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

December 15, 2015

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GEORGIA DEPARTMENT OF COMMUNITY HEALTH

DRUG UTILIZATION REVIEW BOARD MEETING
AGENDA
2 Peachtree Street - 5th Floor DCH Board Room
Atlanta, Georgia 30303
Tuesday, December 15, 2015
9:30 a.m. to 1:30 p.m.

CALL TO ORDER	*Drew Miller, RPh, Chair*
COMMENTS FROM THE DEPARTMENT	*Peter D'Alba, RPh, Pharmacy Director*
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**

●Avycaz, Zerbaxa	●Novoeight
●Cholbam	●Movantik
●Cresemba	●Natpara
●Farydak	●Nplate
●Ixinity	●Signifor LAR

➢ **Non-Supplemental Rebate Class Reviews**

➢ **Follow-Up Items**

➢ **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
Thursday, September 24, 2015

MEMBERS PRESENT

Osgood (Drew) A. Miller, R.Ph., Chair
Gurinder J.S. Doad, M.D., Vice-Chair
Deborah W. Fincher, M.S., R.Ph.
M. Celeste Fowler, Pharm.D.
Thomas B. Gore, M.D.
Yolanda P. Graham, M.D.
Robyn Lorys, Pharm.D.
J. Russell May, Pharm.D.
Brent L. Rollins, R.Ph., Ph.D.
Robert E. Shervette III, M.D.

MEMBERS ABSENT

Mia Avery, Pharm.D.
Ann R. Damon, Pharm.D.

Staff

Janet Carson, M.D., Assistant Chief, Performance and Quality Outcomes
Peter D'Alba, R.Ph., Pharmacy Director, Pharmacy Services
Turkesia Robertson-Jones, Pharm.D., Pharmacy Operations Manager, Pharmacy Services
Patricia Z. Jeter, MPA, R.Ph., Pharmacist, Pharmacy Services
Rose Marie Duncan, MBA, Program Associate, Pharmacy Services
Cherini Ghobrial, Pharm.D. Candidate

NorthStar HealthCare Consulting

Tara R. Cockerham, Pharm.D., Clinical Programs Director
Afzal "Fez" Mistry, Pharm.D., Clinical Pharmacist

Catamaran

Kelly Coleman, 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

Amerigroup

Kelli W. Ferrell, R.Ph., MS

Call to Order

The Drug Utilization Review Board (DURB/DUR Board/Board) held its third meeting for the calendar year on September 24, 2015. The Chair, Osgood (Drew) A. Miller, R.Ph., called the meeting to order at 9:35am.

Comments from the Department

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

1. New Pharmacy Director – Peter D'Alba, R.Ph., was introduced and welcomed as the new Pharmacy Director, Pharmacy Services, Department of Community Health.
2. DUR Board Members – Thomas B. Gore, M.D., and Ann R. Damon, Pharm.D., were thanked for their service. New Board member, Yolanda P. Graham, M.D., was welcomed.
3. Pharmacy Benefits Manager – Catamaran completed a merger with OptumRx and will operate under the name, OptumRx.
4. Pharmacy Students and Resident – A welcome was extended to the following students: Cherini Ghobrial (Florida A&M University), Sabina Kurian (UGA), Amanda Kyle (UGA), Jessie Signorelli, Pharm.D. (UGA/Georgia Regional Medical Center), and Amit Jain (PCOM).
5. Presentation – Janice Carson, M.D., Assistant Chief, Performance and Quality Outcomes, presented a presentation on Performance Measurements (Attachment A). Comments and questions were received on the following: Georgia Families (Managed Care Program) vs. Fee-For-Service (Aged, Blind, Disabled, no case management), claims data (hospital, providers, pharmacy), transportation and formulary issues, HPV data (HEIDIS measure-girls only), no current penalties (if benchmarks not met), transitional care, and electronic medical records.

Minutes from the Previous Meeting

Chair Miller asked for corrections or changes to the minutes from the June 4, 2015 meeting. There were no corrections. A motion was made (J. Russell May, Pharm.D.), seconded (Thomas B. Gore, M.D.) and carried to approve the minutes as written.

External Comments Session

There were no external comments.

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 OptumRx. Pharmacy students, Cherini Ghobrial (Florida A&M University), Sabina Kurian (UGA), Amanda Kyle (UGA), Jessie Signorelli, Pharm.D. (UGA/Georgia Regional Medical Center), and Amit Jain (PCOM) attended the closed session with Board members. A motion was made by Robyn Lorys, Pharm.D., and seconded to adjourn the open session and approve the closed session. There was a unanimous vote approving the closed session. The Chairman, Drew Miller, R.Ph., adjourned the open session at approximately 10:20 am, at which time members took a break then reconvened for the executive (closed) session.

Executive Session

The Executive Session was held from 10:27am to 11:20am.

Reconvening of Open Session

The DUR Board reconvened for the open session at 11:38am.

Manufacturers' Forum

Afzal "Fez" Mistry, Pharm.D., reviewed information regarding the Manufacturers' Forum that was provided in the Manufacturer Information section in the DUR Board binder. A total of five (5) manufacturers participated or provided information regarding the following drugs discussed at the September 2015 DURB meeting:

Manufacturers	Drugs
Pfizer	Ibrance, Embeda
Merck	Belsomra
AstraZeneca	Lynparza
Novartis	Cosentyx
Daiichi-Sankyo	Savaysa

There were no questions or comments.

The next forum will be held on Thursday, November 5, 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
Sedative Hypnotics	*Belsomra*	Afzal Mistry, Pharm.D.
Biologic Immunomodulators	*Cosentyx*	Afzal Mistry, Pharm.D.
Attention Deficit Hyperactivity Disorder (ADHD) Agents	*Evekeo*	Afzal Mistry, Pharm.D.
Antineoplastics, Breast Cancer	*Ibrance*	Afzal Mistry, Pharm.D.
Antineoplastics, Thyroid Cancer	*Lenvima*	Afzal Mistry, Pharm.D.
Antineoplastics, Ovarian Cancer	*Lynparza*	Afzal Mistry, Pharm.D.
Thrombopoietin Receptor Agonists	*Nplate*	Afzal Mistry, Pharm.D.
Anticoagulants	*Savaysa*	Tara Cockerham, Pharm.D.
Dermatologics, Acne Rosacea	*Soolantra*	Tara Cockerham, Pharm.D.
Morquio A Syndrome	*Vimizim*	Tara Cockerham, Pharm.D.

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

- Belsomra – dosing considerations due to increased concentrations in patients with increased BMI; PA criteria-no concomitant use of benzodiazepines
- Evekeo – FDA approved ages; prior approval not required for preferred agents < 21years; less appetite suppression
- Lenvima – limited to specialty pharmacy only; PA criteria would include side effects and appropriate use
- Nplate – durable platelet response in splenectomy vs. nonsplenectomy; postpone recommendation
- Savaysa – beginning to see newer agents recommended over warfarin; comparison data published; may see warfarin just as effective when patients are in range.
- Soolantra – topical use of Afrin for rosacea; potential for nasopharyngitis; genetic and environmental factors associated with etiology

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

Non-Supplemental Rebate Drugs – New Clinical Information Review

Clinical updates to the Non-Supplemental Rebate categories were listed in the Non-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
Antiinfectives, Fluoroquinolones
Antiinfectives, Macrolides
Antiinfectives, Tetracyclines
Antiparkinson Agents
Colony Stimulating Factors
Cough and Cold Prescription (Rx) Products
Dermatologics, Acne Vulgaris
Dermatologics, Corticosteroids-Medium Potency
Immunosuppressive Agents for Organ Transplant Rejection
Nasal Antiallergics

The Board made the following comments:

- Antivirals, Influenza – Review 2014 data to determine if flu shots and flu testing are given before these medications are administered. Put an educational emphasis on the appropriate prevention of the disease state.
- Respiratory, Leukotriene Modifiers – Look at updated guidelines for appropriate use of montelukast in allergic rhinitis.

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

DCH Decisions

DCH Decisions from the June 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

The following future agenda items were noted:

- Future meeting with CMOs for discussion on PA and Formulary

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, December 15, 2015

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

  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 B.

New Drugs and Non-Supplemental Rebate Classes

Sedative Hypnotics

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

including not allowing for concomitant use with benzodiazepines, for ***Belsomra (Oral) Tablet***.

Biologic Immunomodulators

The DUR Board recommended ***Preferred*** status with ***Prior Authorization, including step therapy with Humira, for Cosentyx (Subcutaneous) Syringe/Pens***.

Attention Deficit Hyperactivity Disorder (ADHD)

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

Antineoplastics, Breast Cancer

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

Antineoplastics, Thyroid Cancer

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

Antineoplastics, Ovarian Cancer

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

Thrombopoietin Receptor Agonists

The DUR Board recommended to ***Postpone*** for follow-up and further review for ***Nplate (Subcutaneous) Vial***.

Anticoagulants

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

Dermatologics, Acne Rosacea

The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Soolantra (Topical) Cream***.

Metabolic Enzymes

The DUR Board recommended ***Preferred*** status with ***Prior Authorization*** for ***Vimizim (Intravenous) Vial***.

Antianginal Agents

The DUR Board recommended ***Preferred*** status for ***Nitroglycerin (Translingual) Spray*** and ***Non-Preferred*** status with ***Prior Authorization*** for ***Nitromist (Translingual) Spray***.

Antiinfectives, Cephalosporins

The DUR Board recommended ***Preferred*** status for ***Ceftin (Oral) Suspension***, ***Preferred*** status with ***Prior Authorization and Quantity Limit of 1*** for ***Suprax (Oral) Capsule*** and ***Non-Preferred*** status with ***Prior Authorization*** for ***Cefaclor (Oral) Suspension, Cefixime (Oral) Suspension and Suprax (Oral) Suspension***.

Antiinfectives, Tetracyclines

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

Antiparkinson Agents

The DUR Board recommended ***Preferred*** status for ***Carbidopa (Oral) Tablet*** and ***Non-Preferred*** status with ***Prior Authorization*** for ***Lodosyn (Oral) Tablet***.

Antivirals, Genital Herpes Simplex Virus (HSV)

The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Acyclovir (Topical) Ointment 5%***.

Antivirals, Influenza Agents

The DUR Board recommended ***No Changes*** in the class and recommended a retrospective drug utilization review and intervention to educate prescribers of influenza agents on prevention of influenza, including influenza vaccination, and influenza testing.

Contraceptives

The DUR Board recommended ***Preferred*** status for ***Alyacen (Oral) Tablet, Cyclafem (Oral) Tablet, Dasetta (Oral) Tablet, Femcon FE Chew (Oral) Tablet Chewable, Nor-QD (Oral) Tablet, Nortrel (Oral) Tablet and Pirmella (Oral) Tablet*** and ***Non-Preferred*** status with ***Prior Authorization*** for ***Aranelle (Oral) Tablet***, ***Junel FE 24 (Oral) Tablet, Leena (Oral) Tablet, Lomedia 24 FE (Oral) Tablet, Ortho-Novum (Oral) Tablet, Ortho Tri-Cyclen (Oral) Tablet and Trinessa (Oral) Tablet***.

Cough and Cold Prescription (Rx) Products

The DUR Board recommended ***Preferred*** status for ***Brompheniramine/Pseudoephedrine/ Dextromethorphan (DM) (Oral) Syrup*** on the Cough and Cold PDL located at https://www.mmis.georgia.gov/portal/PubAccess.Pharmacy/Other%20Documents/tabId/86/Default.aspx and scroll to Cough and Cold PDL.

Dermatologics, Acne Vulgaris

The DUR Board recommended ***Preferred*** status for ***Atralin (Topical) Gel, Benzaclin (Topical) Gel, Epiduo (Topical) Gel, Retin-A (Topical) Gel and Tretinoin (Topical) Cream*** and ***Non-Preferred*** status with ***Prior Authorization*** for ***Sodium Sulfacetamide-Sulfur (Topical) Cleanser/Cream, Tretinoin (Topical) Gel and Tretinoin Microsphere (Topical) Gel***.

Dermatologics, Corticosteroids

The DUR Board recommended ***Preferred*** status for ***Amcinonide (Topical) Cream, Desonide (Topical) Cream/Lotion/Ointment, Mometasone Furoate (Topical) Cream/Ointment/Solution Triamcinolone Acetonide (Topical) Lotion*** and ***Non-Preferred*** status with ***Prior Authorization*** for ***Amcinonide (Topical) Lotion, Clobetasol Emollient (Topical) Cream, Clobetasol Propionate (Topical) Cream, Fluocinonide (Topical) Ointment, Hydrocortisone Valerate (Topical) Cream/Ointment, Kenalog (Topical) Aerosol and Prednicarbate (Topical) Ointment***.

Dermatologics, Genital Warts

The DUR Board recommended ***Preferred*** status for ***Imiquimod (Topical) Cream***.

Dermatologics, Local Anesthetics

The DUR Board recommended ***Preferred*** status for ***Lidocaine (Topical) Cream/Lotion 3%*** and ***Non-Preferred*** status with ***Prior Authorization*** for ***Lidocaine (Topical) Ointment 5%***.

Gastrointestinal, Histamine (H-2) Receptor Antagonists

The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Pepcid (Oral) Suspension***.

Gout Agents

The DUR Board recommended ***Preferred*** status for ***Colchicine (Oral) Capsule/Tablet*** and ***Non-Preferred*** status with ***Prior Authorization*** for ***Colcrys (Oral) Tablet***.

Immunosuppressive Agents

The DUR Board recommended ***Preferred*** status for ***Sirolimus (Oral) Tablet, Preferred*** status with ***Prior Authorization*** for ***Cellcept (Oral) Suspension*** and ***Non-Preferred*** status with ***Prior Authorization and Grandfathering*** for ***Rapamune (Oral) Tablet***.

Progestins

The DUR Board recommended ***Preferred*** status for ***Progesterone (Oral) Capsule*** and ***Non-Preferred*** status with ***Prior Authorization*** for ***Prometrium (Oral) Capsule***.

Respiratory, Leukotriene Modifiers

The DUR Board recommended ***No Changes*** in the class and recommended reviewing the montelukast prior authorization criteria to determine if revisions are needed based on the 2015 updated guidelines for allergic rhinitis.

Ulcer Drugs, *H Pylori*

The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Prevpac (Oral) Combination Package***.

Urinary, Antiinfectives

The DUR Board recommended ***Preferred*** status ***Methenamine Mandelate (Oral) Tablet*** and ***Non-Preferred*** status with ***Prior Authorization*** status for ***Uro-Blue (Oral) Tablet and Utira-C (Oral) Tablet***.

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 1:46pm.

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

_____

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

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Georgia Department of Community Health

Performance Measurement

Presentation to: Drug Utilization Review Board

Presented by: Janice Carson, MD
Assistant Chief, PQO

Date: 09/24/15

Mission

The mission of the Department of Community Health is to provide access to affordable, quality health care to Georgians through effective planning, purchasing, and oversight.

We are dedicated to A Healthy Georgia.

Overview

Performance Measures

– What They Are?

– What Purpose Do they Serve?

– How Are The Rates Generated?

– What Populations Do We Monitor?

– Performance Results

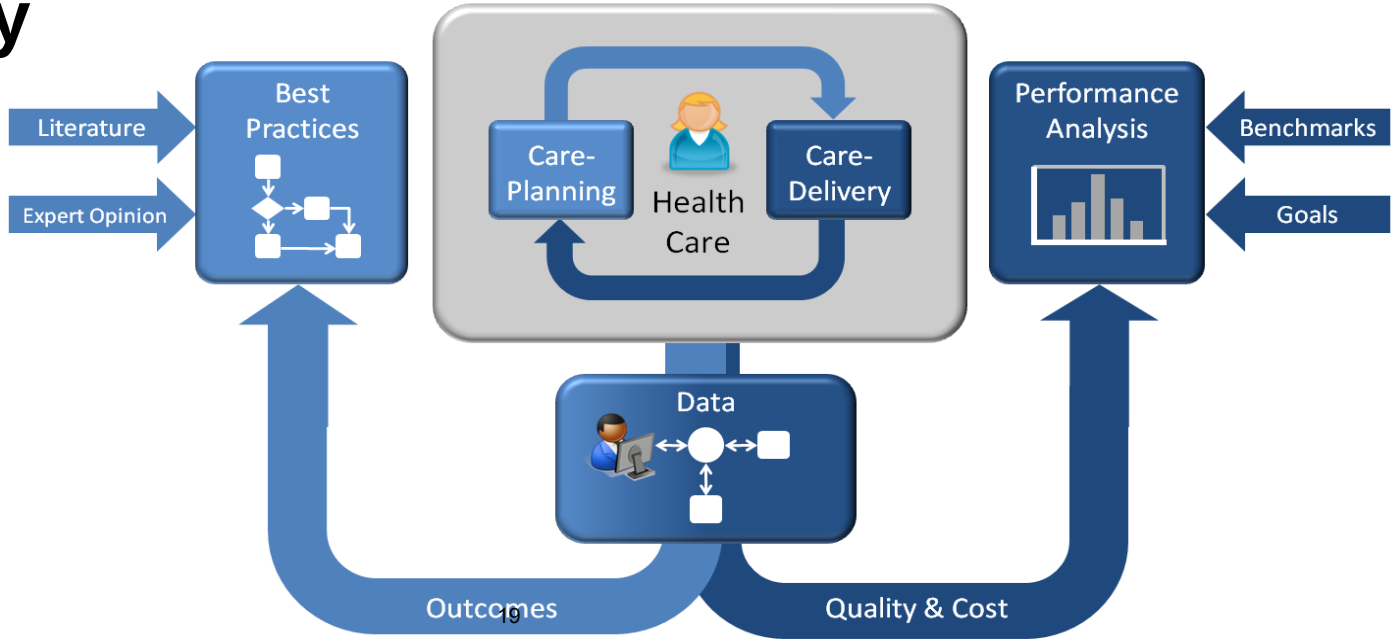
What are Performance Measures?

- Tools to assess the performance of individual clinicians, clinical delivery teams, delivery organizations or health insurance plans in the provision of care to their patients or enrollees.
- Our Measure Stewards include CMS and:
  - NCQA
    - Healthcare Effectiveness Data and Information Set (HEDIS)
    - Consumer Assessment of Healthcare Providers and Systems (CAHPS) Surveys
  - Agency for Healthcare Research and Quality (AHRQ)
  - The Joint Commission

The Purpose of Performance Measurement

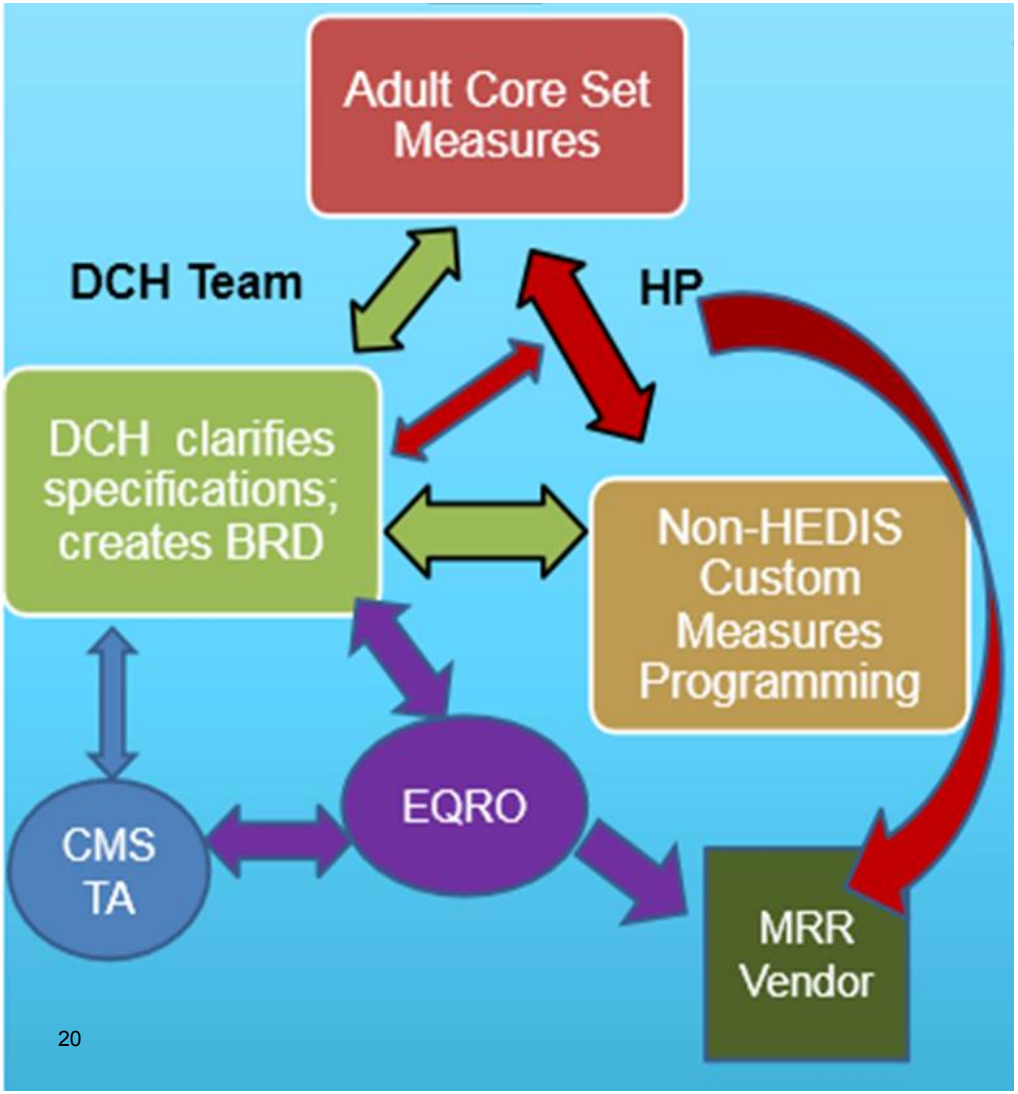
Performance Measurement helps us:

- **Understand the healthcare delivery process**
- **Identify quality of care issues**
- **Increase the effectiveness of healthcare delivery**



How are Performance Measure Rates Generated?

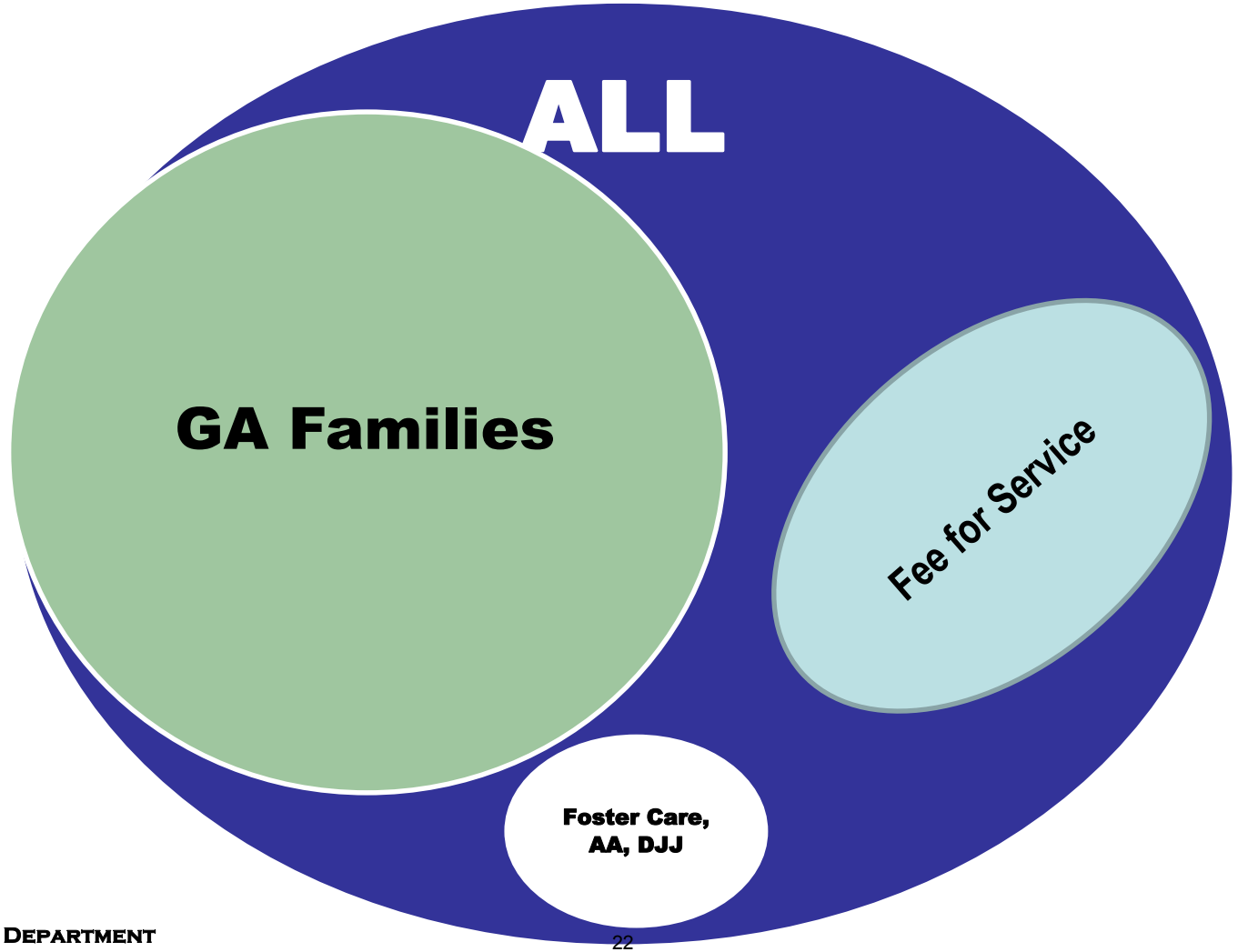
- HP - PM Generating Vendor
  - HEDIS® software subcontractor
  - Medical Record Review subcontractor



How are Performance Measure Rates Generated?

- ✓Specifications
- ✓Claims-based (Administrative Rate)
- ✓Medical Record Review (Hybrid Rates)
- ✓Validation

What Populations Do We Monitor?



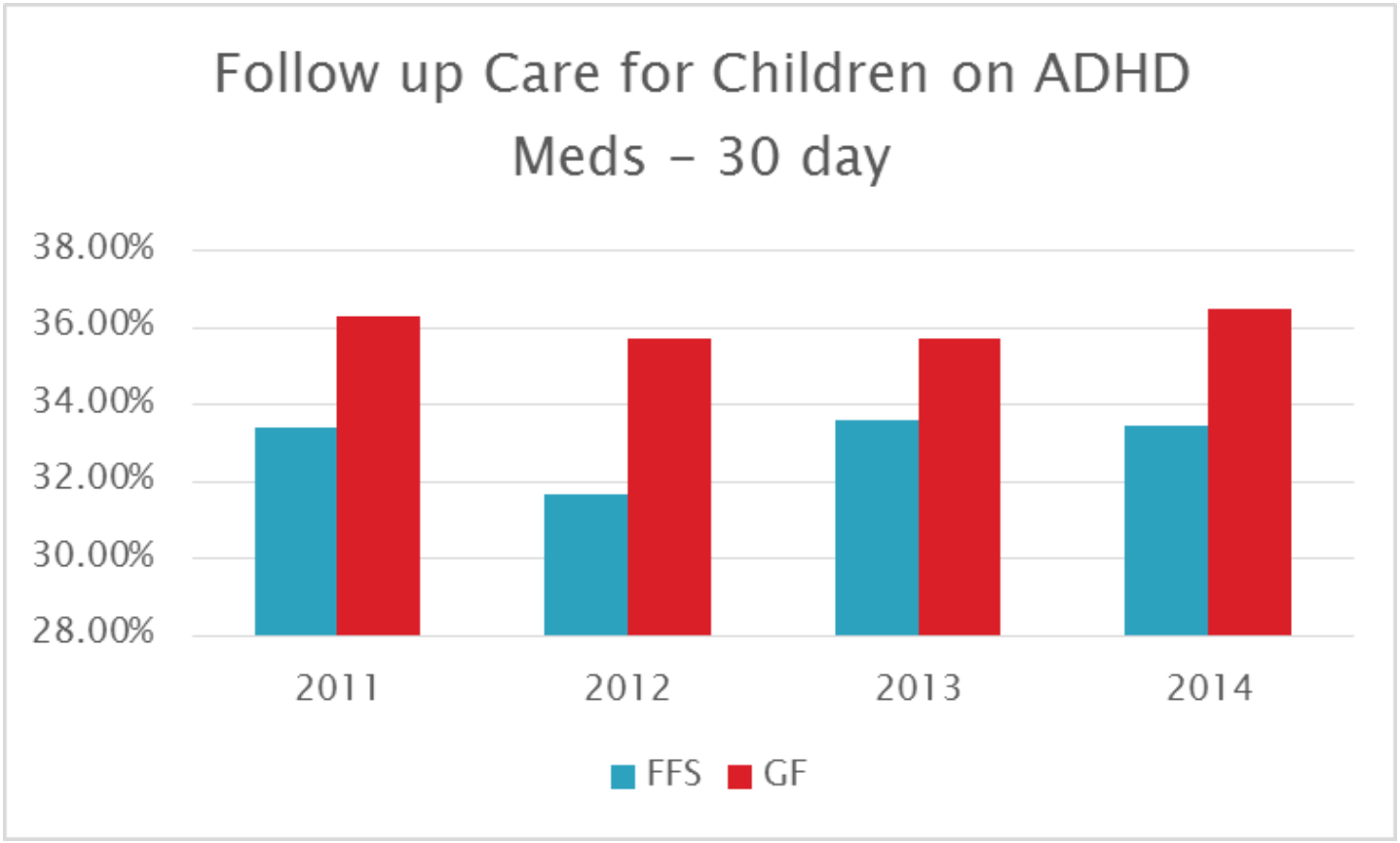
Performance Results for Children

Performance Results

	Georgia Families	FFS
Testing for Pharyngitis	79.50%	76.90%
Approp. Tx for URI	83.67%	81.67%

These measures describe care for sick children. One identifies whether providers are appropriately conducting strep tests for children diagnosed with pharyngitis and the other describes the percentage of practitioners who are not prescribing antibiotics for viral URIs.

Performance Results



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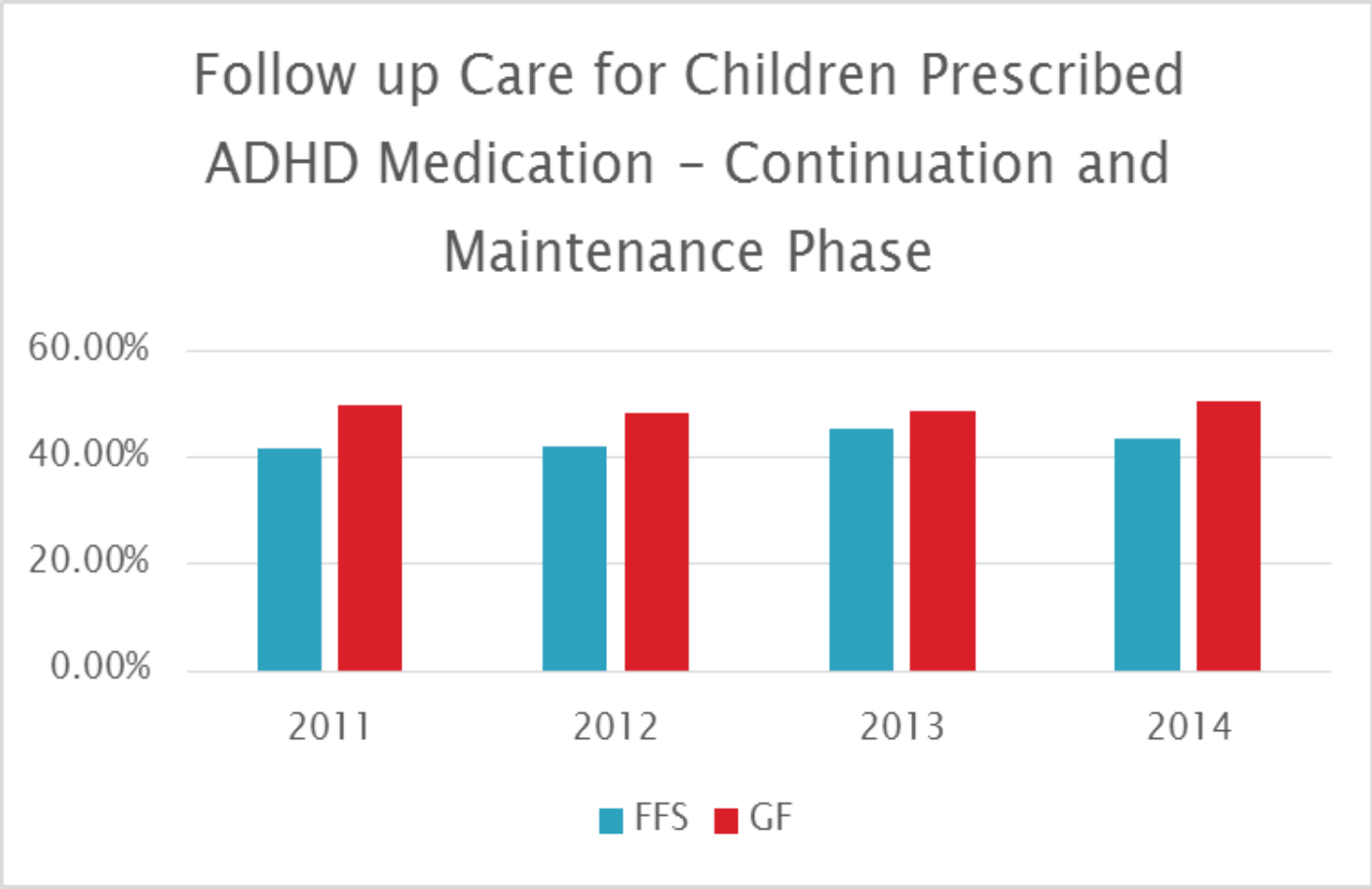

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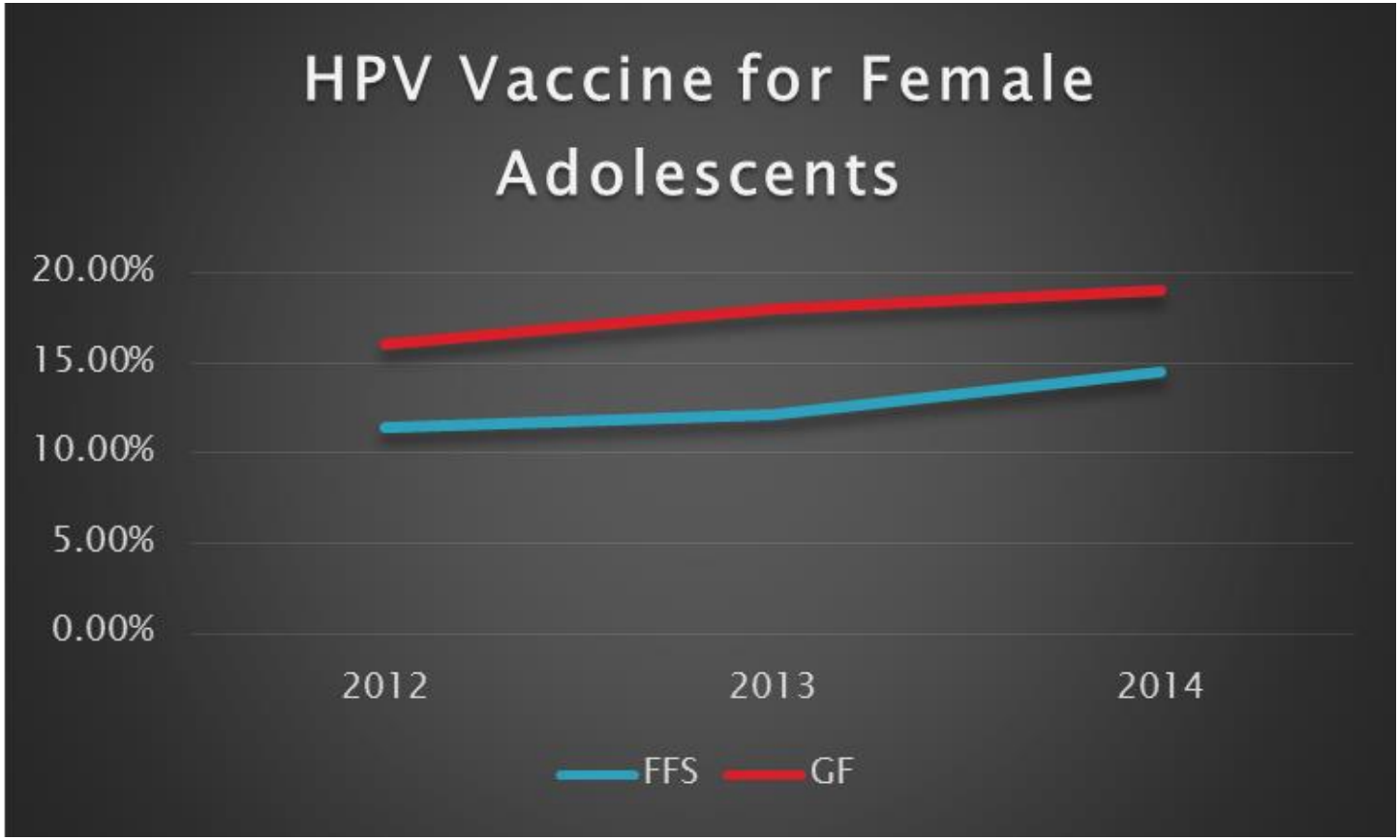

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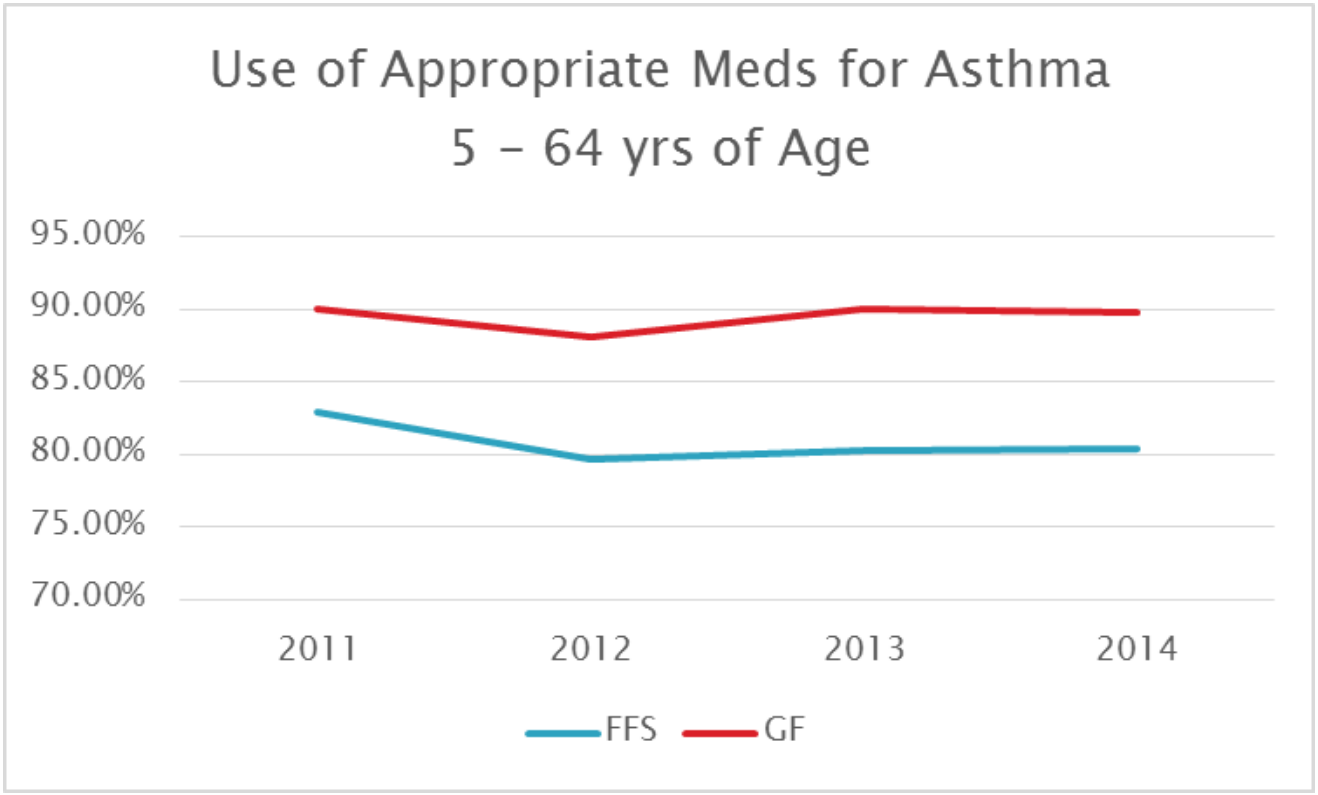
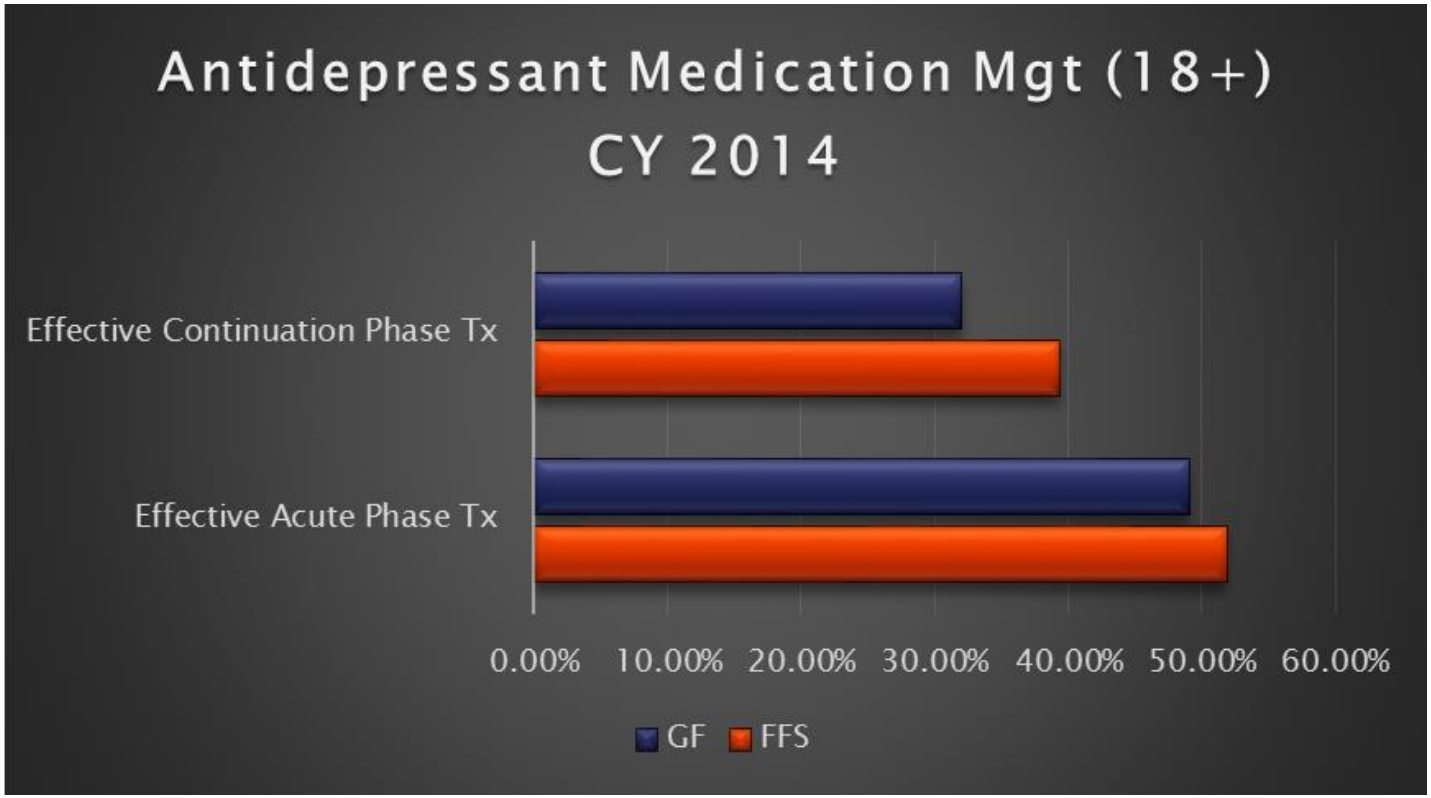


Performance Results for Adults

Performance Results

- Metrics from the 2015 Medicaid Adult CAHPS Survey:
  - Flu Shots for Adults Ages 18 – 64: 41.4%
  - Aspirin Use and Discussion
    - Take Aspirin daily or every other day: 45.1%
    - Doctor has discussed risks and benefits of aspirin to prevent heart attack or stroke: 58%
  - Medical Assistance with Smoking Cessation
    - Doctor recommended or discussed medication to assist with quitting smoking or using tobacco: 43.9%

Performance Results



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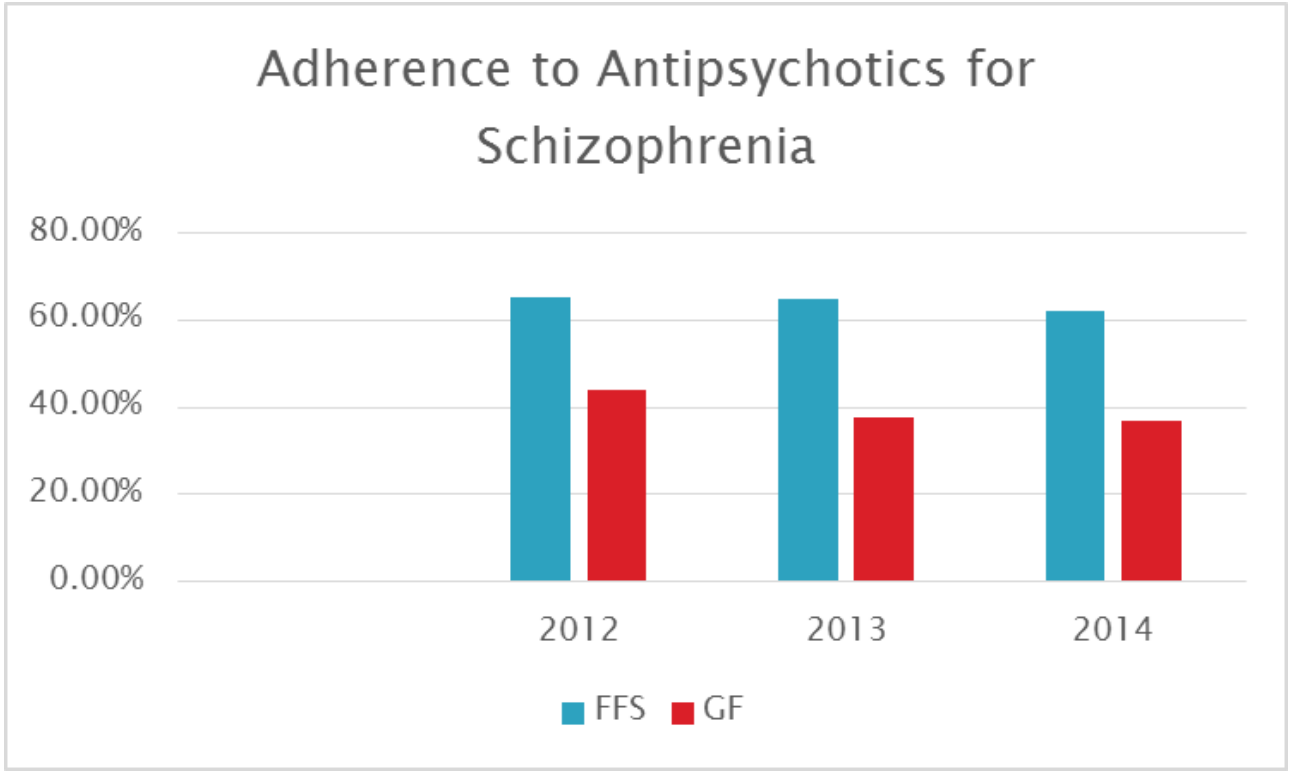

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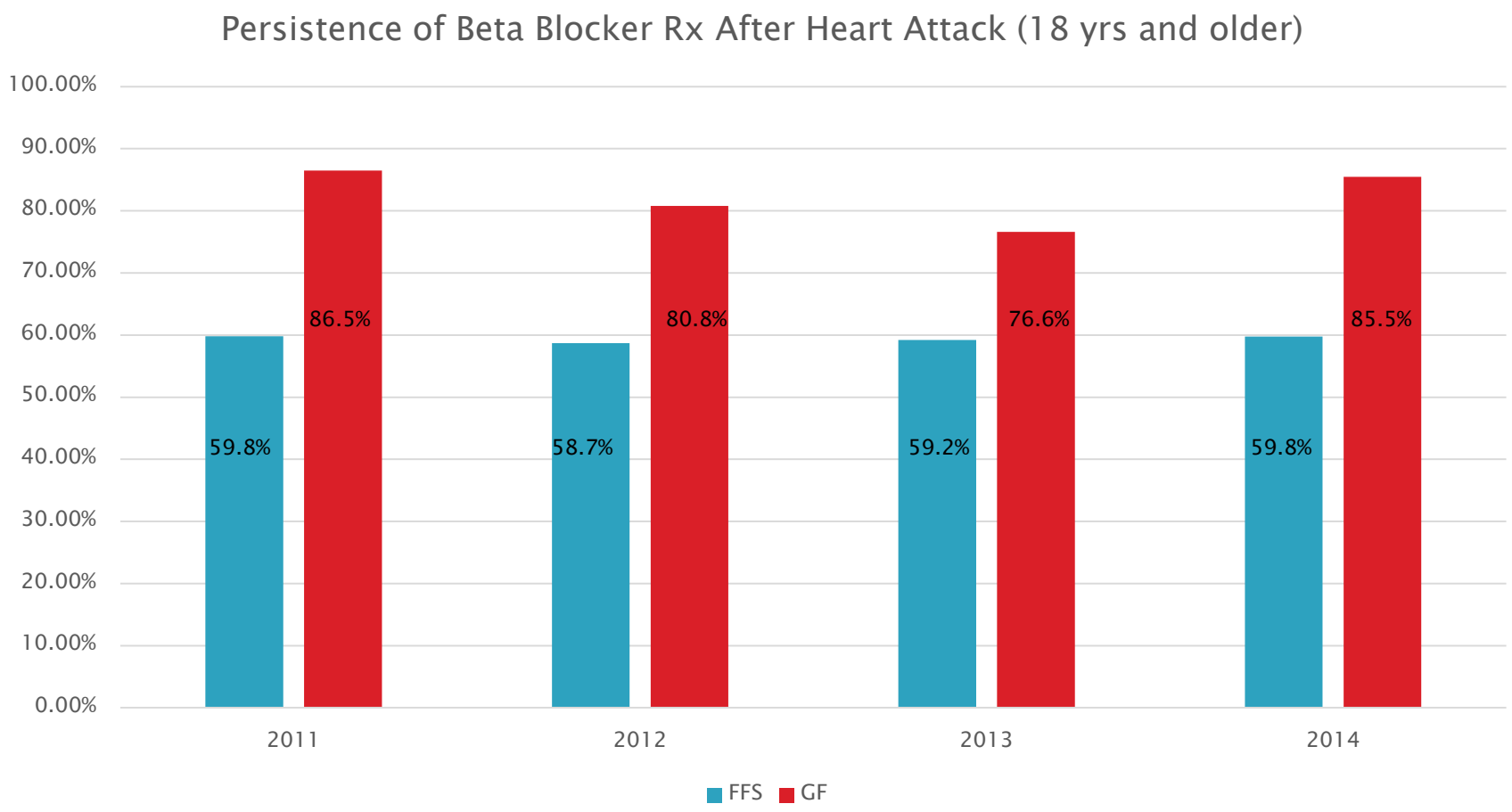
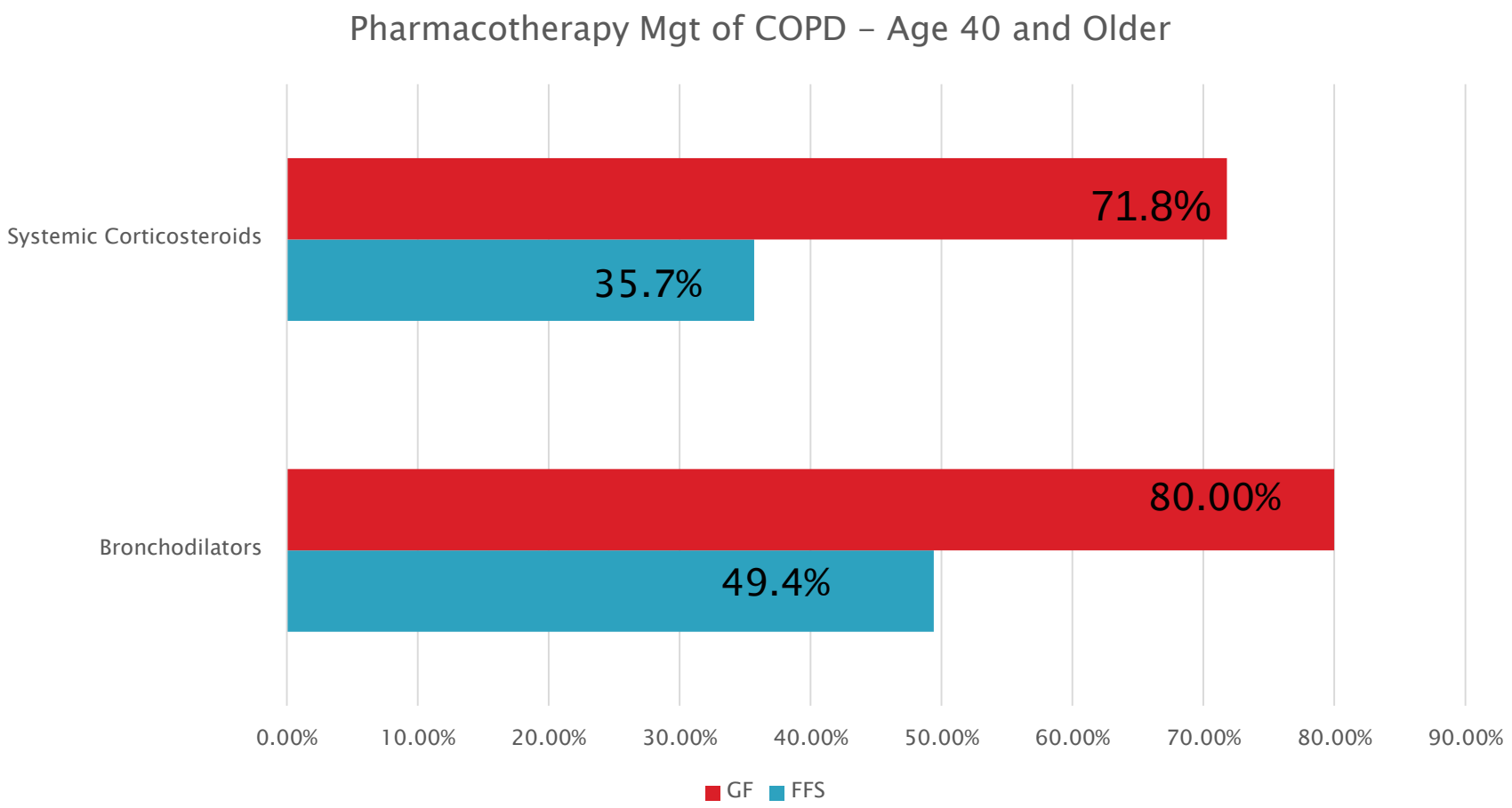


Performance Results



GHA has a Zone Tool for COPD that was shared with the CMOs.

Performance Results

- In CY 2014:
  - 33.35% (35.62% in CY 13) of GF members with a new episode of alcohol and other drug dependence initiated treatment through an inpatient admission, outpatient visit, intensive outpatient encounter or partial hospitalization within 14 days of the diagnosis.
  - 6.61% (7.65% in CY 2013) of those who initiated treatment had two or more additional services within 30 days of the initiation visit.
  - 36.34% (40.15% in CY 2013) of FFS members initiated treatment within 14 days of diagnosis.
  - 4.20% (4.72% in CY 2013) of FFS members had two or more additional services within 30 of initiation.

Questions

Drug Utilization Review Board

Motions - Votes - **New Drugs**

September 24, 2015

New Drug	Drug	PDL Status	Motion - Recommendations	Additional Comments	
SEDATIVE HYPNOTICS	BELSOMRA (ORAL) TABLET	NPPA	NPPA	PA criteria to not allow concomitant use with benzodiazepines	
Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1 Doad, Gurinder J.S., M.D.- **Vice**			√		
2 Fincher, Deborah W., M.S., R.Ph.	√		√		
3 Fowler, M. Celeste, Pharm.D.			√		
4 Gore, Thomas B., M.D.			√		
5 Graham, Yolanda, M.D.			√		
6 Lorys, Robyn Pharm.D.		√	√		
7 May, J. Russell (Rusty)			√		
8 Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
9 Rollins, Brent L., R.Ph., Ph.D.			√		
10 Shervette III, Robert E., M.D.			√		
		TOTAL	10	0	0
Board Members - Absent					
1 Avery, Mia, Pharm.D.					
2 Damon, Ann R., Pharm.D.					

Drug Utilization Review Board

Motions - Votes - **New Drugs**

September 24, 2015

New Drug	Drug	PDL Status	Motion - Recommendations	Additional Comments	
BIOLOGIC IMMUNOMODULATORS	COSENTYX (SUB-Q) SYRINGE/PENS	NPPA	PPA	Step therapy with Humira	
Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1 Doad, Gurinder J.S., M.D.- **Vice**	√		√		
2 Fincher, Deborah W., M.S., R.Ph.			√		
3 Fowler, M. Celeste, Pharm.D.			√		
4 Gore, Thomas B., M.D.			√		
5 Graham, Yolanda, M.D.			√		
6 Lorys, Robyn Pharm.D.			√		
7 May, J. Russell (Rusty)		√	√		
8 Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
9 Rollins, Brent L., R.Ph., Ph.D.			√		
10 Shervette III, Robert E., M.D.			√		
		TOTAL	10	0	0
Board Members - Absent					
1 Avery, Mia, Pharm.D.					
2 Damon, Ann R., Pharm.D.					

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

Drug Utilization Review Board

Motions - Votes - **New Drugs**

September 24, 2015

New Drug	Drug	PDL Status	Motion - Recommendations	Additional Comments	
ANTINEOPLASTICS-BREAST CANCER	IBRANCE (ORAL) CAPSULE	PPA	PPA		
Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1 Doad, Gurinder J.S., M.D.- **Vice**			√		
2 Fincher, Deborah W., M.S., R.Ph.			√		
3 Fowler, M. Celeste, Pharm.D.			√		
4 Gore, Thomas B., M.D.			√		
5 Graham, Yolanda, M.D.			√		
6 Lorys, Robyn Pharm.D.		√	√		
7 May, J. Russell (Rusty)	√		√		
8 Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
9 Rollins, Brent L., R.Ph., Ph.D.			√		
10 Shervette III, Robert E., M.D.			√		
		TOTAL	10	0	0
Board Members - Absent					
1 Avery, Mia, Pharm.D.					
2 Damon, Ann R., Pharm.D.					

Drug Utilization Review Board

Motions - Votes - **New Drugs**

September 24, 2015

New Drug	Drug	PDL Status	Motion - Recommendations	Additional Comments
ANTINEOPLASTICS-THYROID CANCER	LENVIMA (ORAL) CAPSULE	PPA	PPA	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Doad, Gurinder J.S., M.D.- **Vice**	√		√		
2	Fincher, Deborah W., M.S., R.Ph.			√		
3	Fowler, M. Celeste, Pharm.D.			√		
4	Gore, Thomas B., M.D.			√		
5	Graham, Yolanda, M.D.			√		
6	Lorys, Robyn Pharm.D.		√	√		
7	May, J. Russell (Rusty)			√		
8	Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
9	Rollins, Brent L., R.Ph., Ph.D.			√		
10	Shervette III, Robert E., M.D.			√		
			TOTAL	10	0	0

	Board Members - Absent
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.

Drug Utilization Review Board

Motions - Votes - **New Drugs**

September 24, 2015

New Drug	Drug	PDL Status	Motion - Recommendations	Additional Comments	
ANTINEOPLASTICS-OVARIAN CANCER	LYNPARZA (ORAL) CAPSULE	PPA	PPA		
Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1 Doad, Gurinder J.S., M.D.- **Vice**			√		
2 Fincher, Deborah W., M.S., R.Ph.			√		
3 Fowler, M. Celeste, Pharm.D.			√		
4 Gore, Thomas B., M.D.			√		
5 Graham, Yolanda, M.D.			√		
6 Lorys, Robyn Pharm.D.			√		
7 May, J. Russell (Rusty)	√		√		
8 Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
9 Rollins, Brent L., R.Ph., Ph.D.		√	√		
10 Shervette III, Robert E., M.D.			√		
		TOTAL	10	0	0

Board Members - Absent
1 Avery, Mia, Pharm.D.
2 Damon, Ann R., Pharm.D.

Drug Utilization Review Board

Motions - Votes - **New Drugs**

September 24, 2015

New Drug	Drug	PDL Status	Motion - Recommendations	Additional Comments
THROMBOPOIETIN RECEPTOR AGONISTS	NPLATE (SUB-Q) VIA	PPA		Vote postponed for follow-up and further review

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

	Board Members - Absent
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.

Drug Utilization Review Board

Motions - Votes - **New Drugs**

September 24, 2015

New Drug	Drug	PDL Status	Motion - Recommendations	Additional Comments	
ANTICOAGULANTS, ORAL	SAVAYSA (ORAL) TABLET	NPPA	NPPA		
Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1 Doad, Gurinder J.S., M.D.- **Vice**		√	√		
2 Fincher, Deborah W., M.S., R.Ph.			√		
3 Fowler, M. Celeste, Pharm.D.	√		√		
4 Gore, Thomas B., M.D.			√		
5 Graham, Yolanda, M.D.			√		
6 Lorys, Robyn Pharm.D.			√		
7 May, J. Russell (Rusty)			√		
8 Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
9 Rollins, Brent L., R.Ph., Ph.D.			√		
10 Shervette III, Robert E., M.D.			√		
		TOTAL	10	0	0
Board Members - Absent					
1 Avery, Mia, Pharm.D.					
2 Damon, Ann R., Pharm.D.					

Drug Utilization Review Board

Motions - Votes - **New Drugs**

September 24, 2015

New Drug	Drug	PDL Status	Motion - Recommendations	Additional Comments
DERMATOLOGICS, ACNE ROSACEA	SOOLANTRA (TOPICAL) CREAM (G)	NPPA	NPPA	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Doad, Gurinder J.S., M.D.- **Vice**			√		
2	Fincher, Deborah W., M.S., R.Ph.			√		
3	Fowler, M. Celeste, Pharm.D.			√		
4	Gore, Thomas B., M.D.			√		
5	Graham, Yolanda, M.D.			√		
6	Lorys, Robyn Pharm.D.	√		√		
7	May, J. Russell (Rusty)			√		
8	Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
9	Rollins, Brent L., R.Ph., Ph.D.		√	√		
10	Shervette III, Robert E., M.D.			√		
			TOTAL	10	0	0

	Board Members - Absent
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.

Drug Utilization Review Board

Motions - Votes - **New Drugs**

September 24, 2015

New Drug	Drug	PDL Status	Motion - Recommendations	Additional Comments	
METABOLIC ENZYMES	VIMIZIM (INTRAVEN) VIAL	PPA	PPA		
Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1 Doad, Gurinder J.S., M.D.- **Vice**	√		√		
2 Fincher, Deborah W., M.S., R.Ph.			√		
3 Fowler, M. Celeste, Pharm.D.			√		
4 Gore, Thomas B., M.D.			√		
5 Graham, Yolanda, M.D.			√		
6 Lorys, Robyn Pharm.D.		√	√		
7 May, J. Russell (Rusty)			√		
8 Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
9 Rollins, Brent L., R.Ph., Ph.D.			√		
10 Shervette III, Robert E., M.D.			√		
		TOTAL	10	0	0
Board Members - Absent					
1 Avery, Mia, Pharm.D.					
2 Damon, Ann R., Pharm.D.					

NON-SR CLASS	Drug	PDL Status	Motion - Recommendations	Additional Comments
ANTIANGINAL AGENTS	NITROGLYCERIN (TRANSLING) SPRAY	NPPA	P	
	NITROMIST (TRANSLING) SPRAY	P	NPPA	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Doad, Gurinder J.S., M.D.- **Vice**			√		
2	Fincher, Deborah W., M.S., R.Ph.			√		
3	Fowler, M. Celeste, Pharm.D.			√		
4	Gore, Thomas B., M.D.	√		√		
5	Graham, Yolanda, M.D.			√		
6	Lorys, Robyn Pharm.D.		√	√		
7	May, J. Russell (Rusty)			√		
8	Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
9	Rollins, Brent L., R.Ph., Ph.D.			√		
10	Shervette III, Robert E., M.D.			√		
			TOTAL	10	0	0

	Board Members - Absent
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.

NON-SR CLASS	Drug	PDL Status	Motion - Recommendations	Additional Comments	
ANTIHYPERTENSIVES, DIRECT RENIN INHIBITOR			NO CHANGES		
Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1 Doad, Gurinder J.S., M.D.- **Vice**		√	√		
2 Fincher, Deborah W., M.S., R.Ph.			√		
3 Fowler, M. Celeste, Pharm.D.			√		
4 Gore, Thomas B., M.D.	√		√		
5 Graham, Yolanda, M.D.			√		
6 Lorys, Robyn Pharm.D.			√		
7 May, J. Russell (Rusty)			√		
8 Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
9 Rollins, Brent L., R.Ph., Ph.D.			√		
10 Shervette III, Robert E., M.D.			√		
		TOTAL	10	0	0
Board Members - Absent					
1 Avery, Mia, Pharm.D.					
2 Damon, Ann R., Pharm.D.					

NON-SR CLASS	Drug	PDL Status	Motion - Recommendations	Additional Comments
ANTIINFECTIVES, CEPHALOSPORINS	CEFACLOR (ORAL) SUSP RECON	P	NPPA	Quantity level limit of 1 for Suprax capsules (for appropriate indication[s])
	CEFIXIME (ORAL) SUSP RECON	PPA	NPPA	
	CEFTIN (ORAL) SUSP RECON	NP	P	
	SUPRAX (ORAL) CAPSULE	NPPA	PPA	
	SUPRAX (ORAL) SUSP RECON	P	NPPA	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Doad, Gurinder J.S., M.D.- **Vice**	√		√		
2	Fincher, Deborah W., M.S., R.Ph.			√		
3	Fowler, M. Celeste, Pharm.D.			√		
4	Gore, Thomas B., M.D.		√	√		
5	Graham, Yolanda, M.D.			√		
6	Lorys, Robyn Pharm.D.			√		
7	May, J. Russell (Rusty)			√		
8	Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
9	Rollins, Brent L., R.Ph., Ph.D.			√		
10	Shervette III, Robert E., M.D.			√		
			TOTAL	10	0	0

	Board Members - Absent
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.

NON-SR CLASS	Drug	PDL Status	Motion - Recommendations	Additional Comments	
ANTIINFECTIVES, FLUOROQUINOLONES			NO CHANGES		
Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1 Doad, Gurinder J.S., M.D.- **Vice**			√		
2 Fincher, Deborah W., M.S., R.Ph.			√		
3 Fowler, M. Celeste, Pharm.D.			√		
4 Gore, Thomas B., M.D.		√	√		
5 Graham, Yolanda, M.D.			√		
6 Lorys, Robyn Pharm.D.	√		√		
7 May, J. Russell (Rusty)			√		
8 Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
9 Rollins, Brent L., R.Ph., Ph.D.			√		
10 Shervette III, Robert E., M.D.			√		
		TOTAL	10	0	0
Board Members - Absent					
1 Avery, Mia, Pharm.D.					
2 Damon, Ann R., Pharm.D.					

NON-SR CLASS	Drug	PDL Status	Motion - Recommendations	Additional Comments	
ANTIINFECTIVES, MACROLIDES			NO CHANGES		
Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1 Doad, Gurinder J.S., M.D.- **Vice**			√		
2 Fincher, Deborah W., M.S., R.Ph.			√		
3 Fowler, M. Celeste, Pharm.D.			√		
4 Gore, Thomas B., M.D.		√	√		
5 Graham, Yolanda, M.D.			√		
6 Lorys, Robyn Pharm.D.	√		√		
7 May, J. Russell (Rusty)			√		
8 Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
9 Rollins, Brent L., R.Ph., Ph.D.			√		
10 Shervette III, Robert E., M.D.			√		
		TOTAL	10	0	0
Board Members - Absent					
1 Avery, Mia, Pharm.D.					
2 Damon, Ann R., Pharm.D.					

NON-SR CLASS	Drug	PDL Status	Motion - Recommendations	Additional Comments	
ANTIINFECTIVES, TETRACYCLINES	MINOCYCLINE HCL (ORAL) TABLET	P	NPPA		
Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1 Doad, Gurinder J.S., M.D.- **Vice**			√		
2 Fincher, Deborah W., M.S., R.Ph.			√		
3 Fowler, M. Celeste, Pharm.D.			√		
4 Gore, Thomas B., M.D.			√		
5 Graham, Yolanda, M.D.			√		
6 Lorys, Robyn Pharm.D.	√		√		
7 May, J. Russell (Rusty)			√		
8 Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
9 Rollins, Brent L., R.Ph., Ph.D.		√	√		
10 Shervette III, Robert E., M.D.			√		
		TOTAL	10	0	0
Board Members - Absent					
1 Avery, Mia, Pharm.D.					
2 Damon, Ann R., Pharm.D.					

NON-SR CLASS	Drug	PDL Status	Motion - Recommendations	Additional Comments
ANTIPARKINSON AGENTS	CARBIDOPA (ORAL) TABLET	NPPA	P	
	LODOSYN (ORAL) TABLET	P	NPPA	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Doad, Gurinder J.S., M.D.- **Vice**			√		
2	Fincher, Deborah W., M.S., R.Ph.			√		
3	Fowler, M. Celeste, Pharm.D.			√		
4	Gore, Thomas B., M.D.			√		
5	Graham, Yolanda, M.D.	√		√		
6	Lorys, Robyn Pharm.D.		√	√		
7	May, J. Russell (Rusty)			√		
8	Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
9	Rollins, Brent L., R.Ph., Ph.D.			√		
10	Shervette III, Robert E., M.D.			√		
			TOTAL	10	0	0

	Board Members - Absent
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.

Drug Utilization Review Board

Motions - Votes - New Drugs

September 24, 2015

NON-SR CLASS	Drug	PDL Status	Motion - Recommendations	Additional Comments	
ANTIVIRALS, GENITAL HSV	ACYCLOVIR (TOPICAL) OINT. (G) 5 %	P	NPPA		
Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1 Doad, Gurinder J.S., M.D.- **Vice**			√		
2 Fincher, Deborah W., M.S., R.Ph.			√		
3 Fowler, M. Celeste, Pharm.D.			√		
4 Gore, Thomas B., M.D.		√	√		
5 Graham, Yolanda, M.D.			√		
6 Lorys, Robyn Pharm.D.	√		√		
7 May, J. Russell (Rusty)			√		
8 Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
9 Rollins, Brent L., R.Ph., Ph.D.			√		
10 Shervette III, Robert E., M.D.			√		
		TOTAL	10	0	0
Board Members - Absent					
1 Avery, Mia, Pharm.D.					
2 Damon, Ann R., Pharm.D.					

NON-SR CLASS	Drug	PDL Status	Motion - Recommendations	Additional Comments
ANTIVIRALS, HERPES LABIALIS			NO CHANGES	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Doad, Gurinder J.S., M.D.- **Vice**			√		
2	Fincher, Deborah W., M.S., R.Ph.	√		√		
3	Fowler, M. Celeste, Pharm.D.			√		
4	Gore, Thomas B., M.D.		√	√		
5	Graham, Yolanda, M.D.			√		
6	Lorys, Robyn Pharm.D.			√		
7	May, J. Russell (Rusty)			√		
8	Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
9	Rollins, Brent L., R.Ph., Ph.D.			√		
10	Shervette III, Robert E., M.D.			√		
			TOTAL	10	0	0

	Board Members - Absent
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.

NON-SR CLASS	Drug	PDL Status	Motion - Recommendations	Additional Comments
ANTIVIRALS, HERPES AGENTS			NO CHANGES	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Doad, Gurinder J.S., M.D.- **Vice**			√		
2	Fincher, Deborah W., M.S., R.Ph.			√		
3	Fowler, M. Celeste, Pharm.D.			√		
4	Gore, Thomas B., M.D.			√		
5	Graham, Yolanda, M.D.			√		
6	Lorys, Robyn Pharm.D.		√	√		
7	May, J. Russell (Rusty)	√		√		
8	Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
9	Rollins, Brent L., R.Ph., Ph.D.			√		
10	Shervette III, Robert E., M.D.			√		
			TOTAL	10	0	0

	Board Members - Absent
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.

Drug Utilization Review Board

Motions - Votes - New Drugs

September 24, 2015

NON-SR CLASS	Drug	PDL Status	Motion - Recommendations	Additional Comments
ANTIVIRALS, INFLUENZA AGENTS			NO CHANGES	Recommends that the Department reviews 2014 data to determine if influenza shots or testing occur before administration. Additionally, an educaional component is emphasized to encourage prescribers to test influenza virus before prescribing these drugs.

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Doad, Gurinder J.S., M.D.- **Vice**		√	√		
2	Fincher, Deborah W., M.S., R.Ph.			√		
3	Fowler, M. Celeste, Pharm.D.			√		
4	Gore, Thomas B., M.D.			√		
5	Graham, Yolanda, M.D.			√		
6	Lorys, Robyn Pharm.D.	√		√		
7	May, J. Russell (Rusty)			√		
8	Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
9	Rollins, Brent L., R.Ph., Ph.D.			√		
10	Shervette III, Robert E., M.D.			√		
			TOTAL	10	0	0

	Board Members - Absent
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.

NON-SR CLASS	Drug	PDL Status	Motion - Recommendations	Additional Comments	
COLONY STIMULATING FACTORS			NO CHANGES		
Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1 Doad, Gurinder J.S., M.D.- **Vice**			√		
2 Fincher, Deborah W., M.S., R.Ph.			√		
3 Fowler, M. Celeste, Pharm.D.			√		
4 Gore, Thomas B., M.D.			√		
5 Graham, Yolanda, M.D.		√	√		
6 Lorys, Robyn Pharm.D.			√		
7 May, J. Russell (Rusty)			√		
8 Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
9 Rollins, Brent L., R.Ph., Ph.D.	√		√		
10 Shervette III, Robert E., M.D.			√		
		TOTAL	10	0	0
Board Members - Absent					
1 Avery, Mia, Pharm.D.					
2 Damon, Ann R., Pharm.D.					

NON-SR CLASS	Drug	PDL Status	Motion - Recommendations	Additional Comments	
CONTRACEPTIVES - BIPHASIC - ORAL			NO CHANGES		
Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1 Doad, Gurinder J.S., M.D.- **Vice**			√		
2 Fincher, Deborah W., M.S., R.Ph.			√		
3 Fowler, M. Celeste, Pharm.D.			√		
4 Gore, Thomas B., M.D.		√	√		
5 Graham, Yolanda, M.D.			√		
6 Lorys, Robyn Pharm.D.			√		
7 May, J. Russell (Rusty)	√		√		
8 Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
9 Rollins, Brent L., R.Ph., Ph.D.			√		
10 Shervette III, Robert E., M.D.			√		
		TOTAL	10	0	0
Board Members - Absent					
1 Avery, Mia, Pharm.D.					
2 Damon, Ann R., Pharm.D.					

NON-SR CLASS	Drug	PDL Status	Motion - Recommendations	Additional Comments	
CONTRACEPTIVES - COMBOS - NON-ORAL			NO CHANGES		
Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1 Doad, Gurinder J.S., M.D.- **Vice**			√		
2 Fincher, Deborah W., M.S., R.Ph.			√		
3 Fowler, M. Celeste, Pharm.D.			√		
4 Gore, Thomas B., M.D.		√	√		
5 Graham, Yolanda, M.D.			√		
6 Lorys, Robyn Pharm.D.			√		
7 May, J. Russell (Rusty)	√		√		
8 Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
9 Rollins, Brent L., R.Ph., Ph.D.			√		
10 Shervette III, Robert E., M.D.			√		
		TOTAL	10	0	0
Board Members - Absent					
1 Avery, Mia, Pharm.D.					
2 Damon, Ann R., Pharm.D.					

Drug Utilization Review Board

Motions - Votes - New Drugs

September 24, 2015

NON-SR CLASS	Drug	PDL Status	Motion - Recommendations	Additional Comments
CONTRACEPTIVES - COMBOS-ORAL	FEMCON FE (ORAL) TAB CHEW	NPPA	P	
	JUNEL FE 24 (ORAL) TABLET	P	NPPA	
	LOMEDIA 24 FE (ORAL) TABLET	P	NPPA	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Doad, Gurinder J.S., M.D.- **Vice**			√		
2	Fincher, Deborah W., M.S., R.Ph.			√		
3	Fowler, M. Celeste, Pharm.D.			√		
4	Gore, Thomas B., M.D.			√		
5	Graham, Yolanda, M.D.			√		
6	Lorys, Robyn Pharm.D.		√	√		
7	May, J. Russell (Rusty)			√		
8	Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
9	Rollins, Brent L., R.Ph., Ph.D.	√		√		
10	Shervette III, Robert E., M.D.			√		
			TOTAL	10	0	0

	Board Members - Absent
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.

NON-SR CLASS	Drug	PDL Status	Motion - Recommendations	Additional Comments
CONTRACEPTIVES - EMERGENCY			NO CHANGES	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Doad, Gurinder J.S., M.D.- **Vice**			√		
2	Fincher, Deborah W., M.S., R.Ph.	√		√		
3	Fowler, M. Celeste, Pharm.D.			√		
4	Gore, Thomas B., M.D.			√		
5	Graham, Yolanda, M.D.		√	√		
6	Lorys, Robyn Pharm.D.			√		
7	May, J. Russell (Rusty)			√		
8	Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
9	Rollins, Brent L., R.Ph., Ph.D.			√		
10	Shervette III, Robert E., M.D.			√		
			TOTAL	10	0	0

	Board Members - Absent
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.

NON-SR CLASS	Drug	PDL Status	Motion - Recommendations	Additional Comments
CONTRACEPTIVES EXT-CYCLE ORAL			NO CHANGES	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Doad, Gurinder J.S., M.D.- **Vice**			√		
2	Fincher, Deborah W., M.S., R.Ph.	√		√		
3	Fowler, M. Celeste, Pharm.D.			√		
4	Gore, Thomas B., M.D.			√		
5	Graham, Yolanda, M.D.		√	√		
6	Lorys, Robyn Pharm.D.			√		
7	May, J. Russell (Rusty)			√		
8	Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
9	Rollins, Brent L., R.Ph., Ph.D.			√		
10	Shervette III, Robert E., M.D.			√		
			TOTAL	10	0	0

	Board Members - Absent
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.

Drug Utilization Review Board

Motions - Votes - New Drugs

September 24, 2015

NON-SR CLASS	Drug	PDL Status	Motion - Recommendations	Additional Comments	
CONTRACEPTIVES - PROGESTINS	NOR-Q-D (ORAL) TABLET	NPPA	P		
Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1 Doad, Gurinder J.S., M.D.- **Vice**			√		
2 Fincher, Deborah W., M.S., R.Ph.	√		√		
3 Fowler, M. Celeste, Pharm.D.		√	√		
4 Gore, Thomas B., M.D.			√		
5 Graham, Yolanda, M.D.			√		
6 Lorys, Robyn Pharm.D.			√		
7 May, J. Russell (Rusty)			√		
8 Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
9 Rollins, Brent L., R.Ph., Ph.D.			√		
10 Shervette III, Robert E., M.D.			√		
		TOTAL	10	0	0
Board Members - Absent					
1 Avery, Mia, Pharm.D.					
2 Damon, Ann R., Pharm.D.					

NON-SR CLASS	Drug	PDL Status	Motion - Recommendations	Additional Comments
CONTRACEPTIVES - TRIPHASIC - ORAL	ALYACEN (ORAL) TABLET	NPPA	P	
	ARANELLE (ORAL) TABLET	P	NPPA	
	CYCLAFEM (ORAL) TABLET	NPPA	P	
	DASETTA (ORAL) TABLET	NPPA	P	
	LEENA (ORAL) TABLET	P	NPPA	
	NORTREL (ORAL) TABLET	NPPA	P	
	ORTHO TRI-CYCLEN (ORAL) TABLET	P	NPPA	
	ORTHO-NOVUM (ORAL) TABLET	P	NPPA	
	PIRMELLA (ORAL) TABLET	NPPA	P	
	TRINESSA (ORAL) TABLET	P	NPPA	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Doad, Gurinder J.S., M.D.- **Vice**	√		√		
2	Fincher, Deborah W., M.S., R.Ph.			√		
3	Fowler, M. Celeste, Pharm.D.			√		
4	Gore, Thomas B., M.D.			√		
5	Graham, Yolanda, M.D.			√		
6	Lorys, Robyn Pharm.D.		√	√		
7	May, J. Russell (Rusty)			√		
8	Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
9	Rollins, Brent L., R.Ph., Ph.D.			√		
10	Shervette III, Robert E., M.D.			√		
			TOTAL	10	0	0

	Board Members - Absent
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.

Drug Utilization Review Board

Motions - Votes - New Drugs

September 24, 2015

NON-SR CLASS	Drug	PDL Status	Motion - Recommendations	Additional Comments	
COUGH AND COLD RX	BROMPHENIRAMINE-PSEUDOEPHED-DM (ORAL) SYRUP	NC	P		
Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1 Doad, Gurinder J.S., M.D.- **Vice**			√		
2 Fincher, Deborah W., M.S., R.Ph.			√		
3 Fowler, M. Celeste, Pharm.D.			√		
4 Gore, Thomas B., M.D.			√		
5 Graham, Yolanda, M.D.			√		
6 Lorys, Robyn Pharm.D.		√	√		
7 May, J. Russell (Rusty)	√		√		
8 Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
9 Rollins, Brent L., R.Ph., Ph.D.			√		
10 Shervette III, Robert E., M.D.			√		
		TOTAL	10	0	0
Board Members - Absent					
1 Avery, Mia, Pharm.D.					
2 Damon, Ann R., Pharm.D.					

NON-SR CLASS	Drug	PDL Status	Motion - Recommendations	Additional Comments
DERMATOLOGICS, ACNE VULGARIS	ATRALIN (TOPICAL) GEL (GRAM)	NPPA	P	
	BENZACLIN (TOPICAL) GEL (GRAM)	NPPA	P	
	BENZACLIN (TOPICAL) GEL W/PUMP	NPPA	P	
	EPIDUO (TOPICAL) GEL W/PUMP	NPPA	P	
	RETIN-A (TOPICAL) GEL (GRAM)	NPPA	P	
	SODIUM SULFACETAMIDE-SULFUR (TOPICAL) CLEANSER	P	NPPA	
	SODIUM SULFACETAMIDE-SULFUR (TOPICAL) CREAM (G)	P	NPPA	
	TRETINOIN (TOPICAL) CREAM (G)	NPPA	P	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Doad, Gurinder J.S., M.D.- **Vice**	√		√		
2	Fincher, Deborah W., M.S., R.Ph.			√		
3	Fowler, M. Celeste, Pharm.D.			√		
4	Gore, Thomas B., M.D.		√	√		
5	Graham, Yolanda, M.D.			√		
6	Lorys, Robyn Pharm.D.			√		
7	May, J. Russell (Rusty)			√		
8	Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
9	Rollins, Brent L., R.Ph., Ph.D.			√		
10	Shervette III, Robert E., M.D.			√		
			TOTAL	10	0	0

	Board Members - Absent
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.

NON-SR CLASS	Drug	PDL Status	Motion - Recommendations	Additional Comments
DERMATOLOGICS, CORTICOSTEROIDS - LOW POTENCY	DESONIDE (TOPICAL) CREAM (G)	NPPA	P	
	DESONIDE (TOPICAL) OINT. (G)	NPPA	P	
	DESONIDE (TOPICAL) LOTION	NPPA	P	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Doad, Gurinder J.S., M.D.- **Vice**			√		
2	Fincher, Deborah W., M.S., R.Ph.			√		
3	Fowler, M. Celeste, Pharm.D.			√		
4	Gore, Thomas B., M.D.			√		
5	Graham, Yolanda, M.D.			√		
6	Lorys, Robyn Pharm.D.			√		
7	May, J. Russell (Rusty)		√	√		
8	Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
9	Rollins, Brent L., R.Ph., Ph.D.	√		√		
10	Shervette III, Robert E., M.D.			√		
			TOTAL	10	0	0

	Board Members - Absent
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.

NON-SR CLASS	Drug	PDL Status	Motion - Recommendations	Additional Comments
DERM, CORTICOSTEROIDS - MEDIUM POTENCY	AMCINONIDE (TOPICAL) CREAM (G)	NPPA	P	
	CREAM (G)	P	NPPA	
	HYDROCORTISONE VALERATE (TOPICAL) OINT. (G)	P	NPPA	
	KENALOG (TOPICAL) AEROSOL	P	NPPA	
	MOMETASONE FUROATE (TOPICAL) CREAM (G)	NPPA	P	
	MOMETASONE FUROATE (TOPICAL) OINT. (G)	NPPA	P	
	MOMETASONE FUROATE (TOPICAL) SOLUTION	NPPA	P	
	PREDNICARBATE (TOPICAL) OINT. (G)	P	NPPA	
	TRIAMCINOLONE ACETONIDE (TOPICAL) LOTION	NPPA	P	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Doad, Gurinder J.S., M.D.- **Vice**			√		
2	Fincher, Deborah W., M.S., R.Ph.			√		
3	Fowler, M. Celeste, Pharm.D.			√		
4	Gore, Thomas B., M.D.			√		
5	Graham, Yolanda, M.D.			√		
6	Lorys, Robyn Pharm.D.		√	√		
7	May, J. Russell (Rusty)	√		√		
8	Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
9	Rollins, Brent L., R.Ph., Ph.D.			√		
10	Shervette III, Robert E., M.D.			√		
			TOTAL	10	0	0

	Board Members - Absent
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.

NON-SR CLASS	Drug	PDL Status	Motion - Recommendations	Additional Comments
DERMATOLOGICS, CORTICOSTEROIDS - HIGH POTENCY	AMCINONIDE (TOPICAL) LOTION	P	NPPA	
	CLOBETASOL EMOLLIENT (TOPICAL) CREAM (G)	P	NPPA	
	CLOBETASOL PROPIONATE (TOPICAL) CREAM (G)	P	NPPA	
	FLUOCINONIDE (TOPICAL) OINT. (G)	P	NPPA	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Doad, Gurinder J.S., M.D.- **Vice**			√		
2	Fincher, Deborah W., M.S., R.Ph.			√		
3	Fowler, M. Celeste, Pharm.D.			√		
4	Gore, Thomas B., M.D.		√	√		
5	Graham, Yolanda, M.D.			√		
6	Lorys, Robyn Pharm.D.			√		
7	May, J. Russell (Rusty)	√		√		
8	Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
9	Rollins, Brent L., R.Ph., Ph.D.			√		
10	Shervette III, Robert E., M.D.			√		
			TOTAL	10	0	0

	Board Members - Absent
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.

Drug Utilization Review Board

Motions - Votes - New Drugs

September 24, 2015

NON-SR CLASS	Drug	PDL Status	Motion - Recommendations	Additional Comments
DERMATOLOGICS, ENZYMES			NO CHANGES	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Doad, Gurinder J.S., M.D.- **Vice**			√		
2	Fincher, Deborah W., M.S., R.Ph.		√	√		
3	Fowler, M. Celeste, Pharm.D.	√		√		
4	Gore, Thomas B., M.D.			√		
5	Graham, Yolanda, M.D.			√		
6	Lorys, Robyn Pharm.D.			√		
7	May, J. Russell (Rusty)			√		
8	Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
9	Rollins, Brent L., R.Ph., Ph.D.			√		
10	Shervette III, Robert E., M.D.			√		
			TOTAL	10	0	0

	Board Members - Absent
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.

NON-SR CLASS	Drug	PDL Status	Motion - Recommendations	Additional Comments
DERMATOLOGICS, GENITAL WART	IMIQUIMOD (TOPICAL) CREAM PACK	NPPA	P	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Doad, Gurinder J.S., M.D.- **Vice**			√		
2	Fincher, Deborah W., M.S., R.Ph.			√		
3	Fowler, M. Celeste, Pharm.D.			√		
4	Gore, Thomas B., M.D.		√	√		
5	Graham, Yolanda, M.D.			√		
6	Lorys, Robyn Pharm.D.	√		√		
7	May, J. Russell (Rusty)			√		
8	Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
9	Rollins, Brent L., R.Ph., Ph.D.			√		
10	Shervette III, Robert E., M.D.			√		
			TOTAL	10	0	0

	Board Members - Absent
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.

NON-SR CLASS	Drug	PDL Status	Motion - Recommendations	Additional Comments
DERMATOLOGICS, LOCAL ANESTHETICS	LIDOCAINE HCL (TOPICAL) LOTION 3 %	NPPA	P	
	LIDOCAINE HCL (TOPICAL) CREAM (G)	NPPA	P	
	LIDOCAINE (TOPICAL) OINT. (G)	P	NPPA	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Doad, Gurinder J.S., M.D.- **Vice**			√		
2	Fincher, Deborah W., M.S., R.Ph.			√		
3	Fowler, M. Celeste, Pharm.D.		√	√		
4	Gore, Thomas B., M.D.			√		
5	Graham, Yolanda, M.D.			√		
6	Lorys, Robyn Pharm.D.	√		√		
7	May, J. Russell (Rusty)			√		
8	Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
9	Rollins, Brent L., R.Ph., Ph.D.			√		
10	Shervette III, Robert E., M.D.			√		
			TOTAL	10	0	0

	Board Members - Absent
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.

Drug Utilization Review Board

Motions - Votes - New Drugs

September 24, 2015

NON-SR CLASS	Drug	PDL Status	Motion - Recommendations	Additional Comments	
GASTROINTESTINAL, HISTAMINE (H-2) RECEPTOR ANTAGONISTS	PEPCID (ORAL) ORAL SUSP	P	NPPA		
Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1 Doad, Gurinder J.S., M.D.- **Vice**			√		
2 Fincher, Deborah W., M.S., R.Ph.			√		
3 Fowler, M. Celeste, Pharm.D.			√		
4 Gore, Thomas B., M.D.	√		√		
5 Graham, Yolanda, M.D.		√	√		
6 Lorys, Robyn Pharm.D.			√		
7 May, J. Russell (Rusty)			√		
8 Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
9 Rollins, Brent L., R.Ph., Ph.D.			√		
10 Shervette III, Robert E., M.D.			√		
		TOTAL	10	0	0
Board Members - Absent					
1 Avery, Mia, Pharm.D.					
2 Damon, Ann R., Pharm.D.					

NON-SR CLASS	Drug	PDL Status	Motion - Recommendations	Additional Comments
GOUT AGENTS	COLCHICINE (ORAL) CAPSULE	NPPA	P	
	COLCHICINE (ORAL) TABLET	NPPA	P	
	COLCRYS (ORAL) TABLET	P	NPPA	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Doad, Gurinder J.S., M.D.- **Vice**			√		
2	Fincher, Deborah W., M.S., R.Ph.	√		√		
3	Fowler, M. Celeste, Pharm.D.			√		
4	Gore, Thomas B., M.D.			√		
5	Graham, Yolanda, M.D.			√		
6	Lorys, Robyn Pharm.D.		√	√		
7	May, J. Russell (Rusty)			√		
8	Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
9	Rollins, Brent L., R.Ph., Ph.D.			√		
10	Shervette III, Robert E., M.D.			√		
			TOTAL	10	0	0

	Board Members - Absent
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.

NON-SR CLASS	Drug	PDL Status	Motion - Recommendations	Additional Comments
IMMUNOSUPPRESSIVE AGENTS	CELLCEPT (ORAL) SUSP RECON	NPPA	PPA	Grandfather clause applicable to Rapamune (oral) Tablet
	SIROLIMUS (ORAL) TABLET	NPPA	P	
	RAPAMUNE (ORAL) TABLET	P	NPPA	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Doad, Gurinder J.S., M.D.- **Vice**			√		
2	Fincher, Deborah W., M.S., R.Ph.			√		
3	Fowler, M. Celeste, Pharm.D.			√		
4	Gore, Thomas B., M.D.			√		
5	Graham, Yolanda, M.D.			√		
6	Lorys, Robyn Pharm.D.			√		
7	May, J. Russell (Rusty)	√		√		
8	Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
9	Rollins, Brent L., R.Ph., Ph.D.			√		
10	Shervette III, Robert E., M.D.		√	√		
			TOTAL	10	0	0

	Board Members - Absent
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.

Drug Utilization Review Board

Motions - Votes - New Drugs

September 24, 2015

NON-SR CLASS	Drug	PDL Status	Motion - Recommendations	Additional Comments
LAXATIVES, BOWEL EVAC			NO CHANGES	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Doad, Gurinder J.S., M.D.- **Vice**			√		
2	Fincher, Deborah W., M.S., R.Ph.			√		
3	Fowler, M. Celeste, Pharm.D.			√		
4	Gore, Thomas B., M.D.		√	√		
5	Graham, Yolanda, M.D.	√		√		
6	Lorys, Robyn Pharm.D.			√		
7	May, J. Russell (Rusty)			√		
8	Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
9	Rollins, Brent L., R.Ph., Ph.D.			√		
10	Shervette III, Robert E., M.D.			√		
			TOTAL	10	0	0

	Board Members - Absent
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.

NON-SR CLASS	Drug	PDL Status	Motion - Recommendations	Additional Comments	
NASAL ANTIALLERGICS			NO CHANGES		
Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1 Doad, Gurinder J.S., M.D.- **Vice**			√		
2 Fincher, Deborah W., M.S., R.Ph.	√		√		
3 Fowler, M. Celeste, Pharm.D.			√		
4 Gore, Thomas B., M.D.			√		
5 Graham, Yolanda, M.D.			√		
6 Lorys, Robyn Pharm.D.			√		
7 May, J. Russell (Rusty)			√		
8 Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
9 Rollins, Brent L., R.Ph., Ph.D.		√	√		
10 Shervette III, Robert E., M.D.			√		
		TOTAL	10	0	0
Board Members - Absent					
1 Avery, Mia, Pharm.D.					
2 Damon, Ann R., Pharm.D.					

Drug Utilization Review Board

Motions - Votes - New Drugs

September 24, 2015

NON-SR CLASS	Drug	PDL Status	Motion - Recommendations	Additional Comments
PROGESTINS	PROGESTERONE (ORAL) CAPSULE	NPPA	P	
	PROMETRIUM (ORAL) CAPSULE	P	NPPA	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Doad, Gurinder J.S., M.D.- **Vice**			√		
2	Fincher, Deborah W., M.S., R.Ph.			√		
3	Fowler, M. Celeste, Pharm.D.			√		
4	Gore, Thomas B., M.D.			√		
5	Graham, Yolanda, M.D.			√		
6	Lorys, Robyn Pharm.D.		√	√		
7	May, J. Russell (Rusty)			√		
8	Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
9	Rollins, Brent L., R.Ph., Ph.D.	√		√		
10	Shervette III, Robert E., M.D.			√		
			TOTAL	10	0	0

	Board Members - Absent
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.

Drug Utilization Review Board

Motions - Votes - New Drugs

September 24, 2015

NON-SR CLASS	Drug	PDL Status	Motion - Recommendations	Additional Comments	
RESPIRATORY LEUKOTRIENE MODIFIERS			NO CHANGES	Review the 2015 guidelines to ensure compliance with the changes concerning the use of Montelukast.	
Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1 Doad, Gurinder J.S., M.D.- **Vice**			√		
2 Fincher, Deborah W., M.S., R.Ph.		√	√		
3 Fowler, M. Celeste, Pharm.D.			√		
4 Gore, Thomas B., M.D.			√		
5 Graham, Yolanda, M.D.			√		
6 Lorys, Robyn Pharm.D.			√		
7 May, J. Russell (Rusty)	√		√		
8 Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
9 Rollins, Brent L., R.Ph., Ph.D.			√		
10 Shervette III, Robert E., M.D.			√		
		TOTAL	10	0	0
Board Members - Absent					
1 Avery, Mia, Pharm.D.					
2 Damon, Ann R., Pharm.D.					

Drug Utilization Review Board

Motions - Votes - New Drugs

September 24, 2015

NON-SR CLASS	Drug	PDL Status	Motion - Recommendations	Additional Comments
SKELETAL MUSCLE RELAXANTS			NO CHANGES	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Doad, Gurinder J.S., M.D.- **Vice**			√		
2	Fincher, Deborah W., M.S., R.Ph.			√		
3	Fowler, M. Celeste, Pharm.D.			√		
4	Gore, Thomas B., M.D.			√		
5	Graham, Yolanda, M.D.		√	√		
6	Lorys, Robyn Pharm.D.			√		
7	May, J. Russell (Rusty)			√		
8	Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
9	Rollins, Brent L., R.Ph., Ph.D.	√		√		
10	Shervette III, Robert E., M.D.			√		
			TOTAL	10	0	0

	Board Members - Absent
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.

NON-SR CLASS	Drug	PDL Status	Motion - Recommendations	Additional Comments
ULCER DRUGS, ANTISPASMODICS			NO CHANGES	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Doad, Gurinder J.S., M.D.- **Vice**			√		
2	Fincher, Deborah W., M.S., R.Ph.			√		
3	Fowler, M. Celeste, Pharm.D.			√		
4	Gore, Thomas B., M.D.	√		√		
5	Graham, Yolanda, M.D.			√		
6	Lorys, Robyn Pharm.D.			√		
7	May, J. Russell (Rusty)			√		
8	Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
9	Rollins, Brent L., R.Ph., Ph.D.		√	√		
10	Shervette III, Robert E., M.D.			√		
			TOTAL	10	0	0

	Board Members - Absent
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.

NON-SR CLASS	Drug	PDL Status	Motion - Recommendations	Additional Comments	
ULCER DRUGS, H PYLORI	PREVPAC (ORAL) COMBO. PKG	PPA	NPPA		
Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1 Doad, Gurinder J.S., M.D.- **Vice**			√		
2 Fincher, Deborah W., M.S., R.Ph.			√		
3 Fowler, M. Celeste, Pharm.D.			√		
4 Gore, Thomas B., M.D.	√		√		
5 Graham, Yolanda, M.D.			√		
6 Lorys, Robyn Pharm.D.		√	√		
7 May, J. Russell (Rusty)			√		
8 Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
9 Rollins, Brent L., R.Ph., Ph.D.			√		
10 Shervette III, Robert E., M.D.			√		
		TOTAL	10	0	0
Board Members - Absent					
1 Avery, Mia, Pharm.D.					
2 Damon, Ann R., Pharm.D.					

NON-SR CLASS	Drug	PDL Status	Motion - Recommendations	Additional Comments
URINARY ANTI-INFECTIVES	METHENAMINE MANDELATE (ORAL) TABLET	NPPA	P	
	URO-BLUE (ORAL) TABLET	P	NPPA	
	UTIRA-C (ORAL) TABLET	P	NPPA	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Doad, Gurinder J.S., M.D.- **Vice**			√		
2	Fincher, Deborah W., M.S., R.Ph.			√		
3	Fowler, M. Celeste, Pharm.D.			√		
4	Gore, Thomas B., M.D.	√		√		
5	Graham, Yolanda, M.D.			√		
6	Lorys, Robyn Pharm.D.			√		
7	May, J. Russell (Rusty)			√		
8	Miller, Osgood (Drew) A. R.Ph. - **Chair**			√		
9	Rollins, Brent L., R.Ph., Ph.D.		√	√		
10	Shervette III, Robert E., M.D.			√		
			TOTAL	10	0	0

	Board Members - Absent
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.

GEORGIA DEPARTMENT OF COMMUNITY HEALTH

Drug Utilization Review Board Meeting

September 24, 2015

Therapeutic Class	Drug Name	Current PDL Status	DCH Decisions
New Drug Reviews			
Sedative Hypnotics			
	Belsomra (Oral) Tablet	NP/PA	NP/PA – no concomitant use with benzodiazepines
Biologic Immunomodulators			
	Cosentyx (Subcutaneous) Syringe/Pens	NP/PA	P/PA –step therapy with Humira
Attention Deficit Hyperactivity Disorder (ADHD)			
	Evekeo(Oral) Tablet	NP/PA	NP/PA
Antineoplastics, Breast Cancer			
	Ibrance (Oral) Capsule	P/PA	P/PA
Antineoplastics, Thyroid Cancer			
	Lenvima (Oral) Capsule	P/PA	P/PA
Antineoplastics, Ovarian Cancer			
	Lynparza (Oral) Capsule	P/PA	P/PA
Thrombopoietin Receptor Agonists			
	Nplate (Subcutaneous) Vial	P/PA	Postpone for follow-up and further review
Anticoagulants			
	Savaysa (Oral) Tablet	NP/PA	NP/PA
Dermatologics, Acne Rosacea			
	Soolantra (Topical) Cream	NP/PA	NP/PA
Metabolic Enzymes			
	Vimizim (Intravenous) Vial	P/PA	P/PA

Class Reviews			
Antianginal Agents			
	Nitroglycerin (Translingual) Spray	NP	P
	Nitromist (Translingual) Spray	P	NP/PA
Antiinfectives, Cephalosporins			
	Cefaclor (Oral) Suspension	P	NP/PA
	Cefixime (Oral) Suspension	P/PA	NP/PA
	Ceftin (Oral) Suspension	NP	P
	Suprax (Oral) Capsule	NP/PA	P/PA – quantity level limit of 1 {for appropriate indication(s)}
	Suprax (Oral) Suspension	P	NP/PA
Antiinfectives, Tetracyclines			
	Minocycline Hydrochloride (Oral) Tablet	P	NP/PA
Antiparkinson Agents			
	Carbidopa (Oral) Tablet	NP/PA	P
	Lodosyn (Oral) Tablet	P	NP/PA
Antivirals, Genital Herpes Simplex Virus (HSV)			
	Acyclovir (Topical) Ointment 5%	P	NP/PA
Contraceptives			
	Alyacen (Oral) Tablet	NP/PA	P
	Aranelle (Oral) Tablet	P	NP/PA
	Cyclafem (Oral) Tablet	NP/PA	P
	Dasetta (Oral) Tablet	NP/PA	P
	Femcon FE Chew (Oral) Tablet Chewable	NP/PA	P
	Junel FE 24 (Oral) Tablet	P	NP/PA

	Leena (Oral) Tablet	P	NP/PA
	Lomedia 24 FE (Oral) Tablet	P	NP/PA
	Nor-QD (Oral) Tablet	NP/PA	P
	Nortrel (Oral) Tablet	NP/PA	P
	Ortho-Novum (Oral) Tablet	P	NP/PA
	Ortho Tri-Cyclen (Oral) Tablet	P	NP/PA
	Pirmella (Oral) Tablet	NP/PA	P
	Trinessa (Oral) Tablet	P	NP/PA
Cough and Cold Prescription (Rx) Products			
	Brompheniramine/Pseudoephedrine	NC	P
Dermatologics, Acne Vulgaris			
	Atralin	NP/PA	P
	Benzaclin (Topical) Gel	NP/PA	P
	Epiduo (Topical) Gel	NP/PA	P
	Retin-A (Topical) Gel	NP/PA	P
	Sodium Sulfacetamide-Sulfur (Topical) Cleanser/Cream	P	NP/PA
	Tretinoin (Topical) Cream	NP/PA	P
	Tretinoin Microsphere (Topical) Gel	P/PA	NP/PA
Dermatologics, Corticosteroids			
	Amcinonide (Topical) Cream	NP/PA	P
	Amcinonide (Topical) Lotion	P	NP/PA
	Clobetasol Emollient (Topical) Cream	P	NP/PA
	Clobetasol Propionate (Topical) Cream	P	NP/PA
	Desonide (Topical) Cream/Lotion/ Ointment	NP/PA	P

	Fluocinonide (Topical) Ointment	P	NP/PA
	Hydrocortisone Valerate (Topical) Cream/Ointment	P	NP/PA
	Kenalog (Topical) Aerosol	P	NP/PA
	Mometasone Furoate (Topical) Cream/Ointment /Solution	NP/PA	P
	Prednicarbate (Topical) Ointment	P	NP/PA
	Triamcinolone Acetonide (Topical) Lotion	NP/PA	P
Dermatologics, Genital Warts			
	Imiquimod (Topical) Cream	NP/PA	P
Dermatologics, Local Anesthetics			
	Lidocaine (Topical) Cream/Lotion 3%	NP/PA	P
	Lidocaine (Topical) Ointment 5%	P	NP/PA
Gastrointestinal, Histamine (H-2) Receptor Antagonists			
	Pepcid (Oral) Suspension	P	NP/PA
Gout Agents			
	Colchicine (Oral) Capsule/Tablet	NP/PA	P
	Colcrys (Oral) Tablet	P	NP/PA
Immunosuppressive Agents			
	Cellcept (Oral) Suspension	NP	P/PA
	Rapamune (Oral) Tablet	P	NP/PA
	Sirolimus (Oral) Tablet	NP/PA	P
Progestins			
	Progesterone (Oral) Capsule	NP/PA	P

	Prometrium (Oral) Capsule	P	NP/PA
Ulcer Drugs, H. Pylori			
	Prevpac (Oral) Combination Package	P/PA	NP/PA
Urinary, Antiinfectives			
	Methenamine Mandelate (Oral) Tablet	NP/PA	P
	Uro-Blue (Oral) Tablet	P	NP/PA
	Utira-C (Oral) Tablet	P	NP/PA

NP = non-preferred/ P = preferred/ PA = prior authorization

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Manufacturers' Forum
Manufacturer Presentations

Dates: November 5, 2015

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

Attendees
Department of Community Health
Peter D'Alba, RPh, Director of Pharmacy
Gilletta Gray, RPh, Clinical Pharmacy Manager

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. AstraZeneca
Rana Rittgers-Simonds, RD, Regional Account Director
Julie Huber, PharmD, Regional Clinical Account Director

Movantik™ [mo van tic] (naloxegol) [nal-OX-ee-gol] Tablets
Overview: Opioids play an important role in chronic pain relief by binding to mu-receptors in the central nervous system (CNS), but they also bind to mu-receptors in the gastrointestinal (GI) tract, which may result in opioid-induced constipation (OIC). In fact, OIC is 1 of the most common adverse events seen with opioids. OIC may be a burden to the patient and the health care system. It can limit activities of daily living, decrease productivity, reduce overall health-related quality of life, complicate the management of pain, and potentially increase health care resource utilization and costs.

Distinguishing Characteristics:
- ***Targeted Mechanism of Action:*** When administered at the recommended dose levels, MOVANTIK functions as a peripherally acting mu-opioid receptor antagonist in tissues such as the GI tract, thereby decreasing the constipating effects of opioids. MOVANTIK is a PEGylated derivative of naloxone and is a substrate for the P-glycoprotein transporter. The presence of the PEG moiety in MOVANTIK reduces its passive permeability as compared with naloxone. Because of the reduced permeability and increased efflux of MOVANTIK across the blood-brain barrier related to P-glycoprotein transporter substrate properties, the central nervous system penetration of MOVANTIK is expected to be negligible at the recommended dose levels, limiting the for interference with centrally mediated opioid analgesia.
- ***Once-Daily Oral Dosing*****:** MOVANTIK provides a once-daily, single oral tablet for the treatment of OIC in adult patients with chronic non-cancer pain.
- ***Efficacy and Long-Term Safety Data*****:** The KODIAC clinical trial program consisted of Phase III trials (2 pivotal efficacy and safety trials, a safety extension trial, and a long-term safety and tolerability trial) of MOVANTIK for the treatment of OIC in patients with chronic noncancer pain. In the 2 pivotal safety and efficacy trials (KODIAC 4 and

KODIAC 5), MOVANTIK 25 mg resulted in a significantly higher rate of response, including those with an inadequate response to laxatives, when compared to placebo. In a 12-week safety extension trial (KODIAC 7) and a 52-week safety and tolerability study (KODIAC 8), the rate and pattern of AEs observed were generally comparable to that seen in pivotal safety and efficacy trials.

Indication and Dosing: MOVANTIK is indicated for the treatment of OIC in adult patients with chronic non-cancer pain. The recommended dose of MOVANTIK is 25 mg once daily orally in the morning. If patients are not able to tolerate MOVANTIK using concomitant moderate cytochrome P450 3A4 (CYP3A4) inhibitors (if use is unavoidable and adverse reactions are monitored) or have a creatinine clearance lower than 60 mL/min, reduce the dosage to 12.5 mg once daily. Discontinue all maintenance laxative therapy prior to initiation of MOVANTIK. Laxative(s) can be used as needed if there is a suboptimal response to MOVANTIK after 3 days. Alteration in analgesic dosing regimen prior to initiating MOVANTIK is not required.

Contraindications: MOVANTIK is contraindicated in patients with known or suspected GI obstruction and in patients at increased risk of recurrent obstruction, in patients using strong CYP3A4 inhibitors, and in patients who have had a known serious or severe hypersensitivity reaction to MOVANTIK or any of its excipients.

Clinical Data: In KODIAC 4 and KODIAC 5, two identically designed randomized, double-blind, placebo-controlled, Phase III trials evaluating the safety and efficacy of MOVANTIK for OIC in adult patients with non-cancer pain, the primary efficacy outcome was response over Weeks 1-12. Response was defined as ≥3 spontaneous bowel movements (SBM) per week and an increase of ≥1 SBM over baseline per week for ≥9 out of the 12 study weeks and ≥3 out of the last 4 weeks. MOVANTIK 25 mg resulted in a statistically significant higher response rate compared with placebo in both KODIAC 4 (44.4% vs. 29.4%) and KODIAC 5 (39.7% vs. 29.3%). MOVANTIK 25 mg also resulted in a significantly higher rate of response in patients with an inadequate response to laxatives when compared to placebo in KODIAC 4 (48.7% vs. 28.8%) and KODIAC 5 (46.8% vs. 31.4%). MOVANTIK 12.5 mg was associated with a statistically significant higher response rate compared with placebo in KODIAC 4 (40.8% vs. 29.4%), but not in KODIAC 5. As such, significance cannot be claimed for any of the key secondary endpoints for the 12.5-mg dose in KODIAC 5. Additional key secondary endpoints included the time to first postdose SBM and the mean number of days per week with 1-3 SBMs over Weeks 1-12. In KODIAC 4 and KODIAC 5, the median time to first postdose SBM was 5.9 and 12 hours in the MOVANTIK 25 mg groups and 35.8 and 37.2 hours in the placebo group, respectively ($p<0.001$ for all). Treatment with MOVANTIK 25 mg in KODIAC 4 and KODIAC 5 was associated with a statistically significant increase in the mean number of days per week with 1 or more SBMs over Weeks 1-12 ($p<0.001$ for all); this effect remained consistent over the 12-week treatment period.

Safety: Through the KODIAC clinical trial program, 1497 patients have been exposed to MOVANTIK, including 537 patients for longer than 6 months and 320 patients for 12 months. Adverse reactions that occurred in **≥**3% of patients receiving MOVANTIK 12.5 mg or 25 mg and at an incidence greater than placebo (MOVANTIK 25 mg, MOVANTIK 12.5 mg, and placebo, respectively) were abdominal pain (21%, 12%, and 7%), diarrhea (9%, 6%, and 5%), nausea (8%, 7%, and 5%), flatulence (6%, 3%, and 3%), vomiting (5%, 3%, and 4%), headache (4%, 4%, and 3%), and hyperhidrosis (3%, <1%, and <1%). Safety data for patients in KODIAC 7 and in KODIAC 8 are similar to those observed in KODIAC 4 and 5.

Warnings and Precautions: Gastrointestinal Perforation: Consider the overall risk benefit in patients with known or suspected lesions of the GI tract. Monitor for severe, persistent, or worsening abdominal pain; discontinue MOVANTIK if this symptom develops. Opioid Withdrawal: Consider the overall risk benefit in patients with disruptions to the blood-brain barrier. Monitor for symptoms of opioid withdrawal.

Questions and Answers
Q: What is the average time to response?
A: Approximately 6 hours.

Q: How long is the duration of use?
A: There is safety data for up to 52 weeks.

Q: Has a study been conducted in cancer patients?
A: No, KODIAC 6 was to enroll cancer patients but had difficulty enrolling enough patients due to the patients already being enrolled in other clinical trials.

Q: What is a reasonable quantity limit for 30 days?
A: 30 pills per 30 days but anecdotally patients are not taking every day.

Q: Was as needed dosing studied?
A: Only maintenance dosing of once daily has been studied.

Q: Are there any head-to-head trials?
A: No, not currently.

II. Shire

Patrick A. Kelly, PharmD, Medical Science Liaison
Biji Joseph, Director, Medical Affairs

Natpara® (nat-PAH-rah) - (parathyroid hormone) for injection, for subcutaneous use

INDICATIONS AND USAGE

Natpara is a parathyroid hormone indicated as an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism. Because of the potential risk of osteosarcoma, Natpara is recommended only for patients who cannot be well-controlled on calcium supplements and active forms of vitamin D alone, and is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) program. The dose of Natpara should be individualized based on total serum calcium (albumin-corrected) and 24-hour urinary calcium excretion. The recommended Natpara dose is the minimum dose required to prevent both hypocalcemia and hypercalcemia. This dose will generally be the dose that maintains total serum calcium (albumin-corrected) within the lower half of the normal range (i.e. between 8-9 mg/dL) without the need for active forms of vitamin D and with calcium supplementation sufficient and individualized to meet the patient's daily requirements; Natpara was not studied in patients with hypothyroidism caused by calcium-receptor mutations nor in patients with acute post-surgical hypoparathyroidism.

BOXED WARNING - WARNING: POTENTIAL RISK OF OSTEOSARCOMA

- In male and female rats, parathyroid hormone caused an increase in the incidence of osteosarcoma (a malignant bone tumor) that was dependent on dose and treatment duration. A risk to humans could not be excluded.
- Because of the potential risk of osteosarcoma, prescribe Natpara only to patients who cannot be well-controlled on calcium and active forms of vitamin D and for whom the potential benefits are considered to outweigh the potential risk.
- Avoid use of Natpara in patients who are at increased baseline risk for osteosarcoma (including those with Paget's disease of bone or unexplained elevations of alkaline phosphatase, pediatric and young adult patients with open epiphyses, patients with hereditary disorders predisposing to osteosarcoma or patients with a history of prior external beam or implant radiation therapy involving the skeleton)
- Natpara is available only through a restricted program called the Natpara REMS Program

WARNINGS AND PRECAUTIONS

Severe Hypercalcemia: Monitor serum calcium when starting or adjusting Natpara dose and when making changes to co-administered drugs known to raise serum calcium; *Severe Hypocalcemia:* Can occur with interruption or discontinuation of Natpara treatment. Monitor serum calcium and replace calcium and vitamin D; *Digoxin Toxicity:* Hypercalcemia increases the risk of digoxin toxicity. In patients using Natpara concomitantly with digoxin, monitor serum calcium more frequently and increase monitoring when initiating or adjusting Natpara dose.

CLINICAL STUDIES

The efficacy of Natpara was evaluated in a 24-week, randomized, double-blind, placebo-controlled, multicenter trial. In this trial, patients with established hypoparathyroidism receiving calcium and active vitamin D (vitamin D metabolite or analogs) were randomized (2:1) to Natpara (n=84) or placebo (n=40). A responder was defined as an individual who had: at least a 50% reduction from baseline in the dose of active vitamin D, at least a 50% reduction from baseline in the dose of oral calcium supplementation and an albumin-corrected total serum calcium concentration between 7.5 mg/dl and 10.6 mg/dl. At the end of treatment, significantly (p-value < 0.001) more subjects treated with Natpara [46/84 (54.8%)] compared to placebo [1/40 (2.5%)] met the response criterion. Forty-two percent (35/84) of subjects randomized to Natpara were independent of active forms of vitamin D and were on no more than 500mg of oral calcium, compared with 2.5% (1/40) of subjects randomized to placebo (p < 0.001). There were no differences in the

proportion of patients with calcium levels between 7.5mg and 10.6mg at the end of treatment between subjects randomized to Natpara and placebo.

ADVERSE REACTIONS
The most common adverse reaction associated with Natpara and occurring in greater than 10% of individuals were: paresthesia, hypocalcemia, headache, hypercalcemia, nausea, hypoaesthesia, diarrhea, vomiting, arthralgia, hypercalciuria, and pain in extremity.

USE IN SPECIFIC POPULATIONS
Pregnancy Category C: There are no adequate and well-controlled studies in pregnant women; No dose adjustment is recommended in patients 65 years of age and older, or in patients with mild to moderate renal or hepatic impairment; Safety and efficacy in patients less than 18 years of age has not been established.

HOW SUPPLIED
Natpara (parathyroid hormone) for injection for subcutaneous use is supplied as a medication cartridge, which is comprised of a multiple dose, dual-chamber glass cartridge containing a sterile lyophilized powder and a sterile diluent, within a plastic cartridge holder. The medication cartridge is available in four dosage strengths (25, 50, 75, and 100 mcg/dose). The disposable Natpara medication cartridge is designed for use with a reusable mixing device for product reconstitution and a reusable Q-Cliq injector for drug delivery. Using the Q-Cliq pen, each Natpara medication cartridge delivers 14 doses: each dose contains 25, 50, 75, or 100 mcg of Natpara depending on the product dosage strength.

Questions and Answers
Q: Is distribution limited to specialty pharmacies?
A: Yes, limited to 3 specialty pharmacies.

Q: What is the average duration of use?
A: Continuous for life.

Q: Is an indication in osteoporosis being sought?
A: No.

Q: Did any patients dose >100 mcg/day in studies?
A: No.

Q: How are other Medicaid plans covering?
A: Due to cost, with PA per prescribing information and not well controlled on vitamin D and calcium.

III. Biogen

Kendra L. Davies, PharmD, RPh, Senior Medical Outcomes & Science Liaison
Kelli Heathman, Regional Account Manager

Alprolix® [Coagulation Factor IX (Recombinant), Fc Fusion Protein]
Indication and MOA: ALPROLIX was approved in March 2014 in adults and children with hemophilia B for the control and prevention of bleeding episodes, perioperative management, and routine prophylaxis to prevent or reduce the frequency of bleeding episodes. ALPROLIX is a recombinant, fusion protein that temporarily replaces the missing coagulation Factor IX needed for effective hemostasis. ALPROLIX contains the Fc region of human IgG1, which binds to the neonatal Fc receptor (FcRn). FcRn is part of a naturally occurring pathway that delays lysosomal degradation of immunoglobulins by cycling them back into circulation, and prolonging their plasma half-life.

Clinical Trial Data: A Phase III, open-label, multicenter study was conducted to evaluate the safety, efficacy, and pharmacokinetics of ALPROLIX in previously treated males with hemophilia B. Patients were assigned to: Arm 1 weekly prophylaxis with 50 IU/kg of ALPROLIX to start, dose adjusted as needed; Arm 2 interval adjusted prophylaxis with 100 IU/kg of ALPROLIX at intervals of 10 days to start, interval adjusted as needed; Arm 3 20-100 IU/kg of ALPROLIX for bleeding episodes; or Arm 4 ALPROLIX as part of perioperative care. Prophylactic treatment significantly reduced the annualized rate of bleeding in arm 1 (by 83%) and arm 2 (by 87%) as compared with the rate in the episodic treatment arm. Pharmacokinetic analysis in adults showed ALPROLIX and BeneFIX had geometric

mean terminal half-lives of 82.1 hours and 33.8 hours, respectively (p<0.001). The time to reach a factor IX level of 1 IU/dL was 11.2 days with ALPROLIX and 5.1 days with recombinant factor IX. No inhibitors were detected and there were no cases of vascular thrombotic events, serious hypersensitivity or anaphylaxis. The most common adverse events were nasopharyngitis, influenza, arthralgia, upper respiratory tract infection, headache, and hypertension.

The safety and efficacy of ALPROLIX in previously treated children with severe hemophilia B was assessed in a multi-center, open-label phase 3 study with a single once-weekly prophylactic arm. No inhibitors occurred in this study. Most common adverse event on study included nasopharyngitis and fall. There were no reports of anaphylaxis or serious hypersensitivity reactions related to ALPROLIX, no vascular thrombotic events, and no deaths. Among patients previously treated with BeneFIX and with complete and evaluable PK profiles for both BeneFIX and ALPROLIX, the median half-life of ALPROLIX was prolonged compared with prestudy FIX, while incremental recovery was comparable. Overall, a low ABR was observed with once-weekly prophylactic dosing. 91.7% of bleeding episodes were controlled with 1 or 2 infusions. A post-hoc analysis comparison of prestudy and on-study weekly prophylactic dose was performed for patients treated previously with BeneFIX. Patients in both age cohorts reduced their weekly prophylactic dose with ALPROLIX compared with their prior BeneFIX regimen.

Interim data were presented to report long-term safety and efficacy data for ALPROLIX in adults and adolescents (> 12 years old) enrolled in the ongoing B-YOND extension study. As of the interim data cut (October 2014), median annualized bleeding rates (ABRs) were consistently low with prophylaxis: overall weekly prophylaxis 2.28, individualized prophylaxis 2.25, and modified prophylaxis 2.42. Interim data from B-YOND confirm the long-term safety of ALPROLIX and the maintenance of a low ABR with prophylactic dosing (4). Interim data for ALPROLIX in children enrolled in the ongoing B-YOND extension study demonstrated median annualized bleeding rates (ABRs) were consistently low with prophylaxis: overall weekly prophylaxis 0.00 for <6 years and 2.65 for 6 to <12 years, individualized prophylaxis 2.37 in 6 to <12 years, and modified prophylaxis 3.13 in 6 to <12 years. Interim data in hemophilia B children participating in B-YOND confirm the long-term safety of ALPROLIX and the maintenance of a low ABR with extended-interval prophylactic dosing. No inhibitors were observed. No serious allergic reactions or anaphylaxis, or vascular thrombotic events were observed with ALPROLIX treatment, and the pattern of adverse events was typical of the hemophilia population studied.

A retrospective analysis was conducted to evaluate the real-world ALPROLIX dosing and treatment interval patterns. Two prophylactic regimens have been evaluated for ALPROLIX in the B-LONG clinical trial. In the weekly prophylaxis arm, the overall median consumption on-study was 40.5 IU/kg in the last 3 months on-study. The individualized interval prophylaxis arm had a median weekly consumption of 50.0 IU/kg in the last 3 months on-study. For patients on a prophylactic regimen, 76.1% had a dosing interval of once weekly, with 23.9% having an infusion interval greater than every 7 days. The majority of dispensing records indicate patients initiating ALPROLIX therapy may utilize lower amounts of factor than patients receiving other FIX products, while also experiencing a reduction in infusion frequency.

Questions and Answers
Q: What is the approximate frequency of dosing vs. other factor IX recombinants?
A: Approximately every 7-10 days with Alprolix (up to every 14 days for some patients); approximately every 4-5 days with other factor IXs.

Q: Are there any outcomes, cost-effective or pharmacoeconomic studies vs. other factor IXs?
A: These are in progress with intermediate data possibly in 1 year.

Eloctate® [Antihemophilic Factor (Recombinant), Fc Fusion Protein]
Indication and MOA: ELOCTATE was approved in June 2014 for adults and children with Hemophilia A for control and prevention of bleeding episodes, perioperative management, and routine prophylaxis to prevent or reduce the frequency of bleeding episodes. ELOCTATE is a recombinant fusion protein that temporarily replaces the missing Coagulation Factor VIII needed for effective hemostasis. ELOCTATE contains the Fc region of human immunoglobulin G1 (IgG1), which binds to the neonatal Fc receptor (FcRn). FcRn is part of a naturally occurring pathway that delays lysosomal degradation of immunoglobulins by cycling them back into circulation and prolonging their plasma half-life.

Clinical Trial Data: The efficacy of ELOCTATE was evaluated in a phase III clinical trial in 165 previously treated patients (PTPs) with severe hemophilia A. Two prophylactic regimens consisting of fixed weekly doses at 65 IU/kg (n=24) or individualized interval at twice-weekly dosing of 25 IU/kg on day 1, 50 IU/kg on day 4 to start, adjusted to 25-65 IU/kg every 3-5 days (n=118) were compared to episodic treatment (10-50 IU/kg as needed for bleeding episodes). For routine prophylaxis, a reduction in annualized bleeding rate (ABR) of 76% (P<0.001) was observed for subjects in

the fixed weekly interval arm and a reduction of 92% (P<0.001) for subjects in the individualized interval arm compared to the episodic treatment arm. Geometric mean half-life was 19.0 hours for ELOCTATE and 12.4 hours for rFVIII (ADVATE) (p < 0.001). Mean time to 1 IU/dL (1%) FVIII trough level above baseline was 4.9 days for ELOCTATE and 3.3 days for rFVIII (p < 0.001). There were no inhibitors, serious vascular thrombotic events, serious hypersensitivity, or anaphylaxis reported during the study. The most common related AEs were arthralgia and malaise.

Kids A-LONG was a phase 3 open-label study evaluating the safety, efficacy and pharmacokinetics of ELOCTATE in previously treated children with severe hemophilia A. The starting regimen was twice-weekly prophylaxis (Day 1: 25 IU/kg and Day 4: 50 IU/kg. Dose (< 80 IU/kg) and dosing interval (> 2 days) were adjusted as needed. The half-life of ELOCTATE was prolonged relative to that of FVIII, consistent with observations in adults and adolescents. The median ABRs were 1.96 overall and 0.00 for spontaneous bleeds; 46.4% of patients reported no bleeding episodes on study. The median average dosing interval for ELOCTATE prophylaxis was 3.5 days. Among patients who had previously received FVIII prophylaxis, 74.2% reduced their dosing frequency with ELOCTATE. Median average weekly ELOCTATE prophylactic dose was 88.11 IU/kg. No patient developed an inhibitor. There were no reports of anaphylaxis or vascular thrombotic events, and no deaths. Adverse events were typical of a pediatric hemophilic population.

The ongoing extension study, ASPIRE, evaluates the long-term safety and efficacy of ELOCTATE in patients who completed the A-LONG and Kids A-LONG studies. As of the interim data cut (January 6,2014), the median ABR for individualized prophylaxis in A-LONG was 0.66; in Kids A-LONG ABR was 0.00 for <6 years old and 1.54 in 6 to <12 years old. Among prophylactic patients, 21.9% lengthened their prophylactic infusion interval, 71.9% made no change, and 6.3% had a shorter prophylactic infusion interval. Interim data from a United States (US) subgroup analysis of ASPIRE evaluated 49 patients from ALONG and 11 patients from Kids A-LONG. Among patients on prophylaxis on A-LONG, 76% did not change, 17% lengthened their dosing interval; 69% had no change to and 10% reduced their weekly prophylactic dose. Among patients receiving ELOCTATE prophylaxis during ASPIRE, median overall and spontaneous ABRs were low. The median (interquartile range [IQR]) change in weekly prophylactic dose was 0.0 (0.0-0.0) for both A-LONG and Kids A-LONG patients. The percentage of individual and weekly prophylaxis patients with no bleeding episodes on-study was 48.7% and 16.7%, respectively. Among children in the individualized prophylaxis group, the percentage of patients with no bleeding episodes on-study was 66.7%. Overall, 94% (A-LONG) and 100% (Kids A-LONG) of bleeding episodes were controlled with 1 infusion. No patients developed an inhibitor during ASPIRE as of the interim cut (January 6, 2014). There were no reports of anaphylaxis or serious hypersensitivity events, no serious vascular thrombotic events, and no deaths.

A retrospective analysis evaluated real-world patient characteristics and treatment regimens in patients with hemophilia A using ELOCTATE in the US. Overall, the most commonly prescribed infusion frequency was every 4 days (representing 33% of patient records) and 50% of all patients were prescribed an infusion frequency of every 4 days or longer. Of the patients who were prescribed the most common infusion frequencies (every 3-5 days), the majority were prescribed 45-55 IU/kg of ELOCTATE per infusion. Overall, 79% of a subset of patients whose previous FVIII prophylactic therapy was available lengthened their infusion interval with ELOCTATE.

Questions and Answers
Q: Are there any outcomes, cost-effective or pharmacoeconomic studies vs. other factor IXs?
A: These are in progress with intermediate data possibly in 1 year.

Q: How are other Medicaid plans covering?
A: Most in the southeast cover without restrictions.

IV. Novartis

Tom Arnhart, PharmD, MS, Regional Account Scientific Director
Suzette Bannister, Senior Regional Account Manager

Farydak® (panobinostat)
Overview

- Farydak (panobinostat), a histone deacetylase inhibitor, in combination with bortezomib and dexamethasone, is indicated for the treatment of patients with multiple myeloma who have received ≥2 prior regimens, including bortezomib and an immunomodulatory agent. 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 confirmatory trials.

- The recommended starting dose of panobinostat is 20 mg, taken orally once every other day for 3 doses per week in Weeks 1 and 2 of each 21-day cycle for up to 8 cycles. Consider continuing treatment for an additional 8 cycles for patients with clinical benefit who do not experience unresolved severe or medically significant toxicity. The total treatment duration may be up to 16 cycles (48 weeks). Panobinostat is administered in combination with bortezomib 1.3 mg/m2 given as an injection and oral dexamethasone 20 mg per scheduled day, on a full stomach.

Study Design

- PANORAMA-1 was a Phase 3, multicenter, randomized, placebo-controlled, double-blind study (N=768) evaluating the efficacy and safety of panobinostat in combination with bortezomib and dexamethasone in patients with relapsed multiple myeloma who had received 1 to 3 prior lines of therapy. Patients received either the combination of panobinostat, bortezomib, dexamethasone or placebo, bortezomib, dexamethasone (control arm) were stratified by prior use of bortezomib and the number of prior lines of anti-myeloma therapy.
- The primary endpoint was PFS, using modified European Bone Marrow Transplant Group (EBMT) criteria, as assessed by the investigators.
- All patients received 21 days cycles of; intravenous bortezomib 1.3mg/m2 on Days 1, 4, 8 and 11; and oral dexamethasone 20 mg on Days 1, 2, 4, 5, 8, 9, 11 and 12 and oral panobinostat 20 mg on Days 1, 3, 5, 8, 10 and 12 or placebo.
- During Phase I, patients were treated for eight 3-week cycles. At the end of Phase I, patients with clinical benefit (defined as: no change on Day 1 of Cycle 8, as assessed by EBMT criteria), could proceed to Phase 2 which included four 6-week cycles. In Phase 2, bortezomib was only given once a week and dexamethasone twice a week (the day of bortezomib infusion and the day after).

Results

- In the overall trial population, the median PFS (95% CI) was 12 months (10.3, 12.9) in the panobinostat, bortezomib, dexamethasone arm and 8.1 months (7.6, 9.2) in the control arm, [HR: 0.63 (95% CI: 0.52, 0.76)]. At the time of interim analysis, overall survival was not statistically different between arms.
- The approval of panobinostat was based upon the efficacy and safety in a prespecified subgroup analysis of 193 patients who had received prior treatment with both bortezomib and an immunomodulatory agent and a median of 2 prior therapies as the benefit:risk appeared to be greater in this more heavily pretreated population than in the overall trial population.
- Of these 193 patients, 76% of them had received ≥2 prior lines of therapy. The median PFS (95% CI) was 10.6 months (7.6, 13.8) in the panobinostat, bortezomib, and dexamethasone arm and 5.8 months (4.4, 7.1) in the control arm (HR: 0.52 [0.36, 0.76]).The overall response rate using modified EBMT criteria was 59% in the panobinostat, bortezomib, and dexamethasone arm and 41% in the control arm. The complete response or near complete response rate was significantly higher in patients randomized to panobinostat compared with placebo (22.3% vs 9.1%).

Safety

- **WARNING: FATAL AND SERIOUS TOXICITIES: SEVERE DIARRHEA AND CARDIAC TOXICITIES**
- Grade 3/4 diarrhea occurred in 25% of patients receiving panobinostat. Monitor for symptoms, institute antidiarrheal treatment, interrupt panobinostat and reduce dose or discontinue panobinostat.
- Severe and fatal cardiac ischemic events, severe arrhythmias, and ECG changes have occurred in patients receiving panobinostat. Arrhythmias may be exacerbated by electrolyte abnormalities. Obtain ECG and electrolytes at baseline and periodically during treatment as clinically indicated.
- Serious adverse events (SAEs) occurred in 60% of patients in the panobinostat, bortezomib, and dexamethasone compared to 42% of patients in the control arm. The most frequent (≥5%) treatment-emergent SAEs reported for patients treated with panobinostat were pneumonia (18%), diarrhea, (11%), thrombocytopenia (7%), fatigue (6%), and sepsis (6%).Deaths occurred in 8% of patients in the panobinostat arm versus 5% on the control arm. The most frequent causes of death were infection and hemorrhage.
- Grade 3/4 AEs occurred in 364 (96%) patients in the panobinostat group and 310 (82%) in the placebo group. Common Grade 3/4 non-hematologic AEs included diarrhea, asthenia or fatigue and peripheral neuropathy. Grade 3/4 hematologic abnormalities more common in the panobinostat group included thrombocytopenia, lymphopenia and neutropenia. Grade 3/4 hemorrhage occurred in 16 patients treated with panobinostat and nine who received placebo.
- Warnings and Precautions of hemorrhage, hepatotoxicity, embryo-fetal toxicity.

- The most common adverse reactions (incidence of at least 20%) in clinical studies are diarrhea, fatigue, nausea, peripheral edema, decreased appetite, pyrexia, and vomiting.
- The most common non-hematologic laboratory abnormalities (incidence ≥ 40%) are hypophosphatemia, hypokalemia, hyponatremia, and increased creatinine. The most common hematologic laboratory abnormalities (incidence ≥60%) are thrombocytopenia, lymphopenia, leukopenia, neutropenia, and anemia.

Questions and Answers
Q: Is an indication as initial treatment being sought?
A: Not at this time.

Q: How are other Medicaid plans covering?
A: Preferred with prior authorization to ensure use a 3rd line agent.

Q: Is the medication only available through specialty pharmacies?
A: Yes, through approximately 8 specialty pharmacies.

Promacta® (eltrombopag)
Chronic Immune (Idiopathic) Thrombocytopenia (Adults and Pediatrics)
Overview
- The recommended dose for Promacta (eltrombopag) is 50 mg orally once daily for most adult and pediatric patients 6 years and older and 25 mg once daily for pediatric patients aged 1 to 5 years. Dose reductions are needed for patients with hepatic impairment and some patients of East Asian ancestry. Adjust to maintain platelet count ≥ to 50 x 109/L. Do not exceed 75 mg per day.
- Three clinical studies are summarized in the prescribing information for adult refractory or relapsed chronic ITP. A phase II and phase III study showed a statically significant difference in response rate (defined as a shift from baseline platelet count of less than 30 x 109/L to greater than or equal to 50 x 109/L) between eltrombopag and placebo. The third trial, RAISE, evaluated sustained platelet response and is summarized below.
- The Phase II PETIT study evaluated response rate (proportion of patients achieving platelet counts greater than or equal to 50 x 109/L at least once during the randomized, double-blind period of the study) achieved by 62% of Promacta patients compared to 32% of placebo patients (*P* = 0.011). The second study, PETIT2, evaluated sustained platelet response and is summarized below.

Results
Adults
- In the 134 patients who completed 26 weeks of treatment, a sustained platelet count was achieved by 60% of patients in the eltrombopag arm compared to 10% randomized to placebo. Mean number of weeks with platelet counts greater than or equal to 50 x 109/L was 11.3 for eltrombopag and 2.4 for placebo. Eighteen percent (24/235) of patients in the eltrombopag group required rescue therapy versus 40% (25/62) in the placebo group.
- 37 (59%) of 63 patients treated with eltrombopag and 10 (32%) of 31 patients in placebo group discontinued concomitant therapy at some time during the trial.

Pediatrics
- Sustained platelet count was achieved in 41% (age cohort: 12-17 years: 42%, 6-11 years: 44%, and 1 to 5 years 36%) of patients in the eltrombopag group versus 3% (age cohort: 12 – 17 years: 10%, 6 to 11 years: 0%, and 1 to 5 years: 0%) in the placebo group.
- Fewer pediatric patients treated with eltrombopag required rescue treatment during the randomized, double-blind period compared with placebo (19% [12/63] vs 24% [7/29]).
- Among 15 patients receiving other ITP therapy at baseline, eight reduced (n=1) or discontinued (n=7) concomitant therapy, mainly corticosteroids, without rescue therapy.

Safety
Adults
- The most common adverse events (AEs) (≥5% and greater than placebo) from three, placebo controlled trials for adult ITP summarized in the prescribing information were: nausea, diarrhea, upper respiratory tract infection, vomiting, increased ALT, myalgia, and urinary tract infection. Additionally, serum liver test abnormalities were reported in 11% and 7% of patients for eltrombopag and placebo, respectively. Four (1%) treated with eltrombopag and three patients in the placebo group (2%) discontinued due to hepatobiliary laboratory abnormalities.

Pediatrics

- The most common AEs (≥10% and greater than placebo) were upper respiratory tract infections, and nasopharyngitis.

Severe Aplastic Anemia

Overview

- Promacta (eltrombopag) should be initiated at 50 mg orally once daily for most patients. Reduce initial dose in patients with hepatic impairment or patients of East Asian ancestry. Adjust to maintain platelet count greater than 50 x 109/L. Do not exceed 150 mg per day.
- Summarized below is the pivotal, Phase II, single arm, single center, open-label trial that evaluated eltrombopag in patients with severe aplastic anemia who had an insufficient response to at least one prior immunosuppressive therapy.

Results

- The treated population had a median age of 45 years (range: 17 to 77 years). At baseline, the median platelet count was 20 x 109/L, hemoglobin was 8.4 g/dL, ANC was 0.58 x 109/L, and absolute reticulocyte count was 24.3 x 109/L. Eighty-six percent of patients were RBC transfusion dependent and 91% were platelet transfusion dependent. The majority of patients (84%) received at least 2 prior immunosuppressive therapies.
- Hematologic response rate (including single- and multi-lineage) was observed in 40% (17/43) [95% CI: 25, 56] of patients. Median duration of response was not reached.
- In the 17 responders, the platelet transfusion-free period ranged from 8 to 1,096 days with a median of 200 days, and the RBC transfusion-free period ranged from 15 to 1,082 days with a median of 208 days. In the extension phase, 8 patients achieved a multi-lineage response; 4 of these patients subsequently tapered off treatment with Promacta and maintained the response (median follow up: 8.1 months, range: 7.2 to 10.6 months).

Safety

- Eleven patients (26%) were treated for greater than 6 months and 7 patients (16%) were treated for greater than 1 year. The most common adverse reactions (≥20%) were nausea, fatigue, cough, diarrhea, and headache.
- In this trial, patients had bone marrow aspirates evaluated for cytogenetic abnormalities. Eight patients had a new cytogenetic abnormality report on therapy, including 5 patients who had complex changes in chromosome 7.

Questions and Answers

Q: How do most other Medicaid plans cover?
A: Preferred with prior authorization based on indication and guidelines.

Signifor® LAR (pasireotide)

Overview

- The recommended initial dose of Signifor® LAR (pasireotide) for injectable suspension is 40 mg administered by intramuscular injection once every four weeks (28 days).

Study Design

Medically Naïve Patients

- Phase III, randomized, double-blind, multicenter trial in medically naïve patients with active acromegaly (N = 358) evaluating pasireotide LAR 40 mg vs octreotide LAR 20 mg (a somatostatin analog; active comparator) over 12 months.
- The primary endpoint compared the proportion of patients with a reduction in mean growth hormone (GH) level <2.5 mcg/L and normalization of insulin-like growth factor-1 (IGF-1) to within normal limits (age and sex) between the two treatment arms after one year.
- Inclusion criteria included: patients ≥ 18 years of age with active acromegaly who have undergone one or more pituitary surgeries, but have not been treated medically; de-novo patients who refuse pituitary surgery or whom surgery is contraindicated; no pituitary irradiation within the last 10 years.

Patients Inadequately Controlled on Other SSAs

- Phase III, randomized, parallel-group, double-blind, 24-week trial in patients with acromegaly inadequately controlled on other SSAs. This study evaluated pasireotide LAR (40 [n = 65] and 60 mg [n = 65]) vs continued therapy with an active comparator (n = 68), octreotide LAR 30 mg (SSA) or lanreotide Autogel 120 mg (SSA).
- The primary endpoint was the proportion of patients achieving biochemical control (mean GH levels <2.5 mcg/L and normalized IGF-1 levels) at 24 weeks.

- Inclusion criteria included: patients ≥ 18 years with inadequately controlled acromegaly (treated ≥ six months), defined as a mean GH >2.5 mcg/L and IGF-1 >1.3 times the sex and age-adjusted upper normal limit.

Results

Medically Naïve Patients

- Patients receiving pasireotide LAR were 63% more likely than patients on octreotide LAR to have full biochemical control (GH <2.5 mcg/L *and* normal IGF-1).
- At Month 12, 31.3 % (n = 55/176) of pasireotide LAR patients and 19.2% (n = 35/182) of octreotide LAR patients met the primary endpoint (P = .007). In those patients postsurgery, the percentage of patients meeting the primary endpoint at Month 12 were 39.4% (n = 28/71) and 21.8% (n = 17/78), respectively. In the de novo groups, the Month 12 numbers were 25.7% (n = 27/105) and 17.3% (18/104), respectively.

Patients Inadequately Controlled on Other SSAs

- The proportion of patients achieving biochemical control with pasireotide 40 mg, 60 mg or the active controls were 15% (n = 10; *P* .0006 vs active control), 20% (n = 13; *P* <.0001 vs. active control) and 0% (n = 0).

Safety

Medically Naïve Patients

- The most common adverse events (AEs) with pasireotide LAR vs octreotide LAR included: diarrhea (39.3% vs. 45%), cholelithiasis (25.8% vs. 35.6%), hyperglycemia (28.7% vs. 8.3%), and headache (18.5% vs. 26.1%).
- Grade 3/4 hyperglycemia-related AE was reported by 9.0% of pasireotide LAR patients and 1.7% of octreotide LAR patients.

Patients Inadequately Controlled on Other SSAs

- The most common AEs included: hyperglycemia (33%, 31% and 14%, respectively), diabetes mellitus (21%, 26% and 8%) and cholelithiasis (10%, 13% and 14%).
- Hyperglycemia-related AEs were observed more frequently with pasireotide LAR 40 mg and 60 mg (n = 42 [67%] and n = 38 [61%]) compared with active control (n = 20 [30%]).
- There were no deaths and serious AEs were reported in six patients, two patients and three patients in the three treatment groups, respectively.

Warnings and Precautions

- Hyperglycemia and Diabetes: Can be severe sometimes. Monitor glucose levels periodically during therapy. Monitor glucose levels more frequently in the months that follow initiation or discontinuation of Signifor LAR therapy and following Signifor LAR dose adjustment. Use anti-diabetic treatment if indicated per standard of care.
- Bradycardia and QT prolongation: Use with caution in at-risk patients; Evaluate ECG and electrolytes prior to dosing and periodically while on treatment.
- Liver test elevations: Evaluate liver enzyme tests prior to and during treatment.
- Cholelithiasis: Monitor periodically.
- Pituitary hormone deficiencies: Monitor for occurrence periodically and treat if clinically indicated.

Adverse Reactions

Adverse drug reactions associated with Signifor LAR and occurring in ≥20% of patients were diarrhea, cholelithiasis, hyperglycemia and diabetes mellitus.

Questions and Answers

Q: How are other Medicaid plans covering?
A: With prior authorization for indication.

Q: What are considered the advantages of other products for acromegaly?
A: Improved efficacy due to high affinity for hsst2 and hsst5 receptors.

V. Astellas

Tammy Winton, Senior Executive Representative
Barbara H. Taylor, Senior Regional Sales Manager

Cresemba® (isavuconazonium sulfate) (Crē sem' bah)

Indications and Administration

- CRESEMBA is an azole antifungal indicated for patients 18 years of age and older for the treatment of **invasive aspergillosis and invasive mucormycosis.**

- Specimens for fungal culture and other relevant laboratory studies (including histopathology) to isolate and identify causative organism(s) should be obtained prior to initiating antifungal therapy. Therapy may be instituted before the results of the cultures and other laboratory studies are known. However, once these results become available, antifungal therapy should be adjusted accordingly.
- CRESEMBA for injection must be administered through an in-line filter (pore size 0.2 to 1.2 microns) over a minimum of 1 hour in 250 mL of a compatible diluent to reduce the risk for infusion-related reactions. Do not administer as an intravenous bolus injection.
- Do not infuse CRESEMBA with other intravenous medications. Flush IV lines with 0.9 sodium chloride injection, USP, or 5 dextrose injection, USP, prior to and after infusion of CRESEMBA. After dilution of the IV formulation, avoid unnecessary vibration or vigorous shaking of the solution. Do not use a pneumatic transport system. Infusion-related reactions including hypotension, dyspnea, chills, dizziness, paresthesia, and hypoesthesia were reported during intravenous administration of CRESEMBA. Discontinue the infusion if these reactions occur.
- CRESEMBA capsules can be taken with or without food.
- Loading dose: 372 mg isavuconazonium sulfate (equivalent to 200 mg of isavuconazole) every 8 hours for 6 doses (48 hours) via oral (2 capsules) or intravenous administration (1 reconstituted vial).
- Maintenance dose: 372 mg isavuconazonium sulfate (equivalent to 200 mg of isavuconazole) once daily via oral (2 capsules) or intravenous administration (1 reconstituted vial) starting 12 to 24 hours after the last loading dose.
- Switching between the intravenous and oral formulations of CRESEMBA is acceptable as bioequivalence has been demonstrated. Loading dose is not required when switching between formulations.

Efficacy Profile

- CRESEMBA was evaluated in a Phase 3, randomized, double-blind, noninferiority, active-controlled trial designed to evaluate the safety and efficacy vs voriconazole for primary treatment of invasive fungal disease caused by Aspergillus species or other filamentous fungi.
- All-cause mortality (ACM) through Day 42 in the overall population was 18.6 (48/258) in the CRESEMBA treatment group and 20.2 (52/258) in the voriconazole treatment group, for an adjusted treatment difference of -1.0 with 95 confidence interval of -8.0 to 5.9. ACM through Day 42 in patients with proven or probable invasive aspergillosis was 18.7 (23/123) in the CRESEMBA treatment group and 22.2 (241108) in the voriconazole treatment group, for an adjusted treatment difference of -2.7 with 95 confidence interval of -13.6 to 0.2.
- In the subgroup of patients with proven or probable invasive aspergillosis confirmed by serology, culture, or histology, overall success at end of treatment was seen in 35 of CRESEMBA-treated patients compared to 38.9 of voriconazole-treated patients.
- CRESEMBA was also evaluated in an open-label, noncomparative trial designed to evaluate the safety and efficacy in a subset of patients with invasive mucormycosis ACM through Day 42 was 37 (14/37) in patients with proven or probable mucormycosis (33 primary treatment [7/21], 46 refractory [5111], and 40 intolerant [2/5]).
- Overall response success rate at the end of treatment was seen in 31 (11/35) of patients (32 primary treatment [6/19], 36 refractory [4/11], and 20 intolerant [1/5]). Median treatment duration was 102 days for patients classified as primary, 33 days for refractory, and 85 days for intolerant.
- These results provide evidence that CRESEMBA is effective for the treatment of mucormycosis in light of the natural history of untreated mucormycosis. The efficacy of CRESEMBA for the treatment of mucormycosis has not been evaluated in concurrent, controlled clinical trials.

Safety Profile

- The most frequent adverse reactions reported from clinical trials in CRESEMBA-treated patients were nausea, vomiting, diarrhea, headache, elevated liver chemistry tests, hypokalemia, constipation, dyspnea, cough, peripheral edema, and back pain.
- In Trial 1, a randomized, double-blind, active-controlled clinical trial for treatment of invasive aspergillosis, treatment-emergent adverse reactions occurred in 247/257 (96) and 255/259 (99) patients in the CRESEMBA and voriconazole treatment groups, respectively. Treatment-emergent adverse reactions resulting in permanent discontinuation were reported in 37 (14) CRESEMBA-treated patients and 59 (23) voriconazole-treated patients.
- In Trial 2, an open-label, non-comparative trial of CRESEMBA in patients with invasive aspergillosis and renal impairment or invasive mucormycosis, treatment-emergent adverse reactions occurred in 1391146 (95) of patients in the CRESEMBA treatment group. Adverse reactions resulting in permanent discontinuation were reported in 19 (13) CRESEMBA-treated patients.

Questions and Answers
Q: What is the usual duration of therapy for treatment of aspergillosis?
A: Approximately 6 weeks.

Q: What is the usual duration of therapy for treatment of mucormycosis?
A: Approximately 102 days with primary therapy.

Q: In what setting is the medication administered?
A: Inpatient and outpatient; new patients on medication are usually started in hospital unless patient was started on another medication initially and became refractory to that medication, then patient may be switched to Cresemba in an outpatient setting.

Q: Why was the mucormycosis study not conducted in a controlled trial?
A: There were not enough patients to conduct a comparative study.

Q: How are patients assessed for improvement?
A: Monitoring for improvement may include symptoms, chest x-ray and sinus cavity x-ray.

Q: Can the IV formulation be administered in home if patient cannot transition to oral?
A: Yes, the IV can be administered in home or infusion center.

Q: Is there a limited distribution?
A: There is no limited distribution for oral formulation, and IV formulation is limited to specialty pharmacies.

Q: How are other Medicaid plans covering?
A: Some states have as non-preferred with prior authorization, preferred with prior authorization or non-preferred without prior authorization, and some states have not yet reviewed.

VI. Emergent

Gregg Little, RPh, MBA, Director, Scientific Affairs
Debbie Bouchard-Parent, Director, National Accounts & Contracting
Evelyn Gittinger, CPC, Vice-President, Reimbursement & Government Markets, D2 Pharma Consulting

Ixinity® [coagulation factor IX (recombinant)]
IXINITY [coagulation factor IX (recombinant)] is a coagulation factor IX (recombinant) indicated in adults and children ≥ 12 years of age with hemophilia B for control and prevention of bleeding episodes, and for perioperative management. Classified as a third generation recombinant factor IX (FIX) product, IXINITY is a purified protein containing 415 amino acids. IXINITY is the only recombinant factor IX designed to resemble and act more like naturally occurring FIX. The amino acid sequence is comparable to the Thr148 allelic form of plasma-derived factor IX found in 80% of patients with hemophilia B.

Pharmacokinetics: Favorable pharmacokinetic profile: 1) 0.98 IU/dL mean incremental recovery; higher recovery may allow lower doses; and 2) 24-hour mean terminal half-life to help active patients achieve peak factor levels when they need them.

Clinical Studies: The efficacy of IXINITY was evaluated in a prospective, open-label, multicenter trial of 68 PTPs. Subjects in the routine therapy [prophylaxis] group received mean intravenous doses of 55 ± 12.8 IU/kg of IXINITY twice weekly. Subjects in the on-demand therapy group received mean doses of 60 ± 18.2 IU/kg for bleeding episodes. In the routine treatment [prophylaxis] group, the median Annual Bleed Rate (ABR) was 1.52 for all bleeds (see Table). Nineteen of sixty-one (31.1%) evaluable subjects in the routine treatment [prophylaxis] group reported no bleeding episodes when treated with a mean 17.9 months of prophylaxis with IXINITY (see Table).

Table. Efficacy of IXINITY2

	Routine Treatment Regimen (n = 61)	On-Demand Treatment Regimen (n = 12)
Treatment duration (months)		
Mean(± SD)	17.9 (± 9.6)	15.9 (± 11.5)
Median (range)	16.2 (2.4–39.6)	14.1 (2.3–36.9)
Total ABR*		
Median (range)	1.52 (0.00–47.52)	16.39 (0.00–39.43)
Mean (± SD)	3.55 (± 7.19)	16.14 (± 11.83)
Patients with zero bleeding episodes % (n)	19 (31.1%)	2 (16.7%)

*Annual Bleed Rate

Control and Prevention of Bleeding: A total of 508 bleeding episodes were treated with IXINITY, of which 286 bleeding episodes were recorded for patients on the routine [prophylaxis] regimen and 222 on the on-demand regimen.1 Bleeding resolved in 360 episodes (71%) after a single infusion of IXINITY and in 66 episodes (13%) after 2 infusions. Hemostatic efficacy to resolve a bleed was rated by subjects as 'excellent' or 'good' in 84% of treated bleeding episodes.
Perioperative Management: The efficacy analysis of IXINITY in perioperative management included 19 major surgeries, including knee and elbow arthroplasties performed in 16 male PTPs.‡1 In each instance, the performing surgeon characterized blood loss during the procedure as either 'expected' or 'less than expected' (no surgeons rated the loss as 'more than expected'). Hemostasis was rated as 'better than adequate' or 'adequate' at 12 and 24 hours post-surgery. No patients required transfusions during surgery.

Safety: The safety profile of IXINITY was derived from 77 subjects who received 9,641 infusions of IXINITY during clinical trials.1 IXINITY was generally well tolerated. The most common adverse reaction was headache (2.6% of subjects). No subjects developed inhibitors to factor IX, including 55 patients with >50 exposure days and 45 patients with >100 exposure days to IXINITY. In addition, no anaphylactic reactions were reported in patients receiving IXINITY.

How Supplied: IXINITY is supplied as a lyophilized powder in single-use glass vials containing the labeled amount of factor IX activity, expressed in international units (IU).1 Kits include one or two single-use vials containing nominally 500, 1000, or 1500 IU per vial. Additional vial strengths (250, 2000 and 3000 IU single-use vials) are in clinical development. Each vial of IXINITY is vacuum sealed for ease of drawing diluent into the vial. The kit includes a 10 mL syringe pre-filled with 5 mL of Sterile Water for Injection with plunger rod attached, vial adapter with filter, and a sterile 20 mL LUER-LOK Administration Syringe. Patients choose their preferred ancillaries (e.g., butterfly needles, bandages, tourniquets) delivered with IXINITY at no additional cost. IXINITY can be stored at room temperature or under refrigerated conditions (2-25°C [36 to 77°F]) for the 24-month shelf life. The reconstituted solution should be infused immediately or within 3 hrs of room temperature storage.

Questions and Answers
Q: What are considered the advantages over other products?
A: Pharmacokinetic parameters, increase in incremental recovery results in decrease in dosing and 24-hour half-life which results in decrease in dosing frequency that can be especially beneficial for active patients.

Q: For perioperative management, is medication extended to home use?
A: Yes, use of Ixinity can be carried to outpatient setting.

VII. Allergan

Amira Bhalodi, PharmD, Medical Science Liaison, Medical Affairs
Peter Magargee, MBA, RMC, Senior Regional Account Manager

Avycaz™ (ceftazidime and avibactam)
PRONUNCIATION: AVYCAZ (A-vi-kaz); ceftazidime (sef-TAZ-ih-deem) and avibactam (a-vi-BAK-tam)

INDICATIONS AND USAGE: As only limited clinical safety and efficacy data for AVYCAZ (ceftazidime and avibactam) are currently available, reserve AVYCAZ for use in patients who have limited or no alternative treatment options. AVYCAZ, in combination with metronidazole, is indicated for the treatment of complicated intra-abdominal infections (cIAI) caused by the following susceptible microorganisms: *Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, Providencia stuartii, Enterobacter cloacae, Klebsiella oxytoca, and Pseudomonas aeruginosa* in patients 18 years or older. AVYCAZ is also indicated for the treatment of complicated urinary tract infections (cUTI) including pyelonephritis caused by the following susceptible microorganisms: *Escherichia coli, Klebsiella pneumoniae*, *Citrobacter koseri*, *Enterobacter aerogenes*, *Enterobacter cloacae*, *Citrobacter freundii*, *Proteus* spp.*,* and *Pseudomonas aeruginosa* in patients 18 years or older. To reduce the development of drug-resistant bacteria and maintain the effectiveness of AVYCAZ and other antibacterial drugs, AVYCAZ should be used to treat only indicated infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

MECHANISM OF ACTION AND CLINICAL PHARMACOLOGY: The ceftazidime component of AVYCAZ is a cephalosporin antibacterial drug with *in vitro* activity against certain Gram-negative and Gram-positive bacteria. The bactericidal action of ceftazidime is mediated through binding to essential penicillin-binding proteins (PBPs). The avibactam component of AVYCAZ is a non-beta-lactam beta-lactamase inhibitor that inactivates some beta-lactamases and protects ceftazidime from degradation by certain beta-lactamases.

PHARMACOKINETICS: Following administration of single and multiple 2-hour intravenous infusions of AVYCAZ 2.5 grams (2 grams ceftazidime and 0.5 grams avibactam) administered every 8 hours to healthy adult male subjects with normal renal function, the half-life of both ceftazidime and avibactam was approximately 2-3 hours. Less than 10% of ceftazidime was protein bound, and the binding of avibactam to human plasma proteins was 5.7% to 8.2%. Both ceftazidime and avibactam are excreted mainly by the kidneys.

EFFICACY: The determination of efficacy of AVYCAZ was supported in part by the previous findings of the efficacy and safety of ceftazidime for the treatment of cIAI and cUTI. The contribution of avibactam to AVYCAZ was primarily established *in vitro* and in animal models of infection. AVYCAZ was studied in two Phase 2 randomized, blinded, active-controlled, multicenter trials, one each in cIAI and cUTI, including pyelonephritis. These trials were not designed with any formal hypotheses for inferential testing against the active comparators.

ADVERSE REACTIONS: AVYCAZ was evaluated in two active-controlled Phase 2 clinical trials, one each in cIAI and cUTI, including pyelonephritis. The Phase 2 trials included a total of 169 adult patients treated with AVYCAZ and 169 patients treated with comparators. The most common adverse reactions (incidence of ≥10% in either indication) were vomiting (14%), nausea (10%), constipation (10%), and anxiety (10%).

CONTRAINDICATIONS: AVYCAZ is contraindicated in patients with known serious hypersensitivity to the components of AVYCAZ (ceftazidime and avibactam), avibactam-containing products, or other members of the cephalosporin class.

WARNINGS AND PRECAUTIONS: Decreased efficacy in patients with baseline CrCL (creatinine clearance) of 30 to ≤ 50 mL/ min: In a Phase 3 cIAI trial, clinical cure rates were lower in a subgroup of patients with baseline CrCL of 30 to less than or equal to 50 mL/min compared to those with CrCL greater than 50 mL/min. The reduction in clinical cure rates was more marked in patients treated with AVYCAZ plus metronidazole compared to meropenem-treated patients. Clinical cure rates in patients with normal renal function/mild renal impairment (CrCL greater than 50 mL/min) was 85% (322/379) with AVYCAZ plus metronidazole vs. 86% (321/373) with meropenem, and clinical cure rates in patients with moderate renal impairment (CrCL 30 to less than or equal to 50 mL/min) was 45% (14/31) with AVYCAZ plus metronidazole vs. 74% (26/35) with meropenem. Within this subgroup, patients treated with AVYCAZ received a 33% lower daily dose than is currently recommended for patients with CrCL 30 to less than or equal to 50 mL/min. Monitor CrCL at least daily in patients with changing renal function and adjust the dosage of AVYCAZ accordingly. Hypersensitivity reactions: Serious and occasionally fatal hypersensitivity (anaphylactic) reactions and serious skin reactions have been reported in patients receiving beta-lactam antibacterial drugs. Cross-hypersensitivity may occur in patients with a history of penicillin allergy. If an allergic reaction occurs, discontinue AVYCAZ. *Clostridium difficile*-associated diarrhea: *Clostridium difficile*-associated diarrhea (CDAD) has been reported with nearly all systemic antibacterial agents, including AVYCAZ. Evaluate if diarrhea occurs. If CDAD is suspected or confirmed, antibacterials not directed against *C. difficile* may need to be discontinued. Central Nervous System Reactions: Seizures and other neurologic events may occur, especially in patients with renal impairment. Adjust dose in patients with renal

impairment. Development of drug-resistant bacteria: Prescribing AVYCAZ in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

DOSAGE AND ADMINISTRATION: For patients 18 years of age and older with normal renal function, the recommended dosage of AVYCAZ is 2.5 grams (2 grams ceftazidime and 0.5 grams avibactam) administered every 8 hours by IV infusion over 2 hours, with a recommended treatment duration of 5 to 14 days for cIAI, and 7 to 14 days for cUTI, including pyelonephritis. For treatment of cIAI, AVYCAZ should be used in combination with metronidazole. For patients with CrCL less than or equal to 50 mL/min, dosage adjustment according to the AVYCAZ full prescribing is recommended. Because the exposure of both ceftazidime and avibactam is highly dependent on renal function, monitor CrCL at least daily and adjust the dosage of ceftazidime-avibactam accordingly for patients with changing renal function.

Questions and Answers
Q: Are patients started on medication in hospital?
A: Yes.

Q: If patient cannot switch to oral, can patients go home on IV Avycaz?
A: Yes, these patients are usually more sick so may go home on IV antibiotic.

Q: Why did the FDA approve early prior to phase 3 studies?
A: Due to these patients have limited treatment options and patients would previously have to obtain medication through compassionate use which could take a week before patient would receive medication.

VIII. **AbbVie** presented Humira and Technivie, and, as agreed upon with the manufacturer, the summaries of those presentations will be provided to the DURB when these drugs are next under review by the DURB.

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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, February 11, 2016, with an overflow day on Tuesday, February 9, 2016 ***only*** if needed.

Date: **Thursday, February 11, 2016 from 9am-5pm EST**
Tuesday, February 9, 2016 from 9am-5pm EST (overflow day *only* if needed)

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 approximately 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 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 each drug presentation, **factually based,** in a stand-alone, user-friendly document 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, 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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2016

Upcoming Meetings

Drug Utilization Review Board Meeting

2 Peachtree Street, N.W.

5th Floor Board Room

Atlanta, Georgia 30303

Thursday, March 17, 2016:	9:00am – 4:00pm
Thursday, June 16, 2016:	9:30am – 2:30pm
Tuesday, September 13, 2016:	9:30am – 1:30pm
Tuesday, December 13, 2016:	9:30am – 1:30pm

Manufacturers' Forum

NorthStar HealthCare Consulting

1121 Alderman Drive

Suite 112

Alpharetta, Georgia 30005

Thursday, February 11, 2016:	9:00am – 5:00pm
Tuesday, February 9, 2016 (if needed)	9:00am – 5:00pm
Thursday, May 12, 2016:	9:00am – 5:00pm
Thursday, August 11, 2016:	9:00am – 5:00pm
Thursday, November 10, 2016:	9:00am – 5:00pm

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Drug Utilization Review Board

Board Member	Credentials	Specialty/Area of Expertise
Drew A. Miller, Chair	R.Ph.	Retail Pharmacy
Gurinder J.S. Doad, Vice-Chair	M.D.	Family Practice
Mia Avery	Pharm.D.	Oncology Pharmacy
Douglas C. Collins	M.D.	Hematology/Oncology
Rod M. Duraski	M.D., FACP, MBA	Internal Medicine
Deborah W. Fincher	R.Ph., M.S.	HIV/AIDS Pharmacy
M. Celeste Fowler	Pharm.D., HCMBA	Hospital Pharmacy
Yolanda P. Graham	M.D.	Child and Adolescent Psychiatry
Mary S. Harris	Ph.D.	Health Care Information/Education Research
Burton L. Lesnick	M.D., FAAP	Pediatrics/Pediatric Pulmonology
Robyn Lorys	Pharm.D.	Managed Care
J. Russell May	Pharm.D.	Academia - Professor
Brent L. Rollins	R.Ph., Ph.D.	Academia - Professor
Robert E. Shervette, III	M.D.	Child and Adolescent Psychiatry
Danny A. Toth	R.Ph.	Pharmacy Benefit Plans