GEORGIA DEPARTMENT OF COMMUNITY HEALTH

Georgia Department of Community Health

DRUG UTILIZATION REVIEW BOARD MEETING

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

September 18, 2014

catamaran

NorthStar HealthCare Consulting
Let Us Be Your Guide

This page intentionally left blank

GEORGIA DEPARTMENT OF COMMUNITY HEALTH

DRUG UTILIZATION REVIEW BOARD MEETING
AGENDA
2 Peachtree Street – 5th Floor Board Room - Atlanta, Georgia 30303
Thursday, September 18, 2014
9:30 a.m. to 1:30 p.m.

CALL TO ORDER	*Joseph Bona, MD, Chair*
COMMENTS FROM THE DEPARTMENT	*Linda Wiant, PharmD, Pharmacy Director*
MINUTES FROM PREVIOUS MEETING	*Chair*
CONSUMER COMMENTS SESSION	*Chair*
ADJOURNMENT OF OPEN SESSION	*Chair*
EXECUTIVE SESSION	*Steve Liles, PharmD, Goold*
RECONVENING OF OPEN SESSION	*Chair*
CLINICAL REVIEWS	*Tara R. Cockerham, PharmD, NorthStar* *Emily Baker, PharmD, BCPS, NorthStar*

- **Manufacturers' Forum**
- **New Drug Reviews**
  - ●Duavee
  - ●Farxiga
  - ●Iclusig
  - ●Luzu
  - ●Velphoro
  - ●Zohydro ER
- **Non-Supplemental Rebate Class Reviews**
- **Respiratory Syncytial Virus (RSV) Guidelines Update**
- **Retrospective Drug Utilization Review (RDUR) Update**
- **Utilization Trends**
- **Drug Information**
  - ●Drug Update Newsletter
  - ●Horizon Watch Report
  - ●Patent Expiration Report
  - ●Clinical Compass Newsletter
- **TherDose Overview** — *Tami Sweat, PharmD, Catamaran*

FUTURE AGENDA ITEMS	*Chair*
ADJOURNMENT	*Chair*

LUNCH

catamaran

NorthStar HealthCare Consulting *Let Us Be Your Guide*

This page intentionally left blank

Department of Community Health
Drug Utilization Review Board (DURB)
MINUTES
Thursday, June 5, 2014

MEMBERS PRESENT

Joseph R. Bona, M.D., MBA, Chair
Osgood (Drew) A. Miller, R.Ph., Vice-Chair
Gurinder J.S. Doad, M.D.
Traci Ferguson, M.D.
Deborah W. Fincher, M.S., R.Ph.
M. Celeste Fowler, Pharm.D.
Thomas B. Gore, M.D.
John Greeson, M.D., MBA
Robyn Lorys, Pharm.D.
J. Russell May, Pharm.D.
Donald A. Paul, M.D.
Brent L. Rollins, R.Ph., Ph.D.
Robert E. Shervette III, M.D.
Mary Virginia "Ginny" Yates, Pharm.D.

MEMBERS ABSENT

Mia Avery, Pharm.D.
Ann R. Damon, Pharm.D.
Edwina L. Jones, Pharm.D., MBA

Staff

Jerry Dubberly, Pharm.D., MBA, Chief Medical Assistance Plans
Linda Wiant, Pharm.D., Pharmacy Director, Pharmacy Services
Turkesia Robertson-Jones, Pharm.D., Pharmacy Operations Manager, Pharmacy Services
Gilletta Gray, R.Ph., Clinical Manager, Pharmacy Services
Lori Garner, MHS, MBA, R.Ph., Pharmacist, Pharmacy Services
Rose Marie Duncan, MBA, Program Associate, Pharmacy Services
Erin Massarello, Pharm.D. Candidate

NorthStar HealthCare Consulting

Emily Baker, Pharm.D., BCPS, MHA, MBA, President
Tara R. Cockerham, Pharm.D., Clinical Programs Director

Catamaran

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

Goold Health Services

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

Call to Order

The Drug Utilization Review Board (DURB/DUR Board/Board) held its second meeting for the calendar year on June 5, 2014. The Chair, Joseph R. Bona, M.D., MBA, called the meeting to order at 9:34am.

Comments from the Department

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

1. DUR Board Members – Dr. Sandra White was thanked for her service. Dr. Traci Ferguson was welcomed as a new board member from Wellcare.
2. Pharmacy Students – The following pharmacy students were welcomed: Kyley Makanani (UGA), Julianne Jones (UGA), Oaashif Panjwani (Mercer), Ashton Moradi (Mercer) and Erin Massarello (UGA).

Jerry Dubberly, Pharm.D., MBA, Chief Medical Assistance Plan, commented on the following items:

1. Integrated Eligibility System – A single entry for those applying for public assistance. Deloitte was awarded contract. Implementation will be 1.1.16.
2. Healthcare.gov – Received 88,000 applications which are currently being reviewed. The majority are either already active or have a pending Medicaid application.
3. Georgia Families 360 Program – The program is live. Consists of children in Foster Care, Adoption Assistance and Juvenile Justice. There have been success stories of kids being connected to services.
4. Legislative Session – House Bill 772 – Testing of individuals who apply for food stamps when there is a reasonable suspicion of substance abuse; House Bill 899 – Felony to operate an unlicensed personal care home; House Bill 973 – Allows additional federal funding for Program Integrity; Senate Bill 352 – Develop a Lupus Counsel; Senate Resolution 1121 – Develop a strategic plan for prevention and control of Diabetes; Senate Resolution 1175 – Review of the provider enrollment credentialing process for Care Management Organizations; Amendment 14 – Includes a line item to allow more robust quantity level limits on the Physician's Injectable Drug List (PIDL) and funds for Healthy Babies Program.

Minutes from the Previous Meeting

Dr. Bona asked for corrections or changes to the minutes from the March 18, 2014 meeting. There were no corrections. A motion was made (J. Russell May, Pharm.D.), seconded (Osgood (Drew) A. Miller, R.Ph., Vice-Chair), and carried to approve the minutes as written.

Consumer Comments Session

There were no consumer comments.

Guest Expert Speaker

Saurabh Chawla, M.D. spoke on pancreatic enzyme replacement therapy (Attachment A). He addressed questions from the Board regarding alternative treatments, complications with formulary changes, top drugs in this category, long-term chronic use data, and testing.

Adjournment of Open Session

The DUR Board voted to close the open meeting pursuant to the Open Meeting Act of Georgia Section 50-14-1 – 50-14-6 and pursuant to Federal Law Section 1396R-8B3D. The individuals recorded in attendance with the Board members were from the Department of Community Health, Goold Health Services, NorthStar HealthCare Consulting, and Catamaran. Pharmacy students Kyley Makanani (UGA), Julianne Jones (UGA), Oaashif Panjwani (Mercer), Ashton Moradi (Mercer) and Erin Massarello (UGA) attended the closed session with the Board members. A motion was made by Robyn Lorys, Pharm.D., and seconded by Osgood (Drew) A. Miller, R.Ph., Vice-Chair , to adjourn the open session and approve the closed session. There was a unanimous vote approving the closed session. The Chairman, Dr. Joseph R. Bona, adjourned the open session at approximately 10:23 am, at which time members took a break then reconvened for the executive (closed) session.

Executive Session

The Executive Session was held from 10:31am to 11:40am.

Reconvening of Open Session

The DUR Board reconvened for the open session at 12:08pm.

Manufacturers' Forum

Emily Baker, Pharm.D., BCPS, reviewed information regarding the Manufacturers' Forum that was provided in the Manufacturer Information section in the DUR Board binder. A total of twenty-two (22) manufacturers participated and/or provided information regarding the following drugs discussed at the June 2014 DURB meeting:

Manufacturers	Drugs
Boehringer Ingelheim	Pradaxa
Cornerstone	Pertzye
Forest	Bystolic, Linzess
Johnson & Johnson	Xarelto
AstraZeneca	Brilinta, Symbicort
Pharmacyclics	Imbruvica
Actelion	Opsumit
Bristol-Myers Squibb	Eliquis
Pfizer	Lyrica, Quillivant XR
Takeda	Brintellix
Jazz	Versacloz
GlaxoSmithKline	Breo Ellipta
Teva	Granix
Supernus	Oxtellar XR, Trokendi XR
Otsuka	Abilify Maintena
Eisai	Fycompa
Meda	Aerospan
Iroko	Zorvolex
Unither	Orenitram
Amgen	Aranesp
Sunovion	Latuda

Ferring	Prepopik

There were no questions or comments. The next forum will be held on Thursday, August 7, 2014 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
Biologic Immunomodulator	*Adempas, Opsumit*	Emily Baker, Pharm.D., BCPS
Respiratory, Adrenergic Combinations	*Breo Ellipta*	Emily Baker, Pharm.D., BCPS
Antidepressants	*Brintellix, Fetzima*	Emily Baker, Pharm.D., BCPS
Colony Stimulating Factors	*Granix*	Emily Baker, Pharm.D., BCPS
Antineoplastic	*Imbruvica*	Emily Baker, Pharm.D., BCPS

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

- Adempas, Opsumit – availability of other agents; not recommended in guidelines
- Fetzima – Fibromyalgia indication not being sought
- Granix – conduct a formal review of the category
- Imbruvica – accelerated approval with newer cancer agents

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

Therapeutic Class Review

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

Therapeutic Class Name
Anticonvulsants, including new drug Fycompa

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

- Fycompa – indicated as adjunctive therapy in studies

The Board voted and made a recommendation on Fycompa noted in the Board's Recommendations to the Department.

Supplemental Rebate Drugs – New Clinical Information Review

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

Drug Class/Name
Androgens-Anabolics
Anticoagulants
Antidementia
Antihypertensives, Angiotensin Converting Enzyme (ACE) Inhibitors
Antihypertensives, Angiotensin Receptor Blockers (ARB) and Combinations
Antihypertensives, Beta Blockers (BB)
Antihypertensives, Beta Blockers (BB)
Antihypertensive, Direct Renin Inhibitors
Antiinflammatory, Nonsteroidal Antiinflammatory Drugs (NSAIDs)
Antiparkinson Agents
Antipsychotics
Attention Deficit Hyperactivity Disorder (ADHD) Agents
Fibromyalgia Agents
Inflammatory Bowel Agents
Irritable Bowel Syndrome (IBS) Agents
Laxatives, Bowel Evacuants
Migraine Products
Pancreatic Enzymes
Respiratory, Beta Adrenergic Short Acting Inhalers
Respiratory, Inhaled Corticosteroids
Ulcer Drugs, H. Pylori

The Board commented on the following:

- Anticoagulants – patient availability to coagulation clinics, reasons approved through prior authorization, reach out to other groups on their use of newer agents; pharmacoeconomic study, home monitoring

The Board voted and made recommendations for changes to the Supplemental Rebate drugs noted in the Board's Recommendations to the Department.

Utilization Trend Review

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

Drug Information

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

- Drug Update Newsletter

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

Future Agenda Items

The following future agenda items were noted:

- Revisit epinephrine pens
- Tramadol – utilization trends

Upcoming Meetings

The following upcoming meetings were published in the DURB binder:

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

  Thursday, September 18, 2014
  Thursday, December 4, 2014

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

  Thursday, August 7, 2014
  Thursday, November 6, 2014

Disclosure Forms

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

Board's Recommendations to the Department

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

New Drugs and Supplemental Rebate Classes

New Drug Reviews

Pulmonary Antihypertensives

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

Respiratory, Adrenergic Combinations

The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Breo® Ellipta™ (Inhalation) Aerosol Powder***.

Antidepressants

The DUR Board recommended ***Preferred*** status with ***Prior Authorization*** for ***Brintellix™ (Oral) Tablet*** and ***Non-Preferred*** status with ***Prior Authorization*** for ***Fetzima™ (Oral) Capsule***.

Colony Stimulating Factors

The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Granix™ (Subcutaneous) Syringe***.

Antineoplastics

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

Anticonvulsants

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

Supplemental Rebate Class Reviews

Antidementia Agents

The DUR Board recommended ***Preferred*** status for ***Namenda® XR (Oral) Capsule***.

Antidepressants

The DUR Board recommended ***Preferred*** status for ***Clomipramine Hydrochloride (Oral) Capsule*** and ***Non-Preferred*** status with ***Prior Authorization*** for ***Anafranil® (Oral) Capsule, Imipramine Pamoate (Oral) Capsule, Tranylcypromine Sulfate (Oral) Tablet*** and ***Protriptyline Hydrochloride (Oral) Tablet***.

Attention Deficit Hyperactivity Disorder Agents

The DUR Board recommended ***Preferred*** status with ***Prior Authorization*** for members 21 years of age and older for ***Intuniv® (Oral) Tablet***.

Hematopoietic, Growth Factors

The DUR Board recommended ***Preferred*** status with ***Prior Authorization*** for ***Epogen® (Injection) Vial***.

Laxatives, Bowel Evacuants

The DUR Board recommended ***Preferred*** status for ***Prepopik® (Oral) Powder Pack***.

Pulmonary Antihypertensives

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

Respiratory, Phosphodiesterase-4 Inhibitors

The DUR Board recommended ***Preferred*** status with ***Prior Authorization*** for ***Daliresp® (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 Bona adjourned the meeting at 1:11pm.

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

_____

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

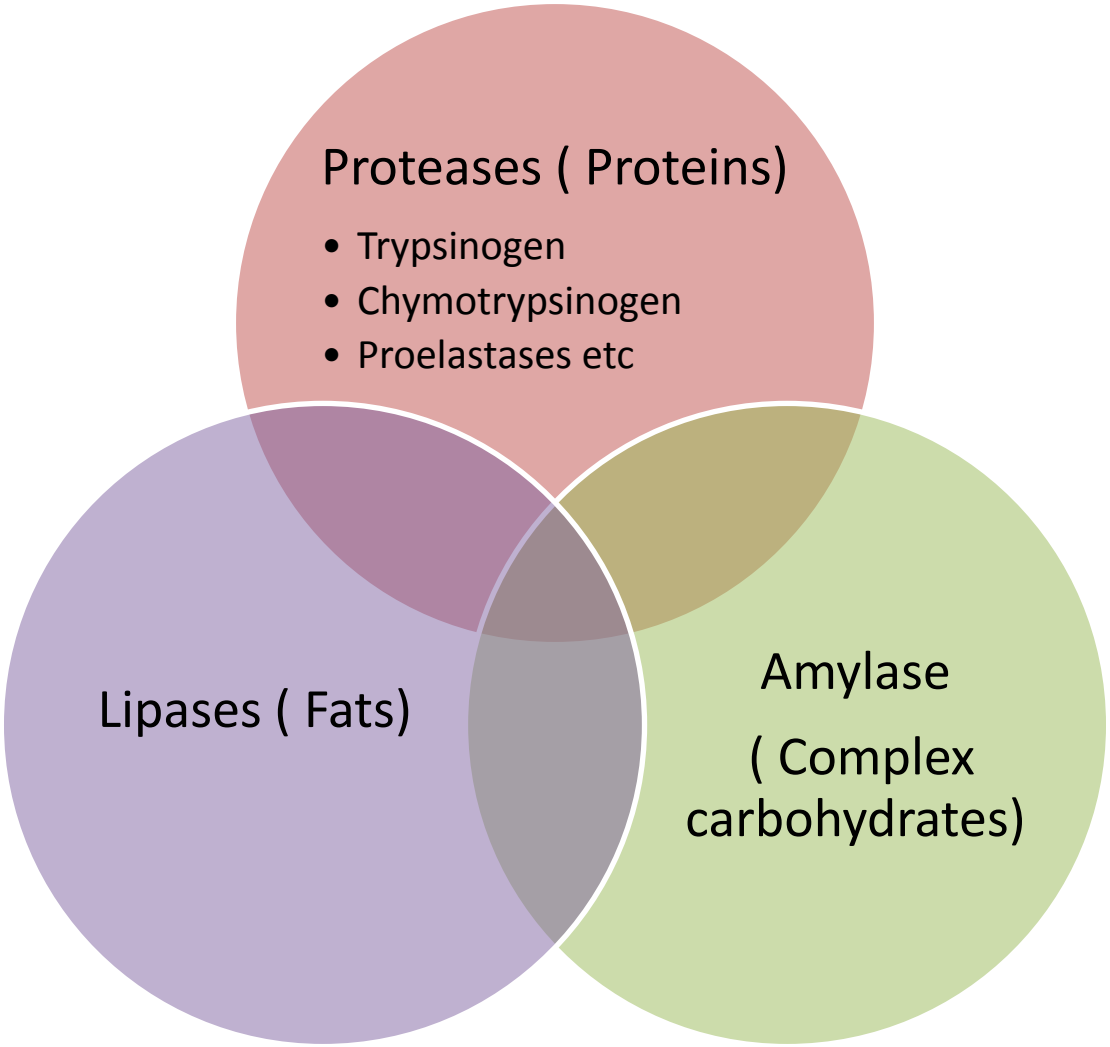
Pancreatic Enzyme Replacement Therapy

Saurabh Chawla MD
Assistant Professor of Medicine
Division of Digestive Diseases
Emory University School of Medicine
Director of Interventional Endoscopy
Grady Memorial Hospital

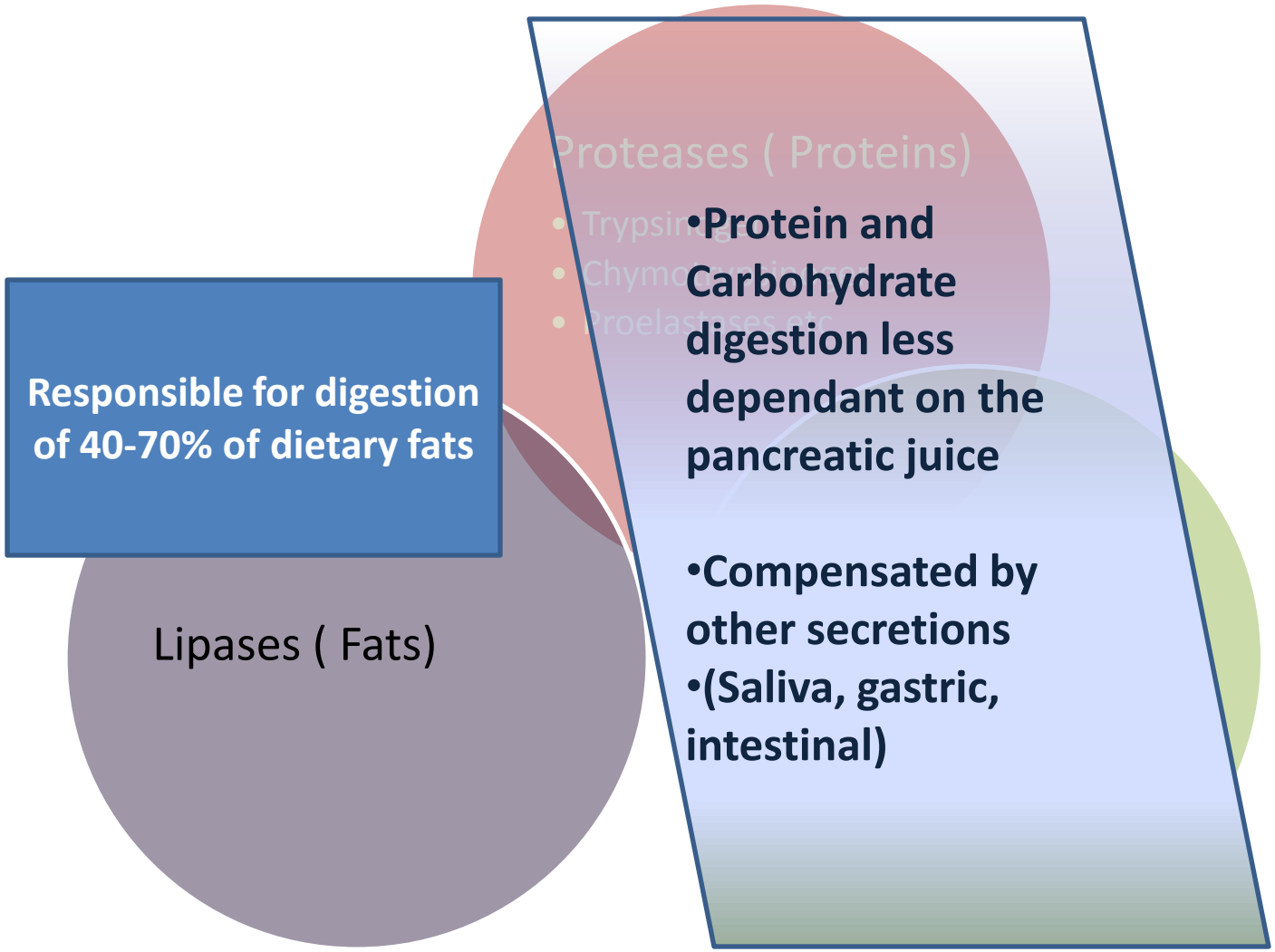
Outline

- Pancreatic enzyme physiology & role in digestion
- Diagnosing pancreatic exocrine insufficiency
- History of pancreatic enzyme products (PEP), their limitations and consequent FDA regulations
- Approved PEP available and differences in their mechanisms of action
- Review of evidence regarding safety and efficacy of PEP
- Recommendations
- Clinical challenges

Pancreatic Enzyme Physiology

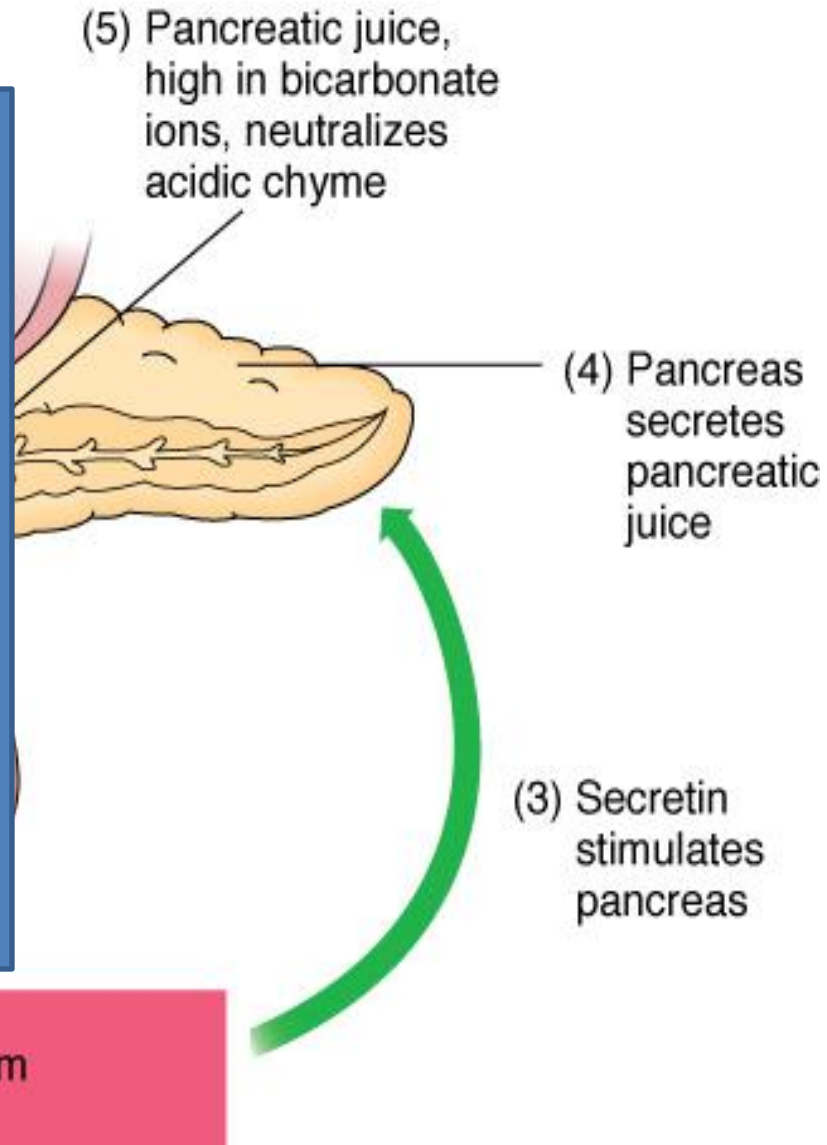


Pancreatic Enzyme Physiology



Pancreatic Enzyme Physiology

1. **Pancreatic enzymes need an alkali environment which is provided by bicarbonate secretion from pancreas**
2. **Pancreatic enzymes inactivated and bile salts denatured in acidic enviroment impairing digestion**
3. **Pancreatic enzymes vary with age/gender/diet**
4. **Clinical pancreatic insufficiency does not develop until loss of 90% of panc enzymes**



Diagnosing pancreatic exocrine insufficiency

OBJECTIVE

Direct:
Secretin-cerulin
Secretin-pancreozymin
Rarely done outside of research settings

Indirect:
Fecal fat (72 hrs/spot)
Fecal elastase
Less sensitive

- What is normal?
- Enzyme activity measured in lab may not represent activity inside the body.
- Very delicate measurements- may vary between labs

SUBJECTIVE= CLINICAL

FAT MALABSORPTION
Steatorrhea (frothy, foul smelling, floating stool)
- Weight loss
- Abdominal discomfort, bloating etc

RIGHT CLINICAL SETTING

Other conditions may mimic

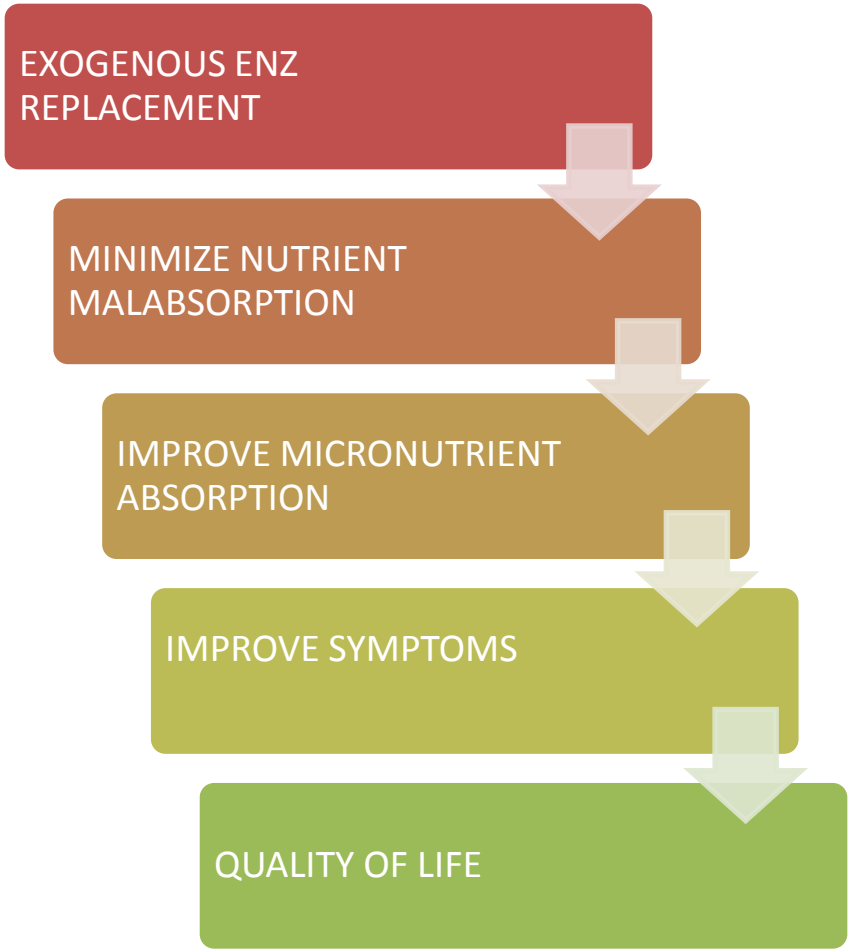
What is the right clinical setting?

Table 4 Etiologies of exocrine pancreatic insufficiency

Mechanism	Etiology
Decreased lipase production and delivery, increase lipase destruction	Chronic pancreatitis, cystic fibrosis, diabetes
Pancreatic duct obstruction	Periampullary tumor, pancreatic head cancer, IPMN, benign tumors
Decreased endogenous lipase stimulation and production	Celiac disease, Crohn's disease, Shwachman–Diamond syndrome
Motility disorders (decrease contact time, interaction with chyme, decrease stimulation of pancreatic enzymes)	Gastrectomy, gastric bypass, extensive small bowel resection
	AIDS

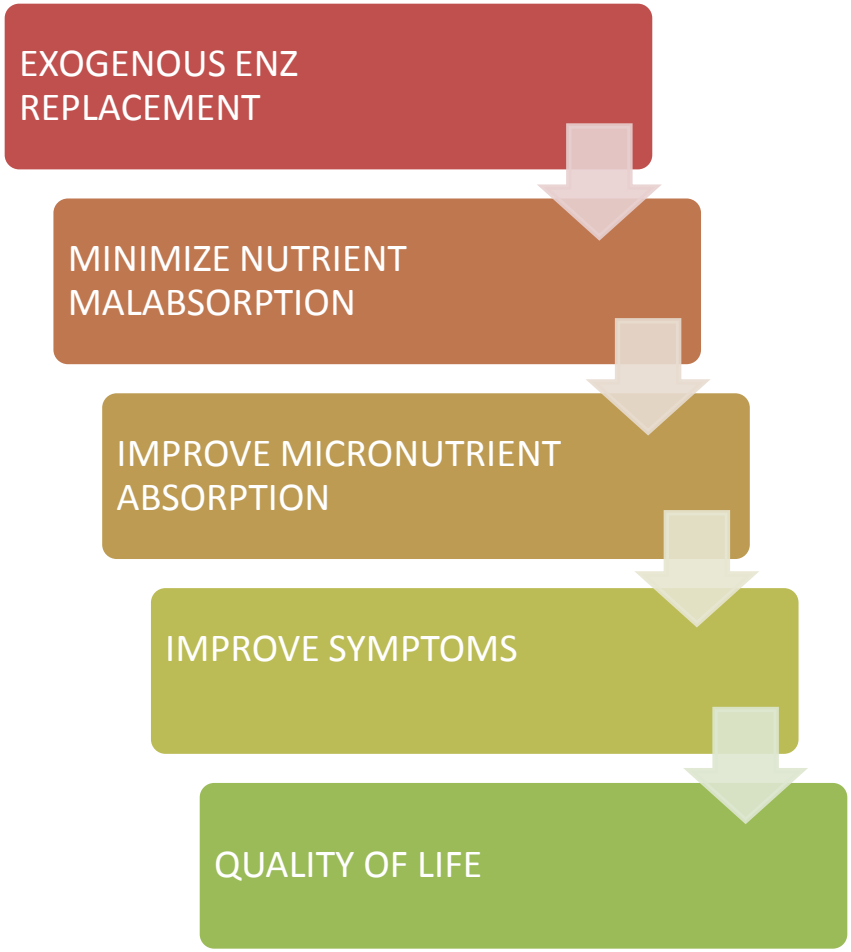
HISTORY OF PANCREATIC ENZYME PRODUCTS (PEP), THEIR LIMITATIONS AND CONSEQUENT FDA REGULATIONS

PEP- HYPOTHESIS



- Replicate physiological process
- Achieve adequate concentration of active panc enzymes in the duodenum
- Resistance to gastric degradation
- Timed with entry of lipids into duodenum

PEP- HYPOTHESIS



- Replicate physiological process
- Achiev
  concen
  panc e
  duoder
- Resista
  degrad
- Timed
  lipids in

Enteric coated preparations:
Natural- carboxymethyl/succinate amylase
Synthetic- Methacrylate copolymers, cellulose acetate phtalate, hydroxyl propyl methyl cellulose phtalate

Concerns:

Animal pancreatic enzyme products (ox/swine) have been marketed since before the creation of FDA in 1938- not FDA regulated previously

- What is appropriate dose and timing of enzyme administration?
- Are exogenous enzymes bioavailable?- enteric coating??
- Shelf life- porcine supplements?
- What is the potency-does it impact efficacy and safety?

FDA 2004:

Exocrine Pancreatic Insufficiency Drug Products; Draft Guidance for Submitting New Drug Applications; Notices

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[[Page 23410]]

Food and Drug Administration

SUMMARY: The Food and Drug Administration (FDA) is announcing that all exocrine pancreatic insufficiency drug products are new drugs and is announcing the conditions for continued marketing of these drug products. Manufacturers who wish to continue to market exocrine pancreatic insufficiency drug products must submit new drug applications (NDAs); manufacturers who contend that a particular drug product is not subject to the new drug requirements of the Federal Food, Drug, and Cosmetic Act (the act) should submit a citizen petition. FDA has determined that prescription exocrine pancreatic insufficiency drug products are medically necessary and, accordingly, is allowing manufacturers 4 years to obtain approved applications.

..differ in composition, activity, formulation, stability and bioavailability….unacceptable variability in…quality and therapeutic performance…

New RCTs (randomized controlled trials) as part of NDA

FDA- May 2012

- 6 PEPs approved
- 2009: Creon*, Zenpep*
- 2010: Pancreaze*
- March 2012: Ultresa*, Viokase*
- May 2012: Pertzye*

•*All brand names

• http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm204745.htm

Pancrelipase prep. (US trade name)	Description and US manufacturer	Administration
Pancreaze 4200, 10500, 16800, 21000	Delayed release capsule containing enteric coated microtablets, porcine origin. (Janssen Pharmaceuticals, Inc)	Swallow capsules whole or sprinkle capsule contents on small amount of acidic soft food with pH of 4.5 or less (eg, applesauce, yogurt, commercially prepared bananas or pears). Do not mix directly into infant formula or breast milk. Do not crush or chew capsule shell or contents. Not recommended for infants or children aged <4 years who weigh less than 14 kg.
Creon 3,6, 12, 36	Delayed release capsule containing enteric coated mini-microspheres, porcine origin. (AbbVie, Inc)	
Zenpep 3,5,10,15,20,25	Delayed release capsule containing enteric coated beads, porcine origin. (Aptalis Pharma)	
Ultresa 13800, 20700, 23000	Delayed release capsule containing enteric coated minitablets, porcine origin. (Aptalis Pharma)	
Viokace 10440, 22880	Regular release (NON enteric coated) tablet, porcine origin. (Aptalis Pharma) ONLY FOR CHRONIC PANCREATITIS AND PANCREATECTOMY	Only indicated for use in adult patients also treated with a proton pump inhibitor. Swallow tablets whole with sufficient liquid.
Pertzye 8,16	Delayed release capsule containing bicarbonate buffered enteric coated microspheres. (Digestive Care, Inc)	Not recommended for infants or children aged <4 years who weigh less than 8 kg.

Pancrelipase prep. (US trade name)	Description and US manufacturer	Administration
Pancreaze 4200, 10500, 16800, 21000	Delayed release capsule containing enteric coated microtablets, porcine origin. (Janssen Pharmaceuticals, Inc)	Swallow capsules whole. Do not sprinkle capsule contents on any amount of acidic soft food or liquid. Do not chew or crush capsules. Not recommended for infants or children aged <4 years who weigh less than 14 kg.
Creon 3,6, 12, 36	Delayed release capsule containing enteric coated mini-microspheres, porcine origin. (AbbVie, Inc)	Swallow capsules whole. Do not sprinkle capsule contents into infant formula or breast milk. Do not crush or chew capsule shell or contents. Not recommended for infants or children aged <4 years who weigh less than 14 kg.
Zenpep 3,5,10,15,20,25	Delayed release capsule containing enteric coated microtablets, porcine origin. (Aptalis Pharma)	
Ultresa 13800, 20...		
Vio... 1044...	Regular release (NON enteric coated) tablet, porcine origin. (Aptalis Pharma) ONLY FOR CHRONIC PANCREATITIS AND PANCREATECTOMY	Only indicated for use in adult patients also treated with a proton pump inhibitor. Swallow tablets whole with sufficient liquid.
Pertzye 8,16	Delayed release capsule containing bicarbonate buffered enteric coated microspheres. (Digestive Care, Inc)	Not recommended for infants or children aged <4 years who weigh less than 8 kg.

NOTE: Products are not equivalent to one another and are not automatically interchangeable with any other pancreatic enzyme replacement product.

THE ANNALS OF PHARMACOTHERAPY

Table 1. Clinical Trials of PEP Products

Reference	Age	Pts.	Design	Inclusion Criteria	Exclusion Criteria	Treatment	Outcome	TEAEs
Graff (2010)[12]	<7 y	N = 18, CF	MC, O single-arm	Stable PEP dose, FE <50 µg/g	Major surgery, fibrosing colonopathy, DIOS, HIV, immunosuppressive agents, GI tract malignancy	Creon 8000 lipase units/kg/day vs home PEP dose	Spot stool fat in new PEP vs home PEP, 28.1% vs 27.9%	50% in both groups
Graff (2010)[13]	7-11 y	N = 16, CF	MC, DB, R, PC, crossover	Stable PEP dose, FE <50 µg/g, stable weight	Major surgery, BMI <10%, ileus, HIV, celiac disease, or CD	Creon 4000 lipase units/g fat vs placebo	Change in CFA, 35.4% vs placebo (82.8% vs 47.4%, p < 0.001); change in CNA vs placebo, 35.3% (80.3% vs 45%, p < 0.001)	29.4% PEP vs 56.3% placebo
Trapnell (2009)[14]	≥12 y	N = 32, CF	MC, DB, R, PC, crossover	Stable PEP dose, FE <50 µg/g, stable weight or CFA <70%	Major surgery, BMI <10%, ileus, HIV, celiac disease, or CD	Creon 4000 lipase units/g fat vs placebo	Change in CFA 39% vs placebo (88.6% vs 49.6%, p < 0.001) Change in CNA 34.2% vs placebo (85.1% vs 49.9%, p < 0.001)	43.8% PEP vs 64.5% placebo
Whitcomb (2010)[15]	≥18 y	N = 54, CP, PT	MC, DB, R, PC parallel group	Abnormal secretin test or FE <100 µg/g or >15 g fecal fat/day or total P	Major surgery, pseudocyst ≥4 cm, continued alcohol abuse, GI tract malignancy, acute abdomen, ileus, HIV, celiac disease, CD	Creon 72,000 lipase units/meal 36,000 lipase units/snack vs placebo	Change in CFA 19.3% vs placebo (85.6% vs 66.3%, p < 0.001); change in CNA 77% vs placebo (13% vs –64%, p < 0.001)	20% in both groups
Wooldridge (2009)[16]	<7 y	N = 19, CF	MC, O, single-arm	Stable PEP dose, FE <50 µg/g BMI >25th percentile	Fibrosing colonopathy or DIOS, hyperuricemia, hepatic insufficiency, CF-related diabetes, FEV <30%, immunosuppressive medications	Zenpep dose[a] vs new titrated PEP dose	10 pts. had response to home PEP; 11 had response to new PEP	Zenpep, 33%
	≥7 y	32 CF	MC, DB, R, PC, crossover	Stable PEP dose, FE <50 µg/g, BMI >25th percentile	Fibrosing colonopathy or DIOS, hyperuricemia, hepatic insufficiency, CF-related diabetes, FEV <30%, immunosuppressive medications	Zenpep 1000 lipase units/kg/meal then titrated vs placebo	Change in CFA 25.5% vs placebo (88.3% vs 62.8%, p < 0.001); change in CNA 21.5% (87.2% vs 65.7%, p < 0.001)	55.9% PEP vs 50% placebo
Pancreaze Trial 1 (2010)[10]	≥8 y	N = 57, CF	DB, R, PC	Not published	Not published	Pancreaze 6300 units/kg/day then titrated vs placebo	Mean CFA difference, 32%	40% PEP vs 60% placebo
Pancreaze Trial 2 (2010)[10]	6-30 mo	N = 16, CF	SB, R, dose-ranging	Not published	Not published	Pancreaze, 4 dosage arms (375, 750, 1125, 1500) units/kg/meal vs placebo	Not published	Not published

BMI = body mass index; CD = Crohn's disease; CF = cystic fibrosis; CFA = coefficient of fat absorption; CNA = coefficient of nitrogen absorption; CP = chronic pancreatitis; DB = double-blind; DIOS = distal ileal obstruction syndrome; FE = fecal elastase; FEV = forced expiratory volume; GI = gastrointestinal; MC = multicenter; O = observational; P = pancreatectomy; PC = placebo-controlled; PEP = pancreatic enzyme products; PT = pancreatectomy; R = randomized; SB = single-blind; TEAEs = treatment-emergent adverse events.

[a]Zenpep dose was patient's home PEP dose.

Data Limitations

- Improves fat absorption
- Improves stool frequency and consistency
- Weight gain not reported in all trials
- Too small and short to assess for adverse events
- Steatorrhea not completely resolved
- Heterogeneous populations
- No direct comparison between different agents

Dosing and Administration

- Typical indications: weight loss, steatorrhea
- Less efficacious for pain (uncoated)
- Dosages based on lipase units
- Normal endogenous lipase release—upto 140,000 U
- Initial dose: 40-60 IU/min—25,000-40,000 IU/meal or 5000 IU-25000 IU/snack
- Total dose not to exceed 10,000 IU lipase/kg
- Pills administered during or immediately after meals
- Not specifically designed for enteral tubes
- Pediatric dosing per Cystic Fibrosis Foundation guidelines or package inserts

Adverse effects

- Treatment related adverse effects common (ranging from 30-50%), usually not much different from placebo
- Do not lead to treatment discontinuation
- Common AE:
  - Nausea, Abdominal pain, vomiting, cough, diarrhea, early satiety, weight loss
  - Hyper or hypoglycemia
  - Increased uric acid levels—>gout, caution in renal impairment
  - Possible viral infection from pigs (NEVER REPORTED)
  - Oral or rectal mucosa irritation

- Pregnancy Category C

- Fibrosing Colonopathy

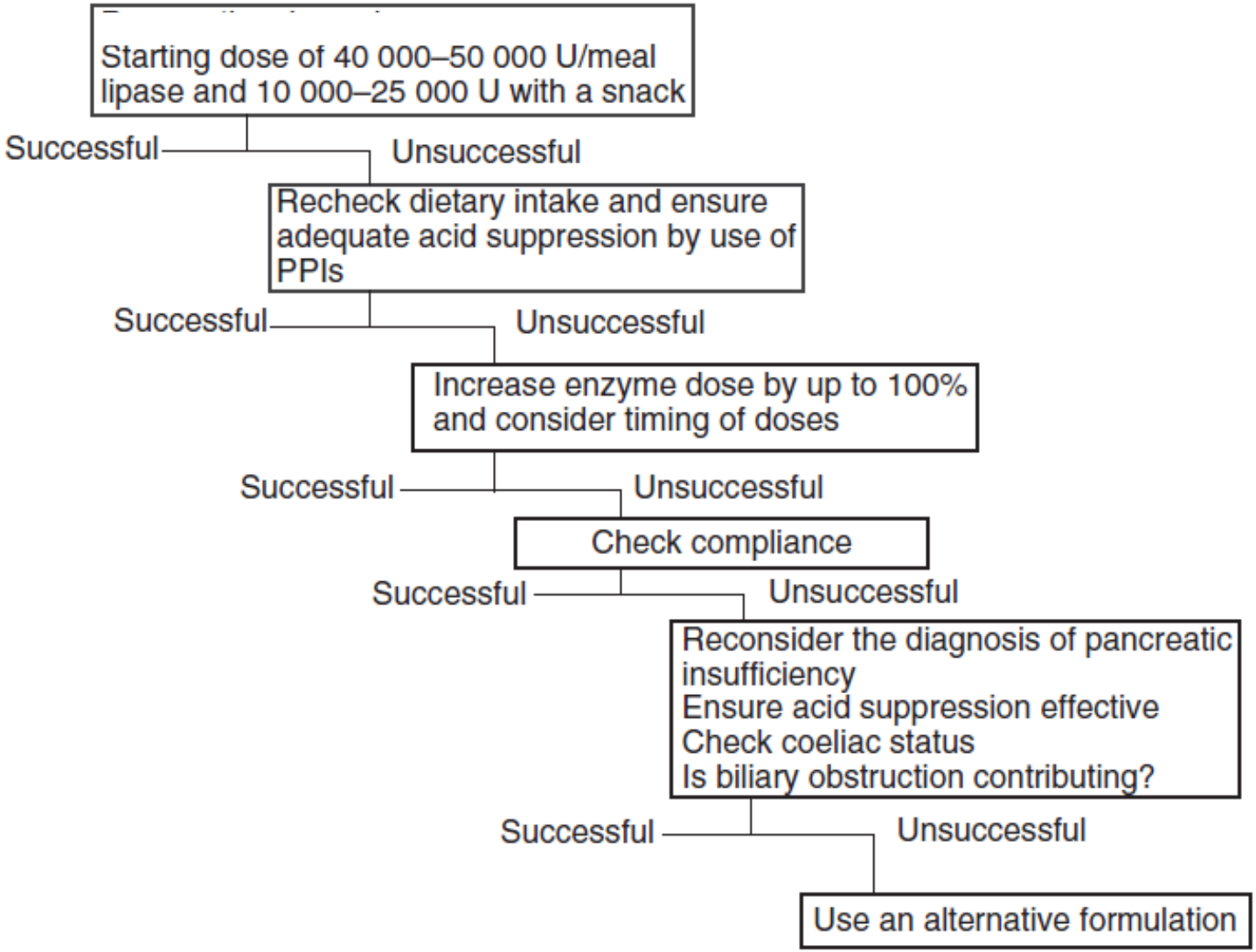
Fibrosing Colonopathy

- Submucosal fibrosis noted in colon of children with cystic fibrosis on pancreatic enzyme replacement therapy.
- Results in colonic stricture- frequently requiring surgery
- Noted with advent of high dose PERT in children
- Possible correlation between colonopathy and use of methacrylic polymer coating- not well proven
- In a case control study done on 29 pediatric patients, strong correlation between dose of PERT and fibrosing colonopathy
- ***Led to current recommendation of total dose not to exceed 10,000 IU Lipase/kg/day → no further reported recent cases***

Recommendations

- Pancreatic function test should be performed to confirm suspicion if possible
  - (fecal elastase, ? C13 MCT breath test)
- General measures should always be recommended
  - alcohol, smoking cessation etc
  - Test endocrine function prior to starting therapy
  - Small meals, replace other deficiencies- Vitamins/trace elements
- Medications should be administered appropriately
- Viokase (uncoated) should be combined with a proton pump inhibitor
- Dose escalation should follow a protocol (<10,000 Units/lipase/kg/day)
- Monitor the patient regularly
- Involve a dietician…social worker!

Clinical Algorithm



Challenges

- Diagnosis of pancreatic insufficiency beyond clinical suspicion
  - Stool testing , breath testing not available
- PT COMPLIANCE
- EXPENSE
- Monitoring treatment success

References

- http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm204745.htm
- Product inserts
- Fieker A. Clin Exp Gastroenterol 2011;4: 55-73
- Lohr JM. United Eur Gastroenterol Journal 1(2) 79-83
- Imrie CW. Aliment Pharmacol Ther 2010;32:1-25
- Giuliano C. Ann Pharmacother. 2011 May;45(5):658-66.
- Fitzsimmons SC. N Engl J Med 1997 May 1;336(18):1283-9.

Drug Utilization Review Board

Motions - Votes - **New Drugs**

June 5, 2014

Attachment B

New Drug	Drug	PDL Status	Motion - Recommendations	Additional Comments
PULMONARY ANTIHYPERTENSIVES	ADEMPAS (ORAL) TABLET	NPPA	NPPA	
	OPSUMIT (ORAL) TABLET	NPPA	NPPA	

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

	Board Members - Absent (Highlight, when present)
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.
3	Jones, Edwina L., Pharm.D., MBA

Drug Utilization Review Board

Motions - Votes - **New Drugs**

June 5, 2014

Attachment B

New Drug	Drug	PDL Status	Motion - Recommendations	Additional Comments
RESPIRATORY, ADRENERGIC COMBOS	BREO ELLIPTA (INHALATION) AER POW BA	NPPA	NPPA	

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

	Board Members - Absent (Highlight, when present)
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.
3	Jones, Edwina L., Pharm.D., MBA

Drug Utilization Review Board

Motions - Votes - **New Drugs**

June 5, 2014

Attachment B

New Drug	Drug	PDL Status	Motion - Recommendations	Additional Comments
ANTIDEPRESSANTS	BRINTELLIX (ORAL) TABLET	NPPA	PPA	
	FETZIMA (ORAL) CAP SA 24H	NPPA	NPPA	

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

	Board Members - Absent (Highlight, when present)
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.
3	Jones, Edwina L., Pharm.D., MBA

Drug Utilization Review Board

Motions - Votes - **New Drugs**

June 5, 2014

Attachment B

New Drug	Drug	PDL Status	Motion - Recommendations	Additional Comments
COLONY STIMULATING FACTORS	GRANIX (SUB-Q) SYRINGE	NPPA	NPPA	

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

	Board Members - Absent (Highlight, when present)
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.
3	Jones, Edwina L., Pharm.D., MBA

Drug Utilization Review Board

Motions - Votes - **New Drugs**

June 5, 2014

Attachment B

New Drug	Drug	PDL Status	Motion - Recommendations	Additional Comments
ANTINEOPLASTICS, MANTLE CELL LYMPHOMA	IMBRUVICA (ORAL) CAPSULE	PPA	PPA	

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

	Board Members - Absent (Highlight, when present)
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.
3	Jones, Edwina L., Pharm.D., MBA

Drug Utilization Review Board

Motions - Votes - **New Drugs**

June 5, 2014

Attachment B

New Drug	Drug	PDL Status	Motion - Recommendations	Additional Comments
ANTICONVULSANTS	FYCOMPA (ORAL) TABLET	NPPA	NPPA	

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

	Board Members - Absent (Highlight, when present)
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.
3	Jones, Edwina L., Pharm.D., MBA

Drug Utilization Review Board
Motions Votes - SR Classes
June 5, 2014
Attachment B

ANDROGENS-ANABOLIC

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

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

	Board Members - Absent (Highlight, when present)
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.
3	Jones, Edwina L., Pharm.D., MBA

Drug Utilization Review Board

Motions Votes - SR Classes

June 5, 2014

Attachment B

ANTICOAGULANTS

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

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

	Board Members - Absent (Highlight, when present)
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.
3	Jones, Edwina L., Pharm.D., MBA

Drug Utilization Review Board
Motions Votes - SR Classes
June 5, 2014
Attachment B

ANTICONVULSANTS

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

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

	Board Members - Absent (Highlight, when present)
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.
3	Jones, Edwina L., Pharm.D., MBA

ANTIDEMENTIA AGENTS

	Drug	PDL Status	Motion - Recommendations	Additional Comments
	NAMENDA XR (ORAL) CAP SPR 24	NPPA	P	

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

	Board Members - Absent (Highlight, when present)
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.
3	Jones, Edwina L., Pharm.D., MBA

Drug Utilization Review Board

Motions Votes - SR Classes

June 5, 2014

Attachment B

ANTIDEPRESSANTS

Drug	PDL Status	Motion - Recommendations	Additional Comments
ANAFRANIL (ORAL) CAPSULE	P	NPPA	
CLOMIPRAMINE HCL (ORAL) CAPSULE	NPPA	P	
IMIPRAMINE PAMOATE (ORAL) CAPSULE	P	NPPA	
PROTRIPTYLINE HCL (ORAL) TABLET	P	NPPA	
TRANYLCYPROMINE SULFATE (ORAL) TABLET	P	NPPA	

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

	Board Members - Absent (Highlight, when present)
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.
3	Jones, Edwina L., Pharm.D., MBA

ANTIEMETICS

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

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

	Board Members - Absent (Highlight, when present)
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.
3	Jones, Edwina L., Pharm.D., MBA

ANTIHEMOPHILIC PRODUCTS

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

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

	Board Members - Absent (Highlight, when present)
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.
3	Jones, Edwina L., Pharm.D., MBA

Drug Utilization Review Board
Motions Votes - SR Classes
June 5, 2014
Attachment B

ANTIHYPERTENSIVE, ANGIOTENSIN CONVERTING ENZYME (ACE) INHIBITORS

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

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

	Board Members - Absent (Highlight, when present)
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.
3	Jones, Edwina L., Pharm.D., MBA

Drug Utilization Review Board

Motions Votes - SR Classes

June 5, 2014

Attachment B

ANTIHYPERTENSIVE, ANGIOTENSIN RECEPTOR BLOCKERS (ARBS) AND COMBOS

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

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

	Board Members - Absent (Highlight, when present)
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.
3	Jones, Edwina L., Pharm.D., MBA

Drug Utilization Review Board
Motions Votes - SR Classes
June 5, 2014
Attachment B

ANTIHYPERTENSIVES, BETA BLOCKERS (BB)

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

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

	Board Members - Absent (Highlight, when present)
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.
3	Jones, Edwina L., Pharm.D., MBA

Drug Utilization Review Board
Motions Votes - SR Classes
June 5, 2014
Attachment B

ANTIHYPERTENSIVE, DIRECT RENIN INHIBITORS

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

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

	Board Members - Absent (Highlight, when present)
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.
3	Jones, Edwina L., Pharm.D., MBA

ANTI-INFECTIVE, MISCELLANEOUS

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

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

	Board Members - Absent (Highlight, when present)
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.
3	Jones, Edwina L., Pharm.D., MBA

Drug Utilization Review Board

Motions Votes - SR Classes

June 5, 2014

Attachment B

ANTIINFLAMMATORY, NONSTEROIDAL ANTIINFLAMMATORY DRUGS (NSAIDs)

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

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

	Board Members - Absent (Highlight, when present)
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.
3	Jones, Edwina L., Pharm.D., MBA

ANTIPARKINSON AGENTS

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

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

	Board Members - Absent (Highlight, when present)
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.
3	Jones, Edwina L., Pharm.D., MBA

Drug Utilization Review Board

Motions Votes - SR Classes

June 5, 2014

Attachment B

ANTIPSYCHOTICS

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

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

	Board Members - Absent (Highlight, when present)
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.
3	Jones, Edwina L., Pharm.D., MBA

Drug Utilization Review Board
Motions Votes - SR Classes
June 5, 2014
Attachment B

ATTENTION DEFICIT HYPERACTIVITY DISORDER (ADHD) AGENTS

	Drug	PDL Status	Motion - Recommendations	Additional Comments
	INTUNIV (ORAL) TAB ER 24H	NPPA	PPA	Recommendation is for only members 21 years of age and older

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

	Board Members - Absent (Highlight, when present)
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.
3	Jones, Edwina L., Pharm.D., MBA

Drug Utilization Review Board

Motions Votes - SR Classes

June 5, 2014

Attachment B

CALCIUM REGULATORS-OSTEOPOROSIS

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

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

	Board Members - Absent (Highlight, when present)
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.
3	Jones, Edwina L., Pharm.D., MBA

Drug Utilization Review Board
Motions Votes - SR Classes
June 5, 2014
Attachment B

C-C-A COMBOS-NON-NARC ANTITUSS RX

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

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

	Board Members - Absent (Highlight, when present)
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.
3	Jones, Edwina L., Pharm.D., MBA

Drug Utilization Review Board
Motions Votes - SR Classes
June 5, 2014
Attachment B

C-C-A -OPIOID ANTITUSSIVE RX

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

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

	Board Members - Absent (Highlight, when present)
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.
3	Jones, Edwina L., Pharm.D., MBA

Drug Utilization Review Board
Motions Votes - SR Classes
June 5, 2014
Attachment B

EPINEPHRINE PENS

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

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

	Board Members - Absent (Highlight, when present)
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.
3	Jones, Edwina L., Pharm.D., MBA

Drug Utilization Review Board
Motions Votes - SR Classes
June 5, 2014
Attachment B

FIBROMYALGIA AGENTS

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

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

	Board Members - Absent (Highlight, when present)
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.
3	Jones, Edwina L., Pharm.D., MBA

Drug Utilization Review Board

Motions Votes - SR Classes

June 5, 2014

Attachment B

HEMATOPOIETIC GROWTH FACTOR

	Drug	PDL Status	Motion - Recommendations	Additional Comments
	EPOGEN (INJECTION) VIAL	NPPA	PPA	

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

	Board Members - Absent (Highlight, when present)
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.
3	Jones, Edwina L., Pharm.D., MBA

HEMATOPOIETIC MIXTURES

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

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

	Board Members - Absent (Highlight, when present)
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.
3	Jones, Edwina L., Pharm.D., MBA

INFLAMMATORY BOWEL AGENTS

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

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

	Board Members - Absent (Highlight, when present)
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.
3	Jones, Edwina L., Pharm.D., MBA

IRRITABLE BOWEL SYNDROME (IBS) AGENTS

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

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

	Board Members - Absent (Highlight, when present)
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.
3	Jones, Edwina L., Pharm.D., MBA

Drug Utilization Review Board

Motions Votes - SR Classes

June 5, 2014

Attachment B

LAXATIVES, BOWEL EVACUANTS

		Drug	PDL Status	Motion - Recommendations	Additional Comments	
		PREPOPIK (ORAL) POWD PACK	NPPA	P		
	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Bona, Joseph R. M.D. - **Chair**			√		
2	Doad, Gurinder J.S., M.D.			√		
3	Ferguson, Traci, M.D.			√		
4	Fincher, Deborah W., M.S., R.Ph.			√		
5	Fowler, M. Celeste, Pharm.D.			√		
6	Gore, Thomas B., M.D.			√		
7	Greeson, John D., M.D., MBA		√	√		
8	Lorys, Robyn Pharm.D.			√		
9	May, J. Russell (Rusty)	√		√		
10	Miller, Osgood (Drew) A. R.Ph. - **Vice**			√		
11	Paul, Donald A., M.D.			√		
12	Rollins, Brent L., R.Ph., Ph.D.			√		
13	Shervette III, Robert E., M.D.			√		
14	Yates, Mary Virginia "Ginny", Pharm.D.			√		
			TOTAL	14	0	0

	Board Members - Absent (Highlight, when present)
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.
3	Jones, Edwina L., Pharm.D., MBA

Drug Utilization Review Board
Motions Votes - SR Classes
June 5, 2014
Attachment B

MIGRAINE PRODUCTS

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

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

	Board Members - Absent (Highlight, when present)
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.
3	Jones, Edwina L., Pharm.D., MBA

PANCREATIC ENZYMES

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

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

	Board Members - Absent (Highlight, when present)
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.
3	Jones, Edwina L., Pharm.D., MBA

Drug Utilization Review Board

Motions Votes - **SR Classes**

June 5, 2014

Attachment B

PLATELET AGGREGATION INHIBITORS

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

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

	Board Members - Absent (Highlight, when present)
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.
3	Jones, Edwina L., Pharm.D., MBA

Drug Utilization Review Board

Motions Votes - SR Classes

June 5, 2014

Attachment B

PROGESTINS

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

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

	Board Members - Absent (Highlight, when present)
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.
3	Jones, Edwina L., Pharm.D., MBA

Drug Utilization Review Board

Motions Votes - SR Classes

June 5, 2014

Attachment B

PULMONARY ANTIHYPERTENSIVES

	Drug	PDL Status	Motion - Recommendations	Additional Comments
	REVATIO (ORAL) TABLET	PPA	NPPA	
	SILDENAFIL (ORAL) TABLET	NPPA	PPA	

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

	Board Members - Absent (Highlight, when present)
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.
3	Jones, Edwina L., Pharm.D., MBA

RESPIRATORY, ANTICHOLINERGICS

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

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

	Board Members - Absent (Highlight, when present)
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.
3	Jones, Edwina L., Pharm.D., MBA

Drug Utilization Review Board

Motions Votes - SR Classses

June 5, 2014

Attachment B

RESPIRATORY,BETA ADRENERGIC SHORT

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

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

	Board Members - Absent (Highlight, when present)
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.
3	Jones, Edwina L., Pharm.D., MBA

RESPIRATORY, INHALED CORTICOSTEROIDS

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

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

	Board Members - Absent (Highlight, when present)
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.
3	Jones, Edwina L., Pharm.D., MBA

Drug Utilization Review Board

Motions Votes - SR Classses

June 5, 2014

Attachment B

RESPIRATORY, PHOSPHODIESTERASE-4 (PDE4) INHIBITORS

	Drug	PDL Status	Motion - Recommendations	Additional Comments
	DALIRESP (ORAL) TABLET (Single step)	NPPA	PPA	

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

	Board Members - Absent (Highlight, when present)
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.
3	Jones, Edwina L., Pharm.D., MBA

ULCER DRUGS, ANTISPASMODICS

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

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

	Board Members - Absent (Highlight, when present)
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.
3	Jones, Edwina L., Pharm.D., MBA

Drug Utilization Review Board

Motions Votes - SR Classses

June 5, 2014

Attachment B

ULCER DRUGS, H PYLORI

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

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

	Board Members - Absent (Highlight, when present)
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.
3	Jones, Edwina L., Pharm.D., MBA

Drug Utilization Review Board

Motions Votes - SR Classses

June 5, 2014

Attachment B

VAGINAL ANTI-INFECTIVES

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

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

	Board Members - Absent (Highlight, when present)
1	Avery, Mia, Pharm.D.
2	Damon, Ann R., Pharm.D.
3	Jones, Edwina L., Pharm.D., MBA

Manufacturers' Forum
Manufacturer Presentations

Dates: August 7, 2014

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

Attendees
Department of Community Health
Linda Wiant, PharmD, Director, Pharmacy Services
Brittany York, PharmD Candidate

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

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

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

Drug Presentations

I. Novartis
Julia Compton, PharmD, Regional Account Scientific Director
Fernando Kuehnel, RN, BSN, DNP, MBA, Regional Account Scientific Director
William Coll, Regional Account Manager II

Zortress® (everolimus)
Pronunciation: ZOR tress (E ver OH li mus)

Indications and Usage
Zortress is indicated for the prophylaxis of organ rejection in adult patients at low-moderate immunologic risk receiving a kidney transplant. In kidney transplant patients, Zortress is to be administered in combination with basiliximab induction and concurrently with reduced doses of cyclosporine and with corticosteroids. Zortress is also indicated for the prophylaxis of allograft rejection in adult patients receiving a liver transplant. In liver transplant patients, Zortress is to be administered no earlier than 30 days post-transplant concurrently in combination with reduced doses of tacrolimus and with corticosteroids. Therapeutic drug monitoring of everolimus, cyclosporine, and tacrolimus is recommended for all patients receiving these products.

Limitations of Use
The safety and efficacy of Zortress has not been established in the following populations:
- Kidney transplant patients at high immunologic risk
- Recipients of transplanted organs other than kidney and liver
- Pediatric patients (<18 years)

Dosage and Administration
- Kidney transplant starting dose of 0.75 mg twice daily (1.5 mg per day) administered as soon as possible after transplantation. Oral prednisone should be initiated once oral medication is tolerated; liver transplant starting dose of 1.0 mg twice daily (2.0 mg per day) starting at least 30 days post-transplant.

- Steroid doses may be tapered on an individualized basis depending on the clinical status of patient and function of graft.
- Patients receiving Zortress may require dose adjustments based on everolimus blood concentrations achieved, tolerability, individual response, change in concomitant medications and the clinical situation. Optimally, dose adjustments of Zortress should be based on trough concentrations obtained 4 or 5 days after a previous dosing change.
- The recommended everolimus therapeutic range is 3 to 8 ng/mL.
- Zortress is available as 0.25 mg, 0.5 mg, and 0.75 mg tablets; tablets should be swallowed whole with a glass of water and not crushed before use.

Clinical Studies

Kidney Transplantation: The A2309 study was a 24-month, randomized, multicenter, open-label, non-inferiority study conducted in 833 *de novo* renal transplant patients, aged 18 to 70 years old, at low to moderate immunologic risk. Recipients of a previous transplant or ABO-incompatible transplant, or patients who had received a kidney from a donor >65 years old, donated after cardiac death or with cold ischemia time >40 hours were not eligible to participate in this study. Eligible patients were randomized to receive either: 1). EVR 1.5 mg + RD-CsA everolimus 1.5mg/day starting dose, target blood levels 3-8 ng/mL) with reduced dose cyclosporine (RD-CsA); 2). EVR 3.0 mg +RD-CsA (everolimus 3.0 mg/day starting dose, target blood levels 6-12 ng/mL) +RD-CsA; or, 3). MPA + ST-CsA (MPA 1.44 g/day + standard dose CsA). All patients received basiliximab induction and corticosteroids. The primary endpoint was efficacy failure, defined as the composite of treated biopsy-proven acute rejection (tBPAR), graft loss, death or loss to follow-up at month 12 (non-inferiority analysis). The main safety endpoint was renal function at month 12, assessed by estimated GFR (eGFR) calculated by the MDRD equation.

- The rates for composite efficacy failure at month 12 were: 25.3%, in the EVR 1.5 mg group, 21.9 %, in the EVR 3.0 mg group, and 24.2%, in the MPA group. Both EVR groups were statistically non-inferior to MPA. At 12 months mean eGFR was 54.6, 51.3 and 52.3 mL/min/1.73 m2 in the EVR 1.5 mg, EVR 3.0 mg and MPA groups, respectively.
- A total of 34% (20% due to adverse reactions) of patients in the EVR 3.0 mg group discontinued the study. This regimen is not recommended.

Liver Transplantation: The H2304 study was a 24-month, randomized, multi-center, open-label, active controlled trial in liver transplant patients. A total of 719 patients were randomized into 3 treatment groups 30 days post-transplant; EVR+Reduced tacrolimus (TAC) (everolimus starting dose 2.0 mg/day, target trough level 3-8 ng/mL; n=245), EVR+TAC elimination (EVR starting dose 2.0 mg/day, target trough level 3-8 ng/mL until month 4 post-transplant then increased to 6-10 ng/mL, TAC elimination completed by the end of month 4; n=231), and TAC control (standard exposure TAC; n=243). All patients received corticosteroids and no induction antibody was administered. Key stratification parameters of HCV status (31-32% HCV positive across groups) and renal function (mean baseline eGFR range 79-83 mL/min/1.73m2) were balanced between groups. Treatment groups were also balanced with respect to background characteristics: the study population consisted of 18 to 70 year old liver transplant recipients undergoing their first transplant, mean age was approximately 54 years, more than 70% of patients were male, and the majority of patients were Caucasian.

- Enrollment into the EVR+TAC elimination group was discontinued due to a higher incidence of acute rejection and adverse events leading to treatment discontinuation during the elimination phase of TAC. This regimen is not recommended.
- The efficacy failure endpoint in the FDA-approved label is a composite of tBPAR, death, graft loss and loss to follow-up. This is consistent with the efficacy failure endpoint in the FDA-approved label for Zortress in kidney transplantation. Results at 12 months indicated that Zortress with reduced exposure tacrolimus is comparable to standard exposure tacrolimus with respect to efficacy failure, defined as tBPAR, graft loss, death or loss to follow-up. A total of 22 (9.0%) of patients in the EVR+Reduced TAC arm experienced efficacy failure vs. 33 (13.6%) of patients in the TAC control arm.
- The original protocol endpoints were non-inferior composite efficacy failure rate of death, graft loss, or loss to follow-up at month 12 post-transplant. The original protocol primary endpoint occurred in 22 patients (9.0%) in the EVR+Reduced TAC arm vs. 24 (9.9%) in the TAC Control arm. After implementation of the protocol amendment to discontinue enrollment in the EVR+TAC Elimination arm the original endpoints were revised. The amended protocol primary endpoint was to compare the composite efficacy failure rate of tBPAR, graft loss, or death with EVR+Reduced TAC vs. TAC Control at 12 months. EVR+Reduced TAC was statistically non-inferior to TAC Control. The Kaplan-Meir incidence rate of the amended protocol primary efficacy endpoint at month 12 was 6.7%

in the EVR+Reduced TAC arm and 9.7% in the TAC Control arm. EVR+Reduced TAC was statistically non-inferior to TAC Control.
- The calculated GFR (MDRD) for EVR+Reduced TAC was 80.9 mL/min/1.73^2 and the TAC Control was 70.3 mL/min/1.73m^2.

Adverse Event Profile
- The most common (incidence =20%) adverse events in kidney transplant patients treated with Zortress were: peripheral edema, constipation, hypertension, nausea, anemia, UTI, and hyperlipidemia. The most common (incidence>10%) adverse events in liver transplant patients were: diarrhea, headache, peripheral edema, hypertension, nausea, pyrexia, abdominal pain, and leukopenia.
- **Black Box Warnings: Malignancies, serious infections, kidney graft thrombosis, nephrotoxicity and mortality in heart transplantation.**
- Warnings/Precautions: Lymphomas and other malignancies, serious infections, hepatic artery thrombosis, nephrotoxicity, angioedema, wound healing/fluid accumulation, interstitial lung disease/non-infectious pneumonitis, hyperlipidemia, proteinuria, polyoma virus infections, interactions with strong inhibitors and inducers of CYP3A4, thrombotic microangiopathy/thrombotic thrombocytopenic purpura/hemolytic uremic syndrome, new onset diabetes, male infertility, immunizations and patients with hereditary disorders.

Questions and Answers
Q: Why can the drug not be administered earlier than 30 days post-transplantation?
A: Due to patients are at risk of thrombosis so need to wait to see which patients will develop thrombosis.

Q: How much dose of calcineurin inhibitors is reduced when used with Zortress?
A: Approximately 50-60% reduction in general but can vary based on patient.

Q: What are considered the advantages of Zortress?
A: Decreases the use of calcineurin inhibitors by approximately 50-60% without affecting efficacy, equivalent safety profile with the standard therapy, non-inferiority efficacy in kidney transplant, statistically lower rejection rate in liver transplant compared to comparator at 12 months, studied in the largest liver transplant registration trial, superior renal function compared to tacrolimus control following liver transplant at 12 months, is the only inhibitor of mammalian target of rapamycin that is indication in liver transplant, lower incidence of CMV and BK virus infections and lower rates of malignancies.

Q: Are other Medicaid plan managing Zortress?
A: For Amerigroup, WellCare, and Peach State, patients are accessing Zortress. Amerigroup and WellCare have a PA in effect for indication and at WellCare, Zortress is at the $3 copay because the cost of the drug is over $50. At Peach State, Zortress is in a Tier 3 position. Remember, Zortress is used to ensure graft survival after transplant and developing significant restrictions to Zortress is detrimental because paying for the transplant and then implementing barriers to medication runs the risk of successful transplant.

II. Bristol-Myers Squibb

James White, PharmD, Associate Director, Medical Oncology
Manan Shah, PharmD, PhD, Director, Health Services & Outcomes Research
Greg Ives, State Access Manager

Sprycel (dasatinib)
Pronunciation: SPRY sell (da SAT i nib)

Sprycel is indicated for the treatment of adults with
- Newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase (CP). The effectiveness of SPRYCEL is based on cytogenetic response and major molecular response rates.
    - The trial is ongoing and further data will be required to determine long-term outcome.
- Chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML with resistance or intolerance to prior therapy including imatinib.
- Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) with resistance or intolerance to prior therapy.

NCCN Guidelines: *Dasatinib is a recommended option within the National Comprehensive Cancer Network Clinical Practice Guidelines for newly diagnosed Ph+ CML-CP (Category 1) and for Ph+ CML-CP with resistance or intolerance to prior therapy (Category 2A)*.

Efficacy and Safety in DASISION Trial (Newly Diagnosed CML-CP)
In an open-label, multicenter, international trial, 519 newly diagnosed CML-CP patients were randomized to receive SPRYCEL 100 mg once daily (n=259) or imatinib 400 mg once daily (n=260). The primary endpoint was the rate of confirmed complete cytogenetic response (cCCyR; defined as a CCyR noted on two consecutive occasions at least 28 days apart), within 12 months (mos). The trial is ongoing. Results

- Formal statistical comparison of cCCyR and major molecular response (MMR) rates was only performed at the time of the primary endpoint.
- **cCCyR rate: Within 12 mos, 76.8% with SPRYCEL vs 66.2% with imatinib (*P*=.007); within 36 mos, 82.6% with SPRYCEL vs 77.3% with imatinib (*P*=N/A).** Median time to confirmed CCyR after 36 mos follow-up was 3.1 mos in 214 SPRYCEL responders and 5.8 mos in 201 imatinib responders.
- **MMR rate: Within 12 mos, 52.1% with SPRYCEL vs 33.8% with imatinib (*P*<.0001); within 36 mos, 69.1% with SPRYCEL vs 56.2% with imatinib (*P*=N/A); within 48 mos, 74% with SPRYCEL vs 60% with imatinib (*P*<.0001).** Median time to MMR after 36 mos follow-up was 8.9 mos in 179 SPRYCEL responders and 13.4 mos in 146 imatinib responders.
- The rate of MMR at any time in each Hasford risk group was higher with SPRYCEL vs imatinib (low risk: 81% and 64%; intermediate risk: 64% and 56%; high risk: 61% and 42%, respectively). The 4-year cumulative rates were 90% and 69% for low risk; 70% and 63% for intermediate risk; and 65% and 52% for high risk, respectively.
- **By 36 mos, 8 SPRYCEL patients (3%) and 13 imatinib patients (5%) progressed to accelerated phase/blast crisis. By 48 mos, 1 additional patient on imatinib transformed on study.**
- SPRYCEL does not appear to be active against the T315I mutation, based on *in vitro* data.
- **The majority of SPRYCEL-treated patients experienced adverse reactions at some time.**
- The most frequently reported adverse reactions (reported in =10% of patients) included myelosuppression, fluid retention events (pleural effusion and superficial localized edema), diarrhea, headache, musculoskeletal pain, rash, and nausea. With 4-year follow up, no new safety signals were identified.

SPRYCEL is associated with the following warnings and precautions:

- **Myelosuppression**, **Bleeding Related Events** (mostly associated with severe thrombocytopenia, **Fluid Retention, QT prolongation, Congestive Heart Failure, Left Ventricular Dysfunction and Myocardial Infarction**, **Pulmonary arterial hypertension (PAH), and Embryo-fetal Toxicity.**

Dosage and Administration (*Sprycel is recommended to be dosed once daily, without meal restrictions***)**

- The recommended starting dosage of SPRYCEL for **chronic phase CML** is **100 mg** administered orally once daily.
- The recommended starting dosage of SPRYCEL for **accelerated phase CML**, **myeloid or lymphoid blast phase CML**, or **Ph+ ALL** is **140 mg** administered orally once daily.
- Tablets should not be crushed or cut; they should be swallowed whole. SPRYCEL can be taken with or without a meal, either in the morning or in the evening. In clinical studies, treatment with SPRYCEL was continued until disease progression or until no longer tolerated by the patient. The effect of stopping treatment after the achievement of a complete cytogenetic response (CCyR) has not been investigated.

Medication taking behaviors of second generation tyrosine kinase inhibitors in patients with chronic myeloid leukemia

- Based on observational retrospective study using pooled Invision Data Mart and Pharmetrics claims data, Bristol-Myers Squibb evaluated the adherence to the newer generation tyrosine kinase inhibitors (TKIs)—dasatinib and nilotinib—in adult CML patients who were followed for maximum of 6 mos. Adherence to treatment was defined by the medication possession ratio (MPR) and persistence was defined as the proportion of patients refilling each subsequent prescription within a period of 1.5-days supply from the fill date. Discontinuation was defined as treatment gap of 2 times days supply and absence of index drug during the remaining follow-up period. Of the 276 CML patients identified, 179 received dasatinib 100 mg once daily (first-line: n=50; second-line: n=129), and 97 received nilotinib (first-line: n=27; second-line: n=70). In first-line setting, MPR=85% was 64% for dasatinib versus 48% for nilotinib. In the second-line setting, this rate was 75% versus 61%, respectively. Persistence rates for first-line setting were 36% for dasatinib versus 26% for nilotinib, and for second-line, 47% versus 39%, respectively. The treatment interruption rates in first-line setting were 34% for dasatinib vs 52% for nilotinib; and in second-line

setting, 36% for dasatinib vs 41% for nilotinib. The discontinuation rates were similar between the two treatment arms.

Treatment adherence and resource use costs in chronic CML

- Adherence to treatment and costs of healthcare resource use among adult CML patients treated with TKI were assessed in real-world setting using a US-based managed care database. Adherence was calculated as a medication possession rate (MPR) of =85%. Among the 545 CML patients assessed, low adherence (MPR<85%) was associated with an increase in average resource use (RU) cost of $24,000 (*P* < .01). Of those receiving treatment in second line setting, MPR was 82% for dasatinib 100 mg (n=47) and 77% for nilotinib 800 mg (n=15). During the follow-up period, the mean RU costs for dasatinib were $64,365, and for nilotinib was $189,260. Excluding 1% high cost outliers, RU costs were $59,808 for dasatinib 100 mg (n=46) and $103,075 for nilotinib 800 mg (n=14).

Questions and Answers

Q: Is Sprycel effecting against T315I mutation?
A: No, the T315I mutation will not respond to Sprycel.

Q: Were the primary drivers in the resource use study inpatient and outpatient procedure?
A: Yes.

Q: Are any other Medicaid plans managing?
A: Not in the other 5 southeast states that account manager covers.

Q: What are considered as advantages of Sprycel?
A: Dosed once daily without meals, was found to be associated with lower resource utilization costs and higher adherence when compared to nilotinib in CML patients in a real-world setting.

III. Pfizer

Donna M. Jermain, PharmD, BCPP, Senior Director, Women's & Men's Health
Tom Heard, RPh, CGP, Associate Director, Medical Outcomes Specialist
Brian K. Gillespie, Account Manager

Duavee (conjugated estrogens/bazedoxifene)

Pronunciation: DEW ah vee (KON joo gay ted ES troe jenz/ba ze DOX i feen)

DUAVEE combines conjugated estrogen (CE) with a selective estrogen receptor modulator (SERM), bazedoxifene (BZA). CE include multiple estrogens that act as agonists at estrogen receptors a and ß, while BZA acts primarily as an agonist in certain estrogen-sensitive tissues and primarily as an antagonist in others (eg, uterus).

Indications and Usage

- DUAVEE is indicated in women with a uterus for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause and for the prevention of postmenopausal osteoporosis.
- ***Limitation of Use:*** DUAVEE should be used for the shortest duration consistent with treatment goals and risks for the individual woman.

Clinical Background and Burden of Illness

- In 2025, an estimated 1.1 billion women globally will be postmenopausal, and up to 80% of these women are expected to experience VMS during the postmenopause. VMS, including hot flushes and night sweats, are often associated with a negative impact on quality of life and may be accompanied by symptoms of anxiety, sleep disturbances, impaired cognitive function, fatigue, and depression. Hormone therapy, including estrogen therapy (ET) alone or estrogen-progestin therapy (EPT), is effective for treating VMS. ET is not recommended for women with an intact uterus because systemic estrogens may stimulate the endometrium, resulting in an increased risk of endometrial cancer. Because the progestogen component of EPT helps counteract these stimulatory effects, EPT may be recommended for nonhysterectomized women.
- Osteoporosis, which is characterized by changes in bone remodeling processes that result in a loss of bone mass and deterioration of the bone architecture, affects more than 8 million women over 50 years of age in the United States and more than 12 million women 50 to 84 years of age across 5 European countries. Osteoporotic

fractures, which are a major negative sequela of osteoporosis, may be painful and may be associated with impaired physical function, disability, and increased mortality. Bisphosphonates, raloxifene, and hormone therapy are pharmacologic options considered for preventing osteoporosis.

Clinical Efficacy

- The efficacy of CE/BZA for the treatment of moderate to severe VMS associated with menopause was shown in a 12-week, randomized, double-blind, placebo-controlled, phase 3 study (the Selective estrogens Menopause, And Response to Therapy [SMART]-2 study). In that study in postmenopausal women who were experiencing $\geq$7 moderate to severe hot flushes per day or $\geq$50 moderate to severe hot flushes per week at screening (N = 318), significant reductions were observed in the average daily number of moderate to severe hot flushes and in the average daily severity of hot flushes with CE/BZA compared with placebo at Weeks 4 and 12 (*P* <0.001).
- The efficacy of CE/BZA for the prevention of postmenopausal osteoporosis was demonstrated in substudies of a 2-year, randomized, double-blind, placebo-and active-controlled phase 3 study (the SMART-1 study) and of a separate 1-year, randomized, double-blind, placebo- and active-controlled phase 3 study (the SMART-5 study). The SMART-1 Osteoporosis Prevention Substudy I (n = 1,454) included women who were >5 years from their last menstrual period (LMP), had a screening lumbar spine or total hip bone mineral density (BMD) T-score between –1 and –2.5 (inclusive), and had =1 additional risk factor for osteoporosis. The SMART-1 Osteoporosis Prevention Substudy II (n = 861) included women who were 1 to 5 years from LMP with =1 risk factor for osteoporosis. In both Substudies, CE/BZA treatment was associated with significant increases in lumbar spine and total hip BMD from baseline at all evaluated timepoints from baseline through 24 months compared with placebo (*P* <0.05). CE/BZA treatment was also associated with a significant decrease in bone turnover markers at all evaluated timepoints during the 2-year treatment period compared with placebo (*P* <0.001). The osteoporosis substudy of SMART-5 (n = 590) included women who were =5 years since LMP and had 2 evaluable BMD scans at screening of the lumbar spine and total hip that differed by <5.0% and <7.5%, respectively. In that substudy, CE/BZA was associated with significant increases in lumbar spine, total hip, and femoral neck BMD and with significant decreases from baseline in serum bone turnover markers compared with placebo at 12 months (*P* <0.01).

Economic Value

- A mathematical model was developed to estimate the burden of evaluative procedures in patients presenting with postmenopausal bleeding (PMB) 6 to 12 and 3 to 12 months after initiation of CE/MPA versus CE/BZA. Based on this exploratory modeling exercise, using CE/MPA to treat moderate to very severe VMS is associated with approximately 63,000 (PMB 6 to 12 months) to 80,000 (PMB 3 to 12 months) evaluation procedures annually. Under assumptions used in the model, this procedure burden may be reduced by 68% to 71% through the use of CE/BZA instead of CE/MPA.

Clinical Safety and Tolerability

- ***Boxed Warning***: Women taking CE/BZA should not take additional estrogens. There is an increased risk of endometrial cancer in a woman with a uterus who uses unopposed estrogens. CE/BZA has been shown to reduce the risk of endometrial hyperplasia, which may be a precursor to endometrial cancer. Adequate diagnostic measures, including directed or random endometrial sampling when indicated should be undertaken to rule out malignancy in postmenopausal women with undiagnosed persistent or recurring abnormal genital bleeding. Estrogen therapy should not be used for the prevention of cardiovascular disease or dementia. The Women's Health Initiative (WHI) estrogen-alone substudy reported increased risks of stroke and deep vein thrombosis (DVT) in postmenopausal women (50 to 79 years of age) during 7.1 years of treatment with daily oral CE (0.625 mg) alone, relative to placebo. The WHI Memory Study (WHIMS) estrogen-alone ancillary study of WHI reported an increased risk of probable dementia in postmenopausal women 65 years of age and older during 5.2 years of treatment with daily CE (0.625 mg) alone, relative to placebo. It is unknown whether this finding applies to younger postmenopausal women. In the absence of comparable data, these risks should be assumed to be similar for other doses of CE and other dosage forms of estrogens. Estrogens should be prescribed at the lowest effective doses and for the shortest duration consistent with treatment goals and risks for the individual woman.
- In placebo-controlled trials, the most common adverse events (incidence =5%) that occurred more frequently with CE/BZA (N = 1224) than with placebo (N = 1069) included the following: nausea (8% vs 5%), diarrhea (8% vs 5%), dyspepsia (7% vs 6%), upper abdominal pain (7% vs 5%), muscle spasms (9% vs 6%), neck pain (5% vs 4%), dizziness (5% vs 3%), and oropharyngeal pain (7% vs 6%). CE/BZA was associated with low (<1%) rates of endometrial hyperplasia in clinical studies of up to 2 years duration ; these rates meet the endometrial safety standard established by the US Food and Drug Administration. In the SMART-5 study, changes from baseline in mammographic breast density at 1 year were similar for CE/BZA and placebo, while mammographic breast density increased significantly from baseline at 1 year with the active comparator CE/medroxyprogesterone acetate (MPA)

compared with placebo (*P* <0.001). In addition, the incidence of breast pain/tenderness with CE/BZA was comparable to that with placebo and significantly lower than that with CE/MPA (*P*<0.01). The rate of vaginal bleeding over 1 year of treatment with CE/BZA was comparable to that with placebo and significantly lower than that with CE/MPA (*P* <0.001).

Questions and Answers
Q: Have any head to head trials been conducted?
A: Yes, a head to head trial was conducted with raloxifene.

Q: What are considered the advantages of Duavee over raloxifene (Evista)?
A: Positive results on bone density as well as breast pain and tenderness.

Q: What are considered overall advantages of Duavee?
A: First and only combination of CE and SERM, works selectively in uterus, has endometrial protection and bleeding rates similar to placebo.

IV. AstraZeneca
Russ Rainwater, PharmD, MBA, Senior Medical Liaison, Diabetes
Negelle Y. Green, LCSW, Account Director

Farxiga (dapagliflozin)
Pronunciation: far SEE guh (da pa gli flow zin)

Overview
- FARXIGA is an oral sodium-glucose cotransporter 2 (SGLT2) inhibitor that works in the kidney to remove glucose via the urine.
- Clinical trials demonstrated that FARXIGA effectively reduces HbA1c with added benefits of weight and blood pressure reduction.

Indication
- FARXIGA is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (T2DM).

Limitation of Use & Dosing
- FARXIGA should not be used to treat patients with type 1 diabetes or diabetic ketoacidosis.
- The recommended starting dose of FARXIGA is 5 mg once daily, taken in the morning, with or without food. In patients tolerating
- FARXIGA 5 mg who require additional glycemic control, the dose can be increased to 10 mg once daily.
- In patients with volume depletion, correcting this condition prior to initiation of FARXIGA is recommended.
- Assess renal function before initiating FARXIGA and periodically thereafter. Do not initiate FARXIGA if eGFR is < 60 mL/min/1.73m2, and discontinue FARXIGA if eGFR falls persistently < 60 mL/min/1.73 m2. No dose adjustment is needed in patients with mild renal impairment (eGFR > 60 mL/min/1.73 m2).

Clinical Data
- FARXIGA demonstrated significant reductions in HbA1c when used as monotherapy and in combination with metformin (MET), glimepiride, pioglitazone, sitagliptin (± MET), or insulin (± up to 2 oral antidiabetic therapies).
- FARXIGA 5 mg demonstrated an HbA1c reduction at week 24 from baseline of -2.1% in an active-controlled initial combination therapy study with MET XR. FARXIGA 10 mg was non-inferior to MET XR in reducing HbA1c at 24 weeks.
- FARXIGA was non-inferior to glipizide in reducing HbA1c in a 52-week add-on to MET active-comparator study.
- Studies within the clinical program that assessed long term data, ranging from 48 weeks to 4 years, showed that the effects of FARXIGA were sustained.
- In placebo-controlled phase 3 studies that evaluated change in mean weight at 24 weeks as a secondary endpoint, placebo-corrected weight reduction in FARXIGA groups ranged from -0.8 kg to -2.2 kg; and with the exception of one monotherapy study, the more reductions were statistically significant for the 5 and 10 mg doses of FARXIGA.

- More than 11,000 patients with T2DM participated in 24 phase 2b and 3 studies, including both placebo-controlled and active comparator designs with durations ranging from 12 weeks to 4 years. Over 6,000 patients received FARXIGA in these trials. Patient populations examined covered the range of T2DM progression: drug-naive patients, patients unable to achieve glycemic control on oral therapies, and patients on insulin-based regimens. The program also provided significant experience in elderly patients, patients with a history of cardiovascular (CV) disease, overweight and obese patients, patients with poorly controlled hypertension, and patients with mild to moderate renal impairment. FARXIGA is not indicated for weight loss, the treatment of hypertension, or to reduce CV outcomes.

Product Characteristics
- SGLT2 inhibition with FARXIGA results in the direct, and insulin-independent, elimination of glucose by the kidney.
- An increase in the amount of glucose excreted in the urine has been demonstrated within 24 hours of FARXIGA administration. Patients receiving FARXIGA 5 mg and 10 mg for 12 weeks excreted 64 + 34 g and 68 + 38 g of glucose per day, respectively.

Health Economic and Outcomes Research Data
- A cost effectiveness analysis was conducted to evaluate the clinical and economic consequences associated with the use of FARXIGA as add-on therapy in T2DM. The Cardiff Model, a validated fixed-time stochastic simulation cost-utility, model was adapted to the U.S. payer perspective. Estimated costs and benefits were discounted at a rate of 3% annually over a 40-year time frame. FARXIGA was evaluated as add-on to MET treatment compared to commonly used classes of agents. FARXIGA is cost effective compared to an SU (Incremental Cost Effectiveness Ratio [ICER]: $35,633), TZD (ICER: $32,955), and DPP-4i (ICER: $32,955).

Safety
- FARXIGA causes intravascular volume contraction. Symptomatic hypotension can occur after initiating FARXIGA, particularly in patients with an eGFR < 60 mL/min/1.73 m2, elderly patients, or patients on loop diuretics. Before initiating FARXIGA in patients with one or more of these characteristics, assessing and correcting volume status is recommended.
- FARXIGA increases serum creatinine and decreases eGFR. Elderly patients and patients with impaired renal function may be more susceptible to these changes. Adverse reactions related to renal function can occur after initiating FARXIGA. Renal function should be evaluated prior to initiation of FARXIGA and monitored periodically thereafter.
- A higher incidence of hypoglycemic events was observed when agents known to cause hypoglycemia, such as insulin and insulin secretagogues, were combined with FARXIGA. Therefore, a lower dose of insulin or insulin secretagogue may be required to minimize the risk of hypoglycemia when these agents are used in combination with FARXIGA.
- Increased rates and genital mycotic infections were identified. Signs and symptoms of these events were all mild or moderate in intensity and most readily responded to standard treatment and rarely resulted in treatment discontinuation. Patients who had a history of recurrent genital mycotic infection were more likely to have another event while on FARXIGA.
- Increases in LDL-C occur with FARXIGA. Monitor LDL-C and treat per standard of care after initiating FARXIGA.
- An imbalance in bladder cancers was observed in clinical trials. FARXIGA should not be used in patients with active bladder cancer and should be used with caution in patients with a prior history of bladder cancer.

Questions and Answers
Q: How much average weight was lost?
A: 61 lbs in 6 months and maintained for 4 years.

Q: Are there any studies evaluating lowering of blood pressure medications when used concomitantly with Farxiga?
A: No, based on anecdotal reports.

Q: What are considered the advantages of Farxiga?
A: Has add-on therapy data with DPP-IV and not associated with hyperkalemia.

V. Astellas
Barbara Kassmann, DNP, PNP-BC, Scientific Associate Director, Health Economics & Clinical Outcomes Research

David Abbott, Director, Access & Reimbursement
J. Darryl Harrison, Access & Reimbursement Manager

Astagraf XL (tacrolimus extended-release)
Pronunciation: AS ta graf XL (ta KROE li mus)

Indication & Administration
- ASTAGRAF XL is the first once-daily extended-release version of tacrolimus, the active ingredient in the immunosuppressant Prograf. It is indicated for the prophylaxis of organ rejection in patients receiving a kidney transplant with mycophenolate mofetil (MMF) and corticosteroids with or without basiliximab induction.
- Prograf is indicated for prophylaxis of organ rejection in patients receiving allogeneic liver, kidney or heart transplants, and is used concomitantly with adrenal corticosteroids in kidney and heart transplant, and in conjunction with azathioprine or MMF.
- Using an ethylcellulose vehicle, ASTAGRAF XL offers once daily dosing in the morning preferably on an empty stomach. It is not interchangeable or substitutable with any tacrolimus twice-daily formulations, including branded Prograf.
- Recommended target whole blood trough ranges and monitoring recommendations are similar for ASTAGRAF XL and Prograf.
- Alcohol should not be consumed with ASTAGRAF XL.

Efficacy
- Two pivotal trials in *de novo* adult kidney transplant recipients showed similar combined efficacy failure rates between ASTAGRAF XL and Prograf, at 14% vs. 15.1% in Study 1 and 28% vs. 23% in Study 2, respectively.
- The primary endpoint in these studies was combined efficacy failure including biopsyproven acute rejection, graft loss, death, and/or lost to follow-up. Both products were given in combination with MMF and corticosteroids.
- The safety of ASTAGRAF XL was studied in these 2 pivotal trials, which included 545 patients on ASTAGRAF XL; however, the studies were not designed to draw comparisons between ASTAGRAF XL and Prograf regarding adverse events.
- A 4-year clinical continuation phase of Study 1 showed similar efficacy results to 1-year data.

Boxed Warnings
- The ASTAGRAF XL label recommends against use in liver transplantation due to increased mortality in female transplant recipients in a clinical trial.
- Both ASTAGRAF XL and Prograf have boxed warnings about susceptibility to infection, development of malignancies, and the need for prescribing by only experienced physicians in immunosuppression and organ transplantation.

Safety
- Adverse events with ASTAGRAF XL are consistent with those noted in the literature for Prograf. The most common adverse reactions (>30%) were: diarrhea, constipation, nausea, peripheral edema, tremor, and anemia.
- One-year treatment discontinuation due to adverse reactions in Study 1 and 2 were 9% and 13% in the ASTAGRAF XL arms and 11% in the Prograf control arms in both studies, respectively; 4-year discontinuation rates in the continuation phase of Study 1 were 21% and 18% in the ASTAGRAF XL and Prograf arms, respectively.
- The most common adverse reactions leading to discontinuation in ASTAGRAF XL- treated patients were infections, renal/urinary disorders, graft dysfunction, renal vascular/ischemic conditions, and diabetes.
- Warnings and precautions include: Medication errors including unintentional substitution between IR tacrolimus and ASTAGRAF XL; New Onset Diabetes After Transplant; nephrotoxicity; neurotoxicity; hyperkalemia; hypertension; recommendations against use with sirolimus; possible dose adjustments necessary when used with strong cytochrome P450 3A4 inhibitors and inducers; QT prolongation; use of live vaccines; pure red cell aplasia; and gastrointestinal perforation.
- Due to inter-subject variability in tacrolimus pharmacokinetics, individualization of dosing regimen is necessary.

Questions and Answers
Q: What are considered advantages of Astagraf XL?

A: Once daily dosing; a European study showed improved adherence with once daily dosing in renal transplant patients. Statistical significance was not measured. The product was brought to the market due to patient and physician requests.

Xtandi (enzalutamide)
Pronunciation: X TAN dee (EN za LOO ta mide)

Indication
- XTANDI is an androgen receptor inhibitor indicated for the treatment of patients with metastatic castration-resistant prostate cancer (mCRPC) who have previously received docetaxel. XTANDI is not FDA approved for use in mCRPC patients who have progressed on androgen deprivation therapy (ADT) and not previously received chemotherapy (i.e., are chemotherapy-naïve).

Efficacy
- The Phase 3 PREVAIL trial was a randomized (1:1), double-blind, placebo-controlled,multi-national trial that enrolled 1,717 men (872 randomized to enzalutamide vs. 845 randomized to placebo) across study sites located in North America, Europe, Australia, and Asian countries, including Japan. The trial enrolled patients with mCRPC whose disease progressed despite treatment with ADT and who had not yet received chemotherapy. The co-primary study endpoints were overall survival (OS) and radiographic progression-free survival (rPFS). The trial was designed to evaluate enzalutamide at a dose of 160 mg taken orally once daily vs. placebo. Given the interim results of these co-primary endpoints, OS at 540 deaths (original data cut-off: September 16, 2013) and rPFS at 439 deaths (data cut-off: May 6, 2012), and considering the observed safety profile, the data and safety monitoring committee recommended that the study be stopped and patients who had received placebo be offered treatment with enzalutamide.
- Enzalutamide demonstrated a statistically significant benefit over placebo, meeting the coprimary endpoints of OS with a 29% reduction in risk of death [hazard ratio (HR) 0.706; 95% CI: 0.60-0.84; p<0.0001] and rPFS with an 81% reduction in risk of radiographic progression or death [HR 0.186; 95% CI: 0.15-0.23; p<0.0001]. An updated analysis of overall survival with 116 additional deaths showed that 82% of patients in the enzalutamide group and 73% of patients in the placebo group were alive at 18 months; the estimated median was not yet reached (NYR) in the enzalutamide group and was 31.0 months in the placebo group (hazard ratio, 0.73; 95% CI, 0.63 to 0.85; p<0.001).
- The superiority of enzalutamide over placebo was shown with respect to all secondary endpoints, including median time until the initiation of cytotoxic chemotherapy (28 vs. 10.8 months), median time until first skeletal-related event (31.1 vs. 31.3 months), best overall soft-tissue response (59% vs. 5%), median time until PSA progression (11.2 vs. 2.8 months), PSA decline of 50% or more from baseline (78% vs. 3%) (p<0.001 for all secondary endpoints).

Safety
- A grade 3 or higher adverse event was reported in 43% of patients treated with enzalutamide vs. 37% of patients who received placebo; however, the median time until the first grade 3 or higher event was 22.3 months with enzalutamide vs. 13.3 months with placebo.
- The most common adverse events (= 10% in the enzalutamide group and = 2% more than the placebo rate) were fatigue (36% vs. 26%), back pain (27% vs. 22%), constipation (22% vs. 17%), arthralgia (20% vs. 16%), decreased appetite (18% vs. 16%), hot flush (18% vs. 8%), diarrhea (16% vs. 14%), hypertension (13% vs. 4%), asthenia (13% vs. 8%), fall (12% vs. 5%), weight loss (11% vs. 8%), peripheral edema (11% vs. 8%), and headache (10% vs. 7%) for enzalutamide vs. placebo, respectively.

Questions and Answers
Q: Are any other indications being sought?
A: Use as initial therapy in metastatic prostate cancer is being studied.

VI. Fresnius
Rashmi Morani, PharmD, MS, Medical Science Liaison

Velphoro (sucroferric oxyhydroxide)
Pronunciation: VEL for OH (SOO kro FAIR ick OXEE hi drox IDE)

- Requesting the P&T Committee to add Velphoro, a new phosphate binder, to the state's preferred drug list as a preferred agent

- Velphoro is a novel non-calcium based, iron-based phosphate binder approved by the FDA in November 2013 for the control of serum phosphorus levels in patients with CKD on dialysis

- Velphoro was developed to address the unmet medical needs in the management of hyperphosphatemia
  - The daily pill burden of dialysis patients is 19 total tablets per day and approximately 50% of the daily pill burden is attributed to phosphate binders
  - Of those prescribed phosphate binders, 62% were found to be non-adherent to their phosphate binders
  - 47% of dialysis patients are above the recommended national treatment guidelines for serum phosphorus target range of 3.5 to 5.5 mg/dL
  - Phosphorus levels above target are associated with an increase in mortality

- In a pivotal Phase III study involving 1,055 dialysis patients, Velphoro was effective in reducing serum P levels to comparable levels as the standard of care, sevelamer carbonate, but with significantly lower daily pill burden over 52 weeks.
  - The pill burden for dialysis Velphoro-treated patients was only 3.3 tablets per day compared to sevelamer-treated patients, who required 8.7 tablets per day
  - Thus, the recommended starting dose for Velphoro is 1 tablet per meal (3 tablets per day)

- Patient safety and tolerability profile was comparable to the standard of care
  - There is no contraindication related to the use of Velphoro
  - As an iron-based phosphate binder with robust phosphate binding capacity, clinical and non-clinical studies have demonstrated low iron absorption and no iron accumulation with Velphoro. Thus, Velphoro can be safely used without any additional monitoring of iron laboratory parameters

- In summary, as a novel non-calcium-based phosphate binder, Velphoro offers a new and effective treatment option for the control of serum phosphorus levels. On behalf of Fresenius Medical Care, we ask that the P&T committee make Velphoro accessible for the dialysis community as a preferred agent on Georgia' s Medicaid PDL.

Questions and Answers
Q: How are other Medicaid plans covering?
A: Some states are requiring generic first, some states are not requiring step of generic first.

Q: What are considered the advantages of Velphoro?
A: Non-calcium so no calcification, iron-based that does not require monitoring of iron levels, decreases pill burden and potent phosphate binder.

VII. Kaleo
Heather Thomson, MS, Medical Science Liaison
Dean P. Erhardt, MBA, Principal, D2 Pharma Consulting

Evzio (naloxone hydrochloride injection)
Pronunciation: Ev'-zee-oh (nah-lox'-own HCl injection)

Evzio (naloxone HCl injection) Auto-injector is a take-home naloxone auto-injector that patients, family members, and other caregivers can have close by in case an opioid overdose occurs. Each Evzio prescription comes with two, single-use, prefilled naloxone auto-injectors containing 0.4 mg of naloxone HCl injection and a Trainer for Practice.

Deaths from prescription opioid overdose in the United States have increased dramatically in the past decade, with close to 17,000 reported for 2011, the latest date where data is available. Naloxone has been drug of choice for reversing the effects of opioids since its approval in 1971, including the respiratory depression that can lead to damage to the central nervous system or death if not rapidly addressed. The only drawback has been that the current formulations of naloxone were developed for the clinical setting for use by trained medical professionals, since approved routes of administration are intravenous, intramuscular and subcutaneous injection. Now family members or caregivers without medical training can successfully administer a potentially life-saving dose of a naloxone

formulation specifically developed for non-medical settings such as the community until emergency medical services personnel arrive.

There are multiple risk factors for opioid overdose; being a Medicaid enrollee is one of them. While a history of substance abuse is the most readily recognized factor for increased risk of overdose, additional factors have been identified that can affect even patients adherent to their opioid therapy for pain:

- A morphine-equivalent dose =20 mg per day
- Switching to another opioid
- Underlying respiratory disease such as chronic pulmonary disease, sleep apnea and asthma
- Chronic kidney and/or liver impairment
- Use of CNS depressants, including benzodiazepines and alcohol, and medications like MAO inhibitors

The hospitalization rate of patients with opioid overdose and the length of stay and intensive use of hospital services makes opioid overdose an expensive event with over 50% of patients who visit the emergency room being admitted at an average event cost of over $30,000. Besides the tragedy of overdose deaths, 20% of patients are discharged to another institution, such as a nursing home or rehabilitation center, so expenses continue to accrue even after the emergency phase of the overdose.

For those patients at an elevated risk of overdose, EVZIO is the length and width of a credit card and thickness of a small cell phone enabling portability and contains a visual and voice instruction system to assist in guiding users through the correct administration process. EVZIO contains a retractable needle that is never seen by either the patient or caregiver, and cannot be accessed following the product's use.

EVZIO is an opioid antagonist indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression. EVZIO is intended for immediate administration as emergency therapy in settings where opioids may be present. EVZIO is not a substitute for emergency medical care.

EVZIO was well tolerated with comparable bioavailability to 0.4 mg naloxone HCl delivered via standard syringe, and in a usability study, 90% of participants successfully simulated using EVZIO without training.

The makers of EVZIO, Kaléo Pharma, anticipate a measured roll-out, with a small sales specialist team focused on educating physicians on opioid overdose risk factors and appropriate patient populations for EVZIO. While it is not the responsibility of third-party payers to solve the nation's opioid overdose public health crisis, a payer's decision to reimburse EVZIO will have a major impact on whether patients will have access to this medicine for early intervention with the potentially for reduced morbidity and mortality.

Questions and Answers

Q: Are prescribers writing refills on prescriptions?
A: Not generally, if medication is used, patient should be seen by physician for evaluation.

Q: Who are prescribers writing the prescriptions for?
A: Primarily for the patient but are making sure patient's circle is trained on administration.

Q: How are Medicaid and Commercial plans covering?
A: Do not know yet for Medicaid plans since CMS rebate effective date is October 1st. Some Commercial plans have open coverage, others have PA to ensure opioid on board.

Q: What ensures an ambulance will be called?
A: The trainer states to call ambulance and all educational materials reinforce.

Q: What is considered a reasonable quantity level limit?
A: 2 prescriptions, 4 active units per year. Some prescribers may write for 2 injections so that parent has one and patient has one.

Q: What is the target patient population for use?

A: High risk patients taking opioids, including patients on high doses or long-acting formulations, patients that have had recent ER or hospitalization visit, patients with serious mental illness and elderly patients that may forget they have taken dose.

Q: What is the risk of seizures?
A: The dose of Evzio is just enough to reverse opioid action but not so much to precipitate withdrawal to cause seizures.

VIII. Takeda
Jennifer Hooks, Regional Account Manager

Colcrys (colchicine)
Pronunciation: KOL kris (KOL chi seen)

Indications
- Prophylaxis of gout flares and treatment of acute gout flares in adults when taken at the first sign of a flare.
- Treatment of familial Mediterranean fever (FMF) in adults and children 4 years or older.
- Colcrys is not an analgesic medication and should not be used to treat pain from other causes.

Dosage and Administration
- Treatment of gout flares: 1.2 mg (2 tablets) at the first sign of a gout flare followed by 0.6 mg (1 tablet) 1 hour later.
- Prophylaxis of gout flares: 0.6 mg once or twice daily in adults and adolescents >16 years of age. Maximum dose 1.2 mg/day.
- Dose adjustments are required in patients with impaired renal or hepatic function or using coadministered drugs known to inhibit cytochrome P450 (CYP) 3A4 and/or P-glycoprotein (P-gp).
- According to the 2012 American College of Rheumatology guidelines for the management of gout, pharmacologic anti-inflammatory prophylaxis should be initiated just prior to or while initiating ULT. Pharmacologic gout attack prophylaxis should be continued in the presence of clinical evidence of gout disease activity (such as ≥ 1 tophi detected on physical examination, recent gout attacks, or chronic gouty arthritis), and/or when the serum urate target has not been achieved. Prophylaxis should be continued for the greater of 1) at least 6 months, 2) 3 months after achieving the target serum urate level for the patient without tophi detected on physical examination, or 3) 6 months after achieving the target serum urate level, where there has been resolution of tophi previously detected on physical examination. It is recommended to lower serum urate to < 6 mg/dL to durably improve signs and symptoms of gout. In those with greater disease severity and urate burden, such as those with tophi detected on physical examination and with chronic tophaceous gouty arthropathy, the goal therapeutic serum urate level may need to be lowered below 5 mg/dL to achieve better disease control.

Safety
- The most common adverse reactions reported in the clinical trial for gout were diarrhea (23%) and pharyngolaryngeal pain (3%).
- The most commonly reported adverse reaction in clinical trials for the prophylaxis of gout was diarrhea.
- FMF: Most common adverse reactions (up to 20%) are abdominal pain, diarrhea, nausea, and vomiting. These effects are usually mild, transient, and reversible upon lowering the dose.

Efficacy
- **Treatment of gout flares:** The efficacy of a low dose regimen of oral colchicine (Colcrys total dose 1.8 mg over 1 hour) for treatment of gout flares was assessed in a multicenter, randomized, double-blind, placebo-controlled, parallel group, 1 week, dose comparison study. A responder achieved at least a 50% reduction in pain score at the 24-hour postdose assessment relative to the pretreatment score and did not use rescue medication prior to a 24-hour postdose assessment. Rates of response were similar for the recommended low-dose treatment group (n = 28 [38%]) and the nonrecommended high-dose (1.2 mg, then 0.6 mg hourly × 6 hours [4.8 mg total]) group (n = 17 [33%]) but were higher when compared with placebo (n = 9 [16%]).
- **Prophylaxis of gout flares** (derived from published literature): In 2 randomized controlled trials colchicine 0.6 mg twice daily decreased the frequency of gout flares in patients initiating treatment with urate lowering therapy.

Adverse Reactions

- In randomized clinical trials, gastrointestinal (GI) adverse reactions occurred in 26% of patients using the recommended dose of Colcrys compared with 77% of patients taking a nonrecommended high-dose of colchicine and 20% of patients taking placebo. Diarrhea was the most commonly reported drug-related GI adverse event (23%, 77%, and 14%, respectively). Severe diarrhea occurred in 19% and vomiting occurred in 17% of patients taking the nonrecommended high-dose colchicine regimen but did not occur in the recommended low-dose Colcrys regimen.

Contraindications, Warnings and Precautions

- Patients with renal or hepatic impairment should not be given Colcrys in conjunction with P-gp or strong CYP3A4 inhibitors.
- **Fatal overdoses** have been reported with colchicine in adults and children.
- **Blood dyscrasias**: Myelosuppression, leukopenia, granulocytopenia, thrombocytopenia, pancytopenia, and aplastic anemia have been reported.
- **Drug interaction with P-gp and/or CYP3A4 inhibitors**: Coadministration of colchicine with P-gp and/or strong CYP3A4 inhibitors has resulted in life-threatening interactions and death.
- **Neuromuscular toxicity**: Myotoxicity including rhabdomyolysis may occur, especially in combination with other drugs known to cause this effect. Consider temporary interruption or discontinuation of Colcrys.

Questions and Answers

Q: What is the average DACON amongst Medicaid?
A: 1 pill per day.

Q: Do other Medicaid plans have QLLs?
A: 14 states, including GA, have QLLs. Of those that the QLL was available: 1 state = 30 pills/30 days, 4 states = 60 pills/30 days, 1 state = 90 pills/30 days, 1 state = 120 pills/30 days, 1 state = 20 pills/90 days. For GA Managed Medicaid: Peach State = 6 pills/30 days, Amerigroup = 69 pills/30 days, WellCare = no QLL listed.

Q: Do other Medicaid plans have PA?
A: AL and SC do not PA; some states have PA for indication.

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

On behalf of the Georgia Department of Community Health (DCH) and in service to the Georgia Medicaid Fee-for-Service (FFS) Drug Utilization Review Board (DURB), NorthStar HealthCare Consulting (NHC), in conjunction with Catamaran, announces the Manufacturers' Forum occurring on Thursday, November 6, 2014.

Date: **Thursday, November 6, 2014 from 9am-5pm EST**

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

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

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

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

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

This page intentionally left blank

Georgia Department of Community Health (GDCH)

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

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

Ongoing Opportunity:

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

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

Presentation Opportunity:

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

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

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

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

Opportunity to Appeal to GDCH:

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

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

This page intentionally left blank

2014

Upcoming Meetings

Drug Utilization Review Board Meeting

2 Peachtree Street, N.W.

5th Floor Board Room

Atlanta, Georgia 30303

Thursday, December 4, 2014: 9:30am – 1:30pm

Manufacturers' Forum

NorthStar HealthCare Consulting

1121 Alderman Drive

Suite 112

Alpharetta, Georgia 30005

Thursday, November 6, 2014: 9:00am – 5:00pm