assessed using a symmetry analysis. The analysis showed clinically meaningful impaired driving performance in some subjects. Four placebo-controlled trials evaluated the effects of nighttime administration of BELSOMRA on next-day memory and balance using word learning tests and body sway tests, respectively. Three trials showed no significant effects on memory or balance compared to placebo. In a fourth trial in healthy non-elderly subjects, there was a significant decrease in word recall after the words were presented to subjects in the morning following a single dose of BELSOMRA 40 mg, and there was a significant increase on body sway area in the morning following a single dose of BELSOMRA 20 mg or 40 mg. Middle-of-the-Night Safety in Elderly Subjects: A double-blind, randomized, placebo-controlled trial evaluated the effect of a single dose of BELSOMRA on balance, memory, and psychomotor performance in healthy elderly subjects (n=12) after being awakened during the night. Nighttime dosing of BELSOMRA 30 mg resulted in impairment of balance (measured by body sway area) at 90 minutes as compared to placebo. Memory was not impaired, as assessed by an immediate and delayed word recall test at 4 hours post-dose. Rebound Effects: In 3-month controlled safety and efficacy trials (Study 1, Study 2), rebound insomnia was assessed following discontinuation of BELSOMRA relative to placebo and baseline in non-elderly adult patients receiving BELSOMRA 40 mg or 20 mg and in elderly patients receiving BELSOMRA 30 mg or 15 mg. No clear effects were observed on measures of sleep onset or maintenance. Withdrawal Effects: In 3-month controlled safety and efficacy trials (Study 1, Study 2), withdrawal effects were assessed following discontinuation in non-elderly adult patients who received BELSOMRA 40 mg or 20 mg and elderly patients who received BELSOMRA 30 mg or 15 mg. The analysis showed no clear evidence of withdrawal in the overall study population based on assessment of patient responses to the Tyrer Withdrawal Symptom Questionnaire or assessment of withdrawal-related adverse events following the discontinuation of BELSOMRA. Respiratory Safety: A randomized, placebo controlled, double-blind, crossover trial in healthy non-elderly subjects (n=12) evaluated the respiratory-depressant effect of BELSOMRA (40 mg and 150 mg) after 1 night of treatment. At the doses studied, BELSOMRA had no respiratory depressant effect as measured by oxygen saturation.

Selected Adverse Events: The incidence of discontinuation due to adverse reactions for patients treated with 15 mg or 20 mg of BELSOMRA was 3% compared to 5% for placebo. No individual adverse reaction led to discontinuation at an incidence ≥1%. In clinical trials of patients with insomnia treated with BELSOMRA 15 mg or 20 mg, the most common adverse reaction (reported in 5% or more of patients treated with BELSOMRA and at least twice the placebo rate) was somnolence (BELSOMRA 7%; placebo 3%).

Questions and Answers

Q: When is the medication recommended to be taken at night?
A: Thirty minutes prior to at least 7 hours before anticipated wake time.

Q: How long should a patient be treated for?
A: There is no information in the product label with respect to duration of treatment. Most clinical trials were short-term trials.

Q: How should patients receiving benzodiazepines for other diagnoses be treated?
A: Concomitant use with benzodiazepines is not recommended.

Q: Is this medication eligible for the Beers criteria?
A: There is no information regarding the Beers criteria yet, as the medication has not been on the market long enough.

III. AstraZeneca
Rana Rittgers-Simonds, RD, Regional Account Director
Chris Tibbetts, PharmD, BCOP, Medical Science Liaison
Julie Huber, Regional Clinical Account Director

Lynparza™ [lin-par-zah] (olaparib) [oh-lap-a-rib]
Indication: Monotherapy in patients with deleterious or suspected deleterious germline *BRCA* mutated (as detected by an FDA-approved test) advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy. The indication is approved under accelerated approval based on objective response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Disease State Background: Epithelial ovarian cancer is the most lethal of the gynecologic malignancies and the fifth-leading cause of cancer-related death among women in the United States. Ovarian cancer (OC) is difficult to diagnose in its early stages and, as a result, approximately 75% of patients present with advanced disease and most have tumor recurrence despite treatment with debulking surgery and chemotherapy. Women with BRCA1 susceptibility genes have an approximate 40% risk of developing ovarian cancer by the age of 70 years and women with BRCA2 mutations have an approximate 18% risk. Women with BRCA-mutated advanced ovarian cancer have limited treatment options besides chemotherapy.

Key Product Characteristics: LYNPARZA is a first in-class oral PARP inhibitor. When administered at recommended doses, LYNPARZA demonstrated an objective response rate of 34% with a median duration of response of 7.9 months as a monotherapy in patients with advanced ovarian cancer who are positive for a deleterious or suspected deleterious germline BRCA (gBRCA) mutation and who have had 3 or more prior lines of chemotherapy. The recommended dose of LYNPARZA is 400 mg (eight 50mg capsules) taken twice daily, for a total daily dose of 800 mg. The most common adverse reactions observed (Grades 1-4) in >20% of patients included anemia, nausea, fatigue (including asthenia), vomiting, diarrhea, dysgeusia dyspepsia, headache, decreased appetite, nasopharyngitis/pharyngitis/URI, cough, arthralgia/musculoskeletal pain, myalgia, back pain, dermatitis/rash and abdominal pain/discomfort. Myelodysplastic syndrome/Acute Myeloid Leukemia (MDS/AML) were reported in <1% of patients treated with LYNPARZA. The majority of MDS/AML cases were fatal and the duration of therapy in patients who developed secondary MDS/AML varied from <6 months to >2 years. Pneumonitis, including fatal cases also occurred in <1% of patients treated with LYNPARZA.

Questions and Answers
Q: Has the confirmatory trial started?
A: Yes.

Q: Are any other indications being investigated?
A: Olaparib is being explored in other BRCA-associated cancers.

Q: Are clinicians potentially using olaparib in combination with other chemotherapeutic agents?
A: There is no data to support concomitant usage. Clinicians may be using concomitantly with other chemotherapeutic agents in an extremely small population, but additive adverse effects would be a concern when administrated with other myelosuppressive agents.

IV. Novartis
Julia Compton, PharmD, Regional Account Medical Science Liaison, Director
Russ Rainwater, PharmD, MBA, Medical Science Liaison
Fred McClellan, MBA, Account Manager

Cosentyx® (secukinumab)
Indication: Cosentyx is indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy.

Mechanism of Action: Secukinumab is a human IgG1 monoclonal antibody that selectively binds to the interleukin-17A (IL-17A) cytokine and inhibits its interaction with the IL-17 receptor. IL-17A is a naturally occurring cytokine that is involved in normal inflammatory and immune responses. Secukinumab inhibits the release of proinflammatory cytokines and chemokines and is considered to play a key role in the pathogenesis of plaque psoriasis.

Dosage and Administration: The recommended dose is 300 mg by subcutaneous injection at Weeks 0, 1, 2, 3, and 4 followed by 300 mg every 4 weeks. Each 300 mg dose is given as 2 subcutaneous injections of 150 mg. For some patients, a dose of 150 mg may be acceptable. Cosentyx is intended for use under the guidance and supervision of a physician. Patients may self-inject after proper training in subcutaneous injection technique using the Sensoready pen or prefilled syringe and when deemed appropriate. The lyophilized powder for reconstitution is for healthcare provider use only. Administer each injection at a different anatomic location (such as upper arms, thighs or any quadrant of abdomen) than the previous injection, and not into areas where the skin is tender, bruised, erythematous, indurated or affected by psoriasis. Administration of Cosentyx in the upper, outer arm may be performed by a caregiver or healthcare provider. The “Instructions for Use” insert contains more detailed instructions on the preparation and administration of Cosentyx for each presentation (Sensoready pen, prefilled syringe, and lyophilized powder in vial for reconstitution).

Efficacy: The efficacy and safety of Cosentyx has been evaluated in 4 multicenter, randomized, double-blind, placebo controlled trials in a total of 2403 enrolled subjects 18 years of age and older with plaque psoriasis who had a minimum body surface area involvement of 10%, and Psoriasis Area and Severity Index (PASI) score greater than or equal to 12, and who were candidates for phototherapy or systemic therapy. Across all treatment groups the baseline PASI score ranged from 11 to 72 with a median of 20 and the baseline IGA score ranged from “moderate” (62%) to “severe” (38%). Of the 2077 plaque psoriasis subjects who were included in the placebo-controlled trials, 79% were biologic-naïve (have never received a prior treatment with biologics) and 45% were non-biologic failures (failed to respond to a prior treatment with non-biologics therapies). Of the subjects who received a prior treatment with biologics, over one-third were biologic failures. Approximately 15 to 25% of trial subjects had a history of psoriatic arthritis. The trials demonstrated efficacy of Cosentyx 300 mg and Cosentyx 150mg at Week 12 based on co-primary endpoints including the proportion of subjects who achieved a reduction in PASI score of at least 75% (PASI 75) from baseline and treatment success (clear or almost clear) on the Investigator’s Global Assessment modified 2011 (IGA). Other evaluated outcomes (key secondary endpoints) included the proportion of subjects who achieved a reduction in PASI score of at least 90% (PASI 90) from baseline at Week 12, maintenance of efficacy to Week 52, and improvements in itching, pain, and scaling at Week 12 based on the Psoriasis Symptom Diary.
Trial 1 (ERASURE): Percentage of subjects achieving a PASI 75 response at Week 12 was statistically significant with Cosentyx 300 mg and 150 mg compared to placebo in 82% (200/245) and 71% (174/245) versus 4% (11/248) of subjects, respectively ($p<0.001$ for each Cosentyx dose).
Trial 2 (FIXTURE): Percentage of subjects achieving a PASI 75 response at Week 12 was statistically significant with Cosentyx 300 mg and 150 mg compared to placebo in 76% (249/327) and 67% (219/327) versus 5% (16/326) of subjects, respectively ($p<0.001$ for each Cosentyx dose).
Trial 3 (FEATURE): Percentage of subjects achieving a PASI 75 response at Week 12 was statistically significant with Cosentyx 300 mg and 150 mg compared to placebo in 75% (44/59) and 69% (41/59) versus 0% (0/59) of subjects, respectively ($p<0.0001$ for each Cosentyx dose).
Trial 4 (JUNCTURE): Percentage of subjects achieving a PASI 75 response at week 12 was statistically significant with Cosentyx 300 mg and 150 mg compared to placebo in 87% (52/60) and 70% (43/61) versus 3% (2/61) of subjects, respectively ($p< 0.0001$ for each Cosentyx dose).

Adverse Event Profile: The most common adverse reactions (>1%) during the 12-week placebo-controlled period of the placebo-controlled trials for Cosentyx were nasopharyngitis, diarrhea, and upper respiratory tract infection.

Contraindications: Serious hypersensitivity reaction to secukinumab or to any of the excipients.

Warnings and Precautions include risk of infections, hypersensitivity reactions, recommendation against administering to patients with active tuberculosis, and additional caution in latex-sensitive individuals and patients with Crohn’s disease.

Questions and Answers
Q: Are other indications being studied?
A: Phase III data for a few indications (psoriatic arthritis and ankylosing spondylitis) has been submitted to the FDA.

Q: Is the first dose given in the prescriber's office?
A: Yes, and subsequent doses can be given at home.

Q: What was the rate of infection compared to patients treated with biologic active control?
A: In the clinical trial, patients treated with Cosentyx experienced increased *Candida* infections, for which they received amphotericin lozenges and did not require discontinuation.

V. Daiichi-Sankyo

Edward Paiewonsky, PharmD, Medical Science Liaison
Jeff Hardin, Regional Account Manager

Savaysa® [sa vavé sah] (edoxaban) [e dox´ a ban]

Savaysa is a once-daily Factor Xa inhibitor indicated to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation (NVAF). The indication for SAVAYSA contains a limitation of use for NVAF: SAVAYSA should not be used in patients with creatinine clearance (CrCL) greater than 95 mL/min because of an increased risk of stroke compared to warfarin. SAVAYSA is also indicated for the treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) following 5 to 10 days of initial therapy with a parenteral anticoagulant. SAVAYSA is available in doses of 30 and 60 mg.

SAVAYSA offers convenient once-daily dosing with no mealtime restrictions and requires no routine anticoagulation blood monitoring.

SAVAYSA is a substrate of the P-gp transporter. For both indications, avoid concomitant use of SAVAYSA with the P-gp inducer rifampin. For P-gp inhibitors, in patients with NVAF, no SAVAYSA dose reduction is recommended. In patients with DVT/PE, SAVAYSA dose should be reduced to 30 mg when used concomitantly with certain P-gp inhibitors. Coadministration of SAVAYSA with anticoagulants, antiplatelets, and thrombolytics may increase the risk of bleeding.

Specific to the NVAF indication, SAVAYSA was evaluated in ENGAGE AF-TIMI 48, a multi-national, double-blind, noninferiority study which included over 21,000 patients with NVAF who had an average CHADS2 score of 2.8, and measured against a warfarin arm with a mean time in therapeutic range (TTR) of 65% (based on an international normalized ratio [INR] of 2.0 to 3.0). In the study, 77% of NVAF patients in ENGAGE AF-TIMI 48 had creatinine clearance less than or equal to 95 mL/min. In patients with CrCL less than or equal to 95 mL/min, SAVAYSA was superior to warfarin in demonstrating fewer major bleeding events (3.1%/year vs 3.7%/year, respectively; [HR (95% CI): 0.84 (0.73, 0.97)]). In addition, the annual rates of intracranial hemorrhage were 0.5% for SAVAYSA and 1.0% for warfarin and fatal bleeding annual rates were 0.2% for SAVAYSA and 0.4% for warfarin, however there were higher annual rates of major gastrointestinal bleeding (1.8% for SAVAYSA and 1.3% for warfarin).

ENGAGE AF-TIMI 48 showed that the annual rate of stroke or systemic embolism for once-daily SAVAYSA was 1.2% compared with 1.8% for warfarin in patients with CrCL less than or equal to 95 mL/min [HR (95% CI): 0.68 (0.55, 0.84)]. The annual rates of ischemic stroke in the indicated population were similar (0.9% for SAVAYSA vs 1.1% for warfarin). In addition, the annual rate of cardiovascular death in the indicated population was 2.95% for SAVAYSA and 3.59% for warfarin [HR (95% CI): 0.82 (0.72, 0.93)].

Specific to the indication for treatment of venous thromboembolism (VTE), SAVAYSA was evaluated in Hokusai-VTE, a clinical trial of 8240 patients with acute symptomatic VTE. For the primary safety endpoint in Hokusai-VTE, SAVAYSA was superior to warfarin in demonstrating less clinically relevant bleeding (8.5% vs 10.3%, respectively; [HR (95% CI): 0.71, 0.94; p=0.004]). The rate of major bleeding was similar to warfarin, with 1.4% of SAVAYSA patients experiencing a major bleeding event compared with 1.6% of warfarin patients. For the primary efficacy endpoint of symptomatic recurrent VTE, SAVAYSA was noninferior to a warfarin arm with a median TTR of 65.6% (based on an INR of 2.0 to 3.0). Rates of symptomatic recurrent VTE were 3.2% among patients taking SAVAYSA vs 3.5% among patients taking warfarin [HR (95% CI): 0.89 (0.70, 1.13)].

There are 2 approved doses for SAVAYSA, and clinicians will select the most appropriate dose based on the indication. SAVAYSA is not recommended in patients with CrCL less than 15 mL/min for both indications; and should not be used for NVAF patients with a CrCL > 95 mL/min. In a cost-effectiveness analysis using data from the indicated population in ENGAGE AF-TIMI 48, SAVAYSA was shown to be highly cost-effective relative to warfarin. The model

estimated healthcare costs associated with edoxaban and warfarin treatment from a lifetime perspective, which is beyond the 2.8 years trial duration. The financial impact to a healthcare plan one year after adding SAVAYSA to the formulary for SPAF was evaluated in a budget impact analysis. Assuming a 3% market share for SAVAYSA in the first year after adoption and using the current WAC prices for OACs, the incremental budget impact was estimated to be $0.004 per member per month. Once-daily SAVAYSA can provide Medicaid patients with the combination of significantly less major bleeding vs warfarin and reduced risk of stroke or systemic embolism for NVAF patients with creatinine clearance less than or equal to 95 mL/min vs warfarin, and provide a treatment option for patients with DVT or PE following initial therapy with a parenteral anticoagulant for 5-10 days. You can offer these patients a combination of significantly less clinically relevant bleeding vs warfarin and noninferior efficacy to warfarin in treating DVT and PE. Overall, SAVAYSA has convenient once-daily dosing that has no mealtime restrictions, and requires no routine anticoagulation blood monitoring.

SAVAYSA has 3 **Boxed WARNINGS**, including reduced efficacy in NVAF patients with creatinine clearance greater than 95 mL/min, premature discontinuation of SAVAYSA and increased risk of ischemic events, and risk of epidural or spinal hematomas in patients treated with SAVAYSA who are receiving neuraxial anesthesia or undergoing spinal puncture. SAVAYSA is contraindicated in patients with active pathological bleeding. SAVAYSA increases the risk of bleeding and can cause serious and potentially fatal bleeding. There is no established way to reverse the anticoagulant effects of Savaysa. Savaysa is not recommended in patients with mechanical heart valves or moderate to severe mitral stenosis. The most common adverse reactions include bleeding, anemia, rash, and abnormal liver function tests.

Questions and Answers
Q: Is the indication for DVT prophylaxis being investigated?
A: Not at the moment.

Q: What are considered the advantages of edoxaban over other novel oral anticoagulants?
A: Dosed once-daily with or without food. There is one set dose without any dose titration. Moreover, no CYP450-related dose reductions are required.

Q: Are there any head-to-head studies planned with other novel oral anticoagulants?
A: Not at the moment.

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GEORGIA DEPARTMENT OF COMMUNITY HEALTH

Manufacturers' Forum

ANNOUNCEMENT

NorthStar HealthCare Consulting
Georgia Department of Community Health

On behalf of the Georgia Department of Community Health (DCH) and in service to the Georgia Medicaid Fee-for-Service (FFS) Drug Utilization Review Board (DURB), NorthStar HealthCare Consulting (NHC), in conjunction with OptumRx, announces the Manufacturers' Forum occurring Thursday, November 5, 2015.

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

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

Appointments: ***The Manufacturers' Forum is by appointment only*****.** Appointments may be requested and will be scheduled ***after*** the Drugs Under Review are posted to the DCH website at **http://dch.georgia.gov/durb-meeting-information** approximately 30 days prior to the Forum. Manufacturers with drugs up for review at the current DURB meeting will be granted preference when seeking appointments. All requests for appointments must be made in writing to **GAMedicaid@nhc-llc.com** and include the drug name. New drug entities are generally not reviewed by the DURB until the drug has been on the market for at least 6 months.

Guidelines for Participation:

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

Comments and Inquiries:

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

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

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GEORGIA DEPARTMENT OF COMMUNITY HEALTH

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

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

Ongoing Opportunity:

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

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

Presentation Opportunity:

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

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

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

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

Opportunity to Appeal to GDCH:

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

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

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2015

Upcoming Meetings

Drug Utilization Review Board Meeting

2 Peachtree Street, N.W.

5th Floor Board Room

Atlanta, Georgia 30303

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

Manufacturers' Forum

NorthStar HealthCare Consulting

1121 Alderman Drive

Suite 112

Alpharetta, Georgia 30005

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

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Drug Utilization Review Board

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