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 13, 2016

OPTUMRx

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 DCH Board Room
Atlanta, Georgia 30303
Tuesday, September 13, 2016
9:30 a.m. to 1:30 p.m.

CALL TO ORDER	*Gurinder Doad, MD, Chair*
COMMENTS FROM THE DEPARTMENT	*Peter D'Alba, RPh, Pharmacy Director, DCH*
BIOSIMILARS PRESENTATION	*Stefanie Cribb, PharmD, US Biosimilars Field Medical Director, Pfizer*
MINUTES FROM PREVIOUS MEETING	*Chair*
EXTERNAL COMMENTS SESSION	*Chair*
CLINICAL REVIEWS ➢ **New Drugs** ●Varubi ●Veltassa ●Vraylar	*Afzal Mistry, PharmD, NorthStar* *Chad Nicholson, PharmD, NorthStar* *Emily Baker, PharmD, BCPS, NorthStar*
ADJOURNMENT OF OPEN SESSION	*Chair*
EXECUTIVE SESSION	*Steve Liles, PharmD, Senior Director, Goold*
RECONVENING OF OPEN SESSION	*Chair*
BOARD'S RECOMMENDATIONS AND VOTES	*Chair*
FUTURE AGENDA ITEMS	*Chair*
ADJOURNMENT OF MEETING	*Chair*

This page intentionally left blank

Department of Community Health
Drug Utilization Review Board (DURB)
MINUTES
Thursday, June 16, 2016

MEMBERS PRESENT

Gurinder J.S. Doad, M.D., Chair
Deborah Fincher, M.S., R.Ph.,Vice Chair
Mia Avery, Pharm.D.
Rod M. Duraski, M.D., FACP, MBA
M. Celeste Fowler, Pharm.D.
Yolanda P. Graham, M.D.
Mary S. Harris, Ph.D.
Burton L. Lesnick, M.D., FAAP
Robyn Lorys, Pharm.D.
J. Russell May, Pharm.D.
Brent L. Rollins, R.Ph., Ph.D.
Robert E. Shervette III, M.D.
Danny A. Toth, R.Ph.

MEMBERS ABSENT

Douglas Collins, M.D.
Osgood (Drew) A. Miller, R.Ph.

Staff

Peter D'Alba, R.Ph., Pharmacy Director, Pharmacy Services
Gilletta Gray, R.Ph., Clinical Manager, Pharmacy Services
Lori Garner, MHS, MBA, R.Ph., Pharmacist, Pharmacy Services

NorthStar HealthCare Consulting

Emily Baker, Pharm.D., BCPS, MHA, MBA, President
Afzal "Fez" Mistry, Pharm.D., Clinical Pharmacist

OptumRx

Susan McCreight, VP, Public Sector Account Management
Mark Hall, MBA, PMP, Sr. Account Manager, Government Markets, Relations & Reform
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 16, 2016. The Chair, Gurinder J.S. Doad, M.D., called the meeting to order at 9:41am. Board members were welcomed and shared their favorite volunteer or community service activity.

Comments from the Department

- There were no comments from the Department.

Minutes from the Previous Meeting

Chair Doad asked for corrections or changes to the minutes from the March 17, 2016 meeting. There was one spelling correction for a student's name, Kineta Naidu. A motion was made (Danny A.Toth, R.Ph.), seconded, and carried to approve the minutes with the correction.

External Comments Session

External comments were presented to the Board from the following:

- Viva Boyett – family member has schizophrenia; successful treatment with long-acting injectable antipsychotics
- Tammy Kinney, Sister Love, co-chair Positive Women Network – once-a-day therapy for HIV positive patients
- Kim Jones, NAMI Georgia (National Alliance for Mental Illness) – keep open access to meds
- Todd Estroff, M.D. (psychiatrist) – provides care for patients on ACT (Assertive Community Treatment) teams; consider easier access and PA approval to get long-acting injectables and newer agents on the market
- Zan Cook, M.D. (infectious disease) – single tablet HIV regimen
- Afzal "Fez" Mistry, Pharm.D., provided an overview of written comments received by the following:
    - Dr. Kathleen McKie, Augusta University Cystic Fibrosis (CF) Center – coverage for all inhaled antibiotics approved for CF and continued coverage for Orkambi and Kalydeco
    - Lisa Feng, MPH, Cystic Fibrosis Foundation, Sr. Director, Access, Policy and Innovation – include all pancreatic enzymes and inhaled antibiotics for treatment of CF on the Preferred Drug List
    - Dr. Jeffery English, Director of Clinical Research, Multiple Sclerosis (MS) Center of Atlanta – access to all meds of different forms for patients with MS
    - Dr. Yvonne Carter, MPH, Medical Director, Capstone Health – include open access to new agents for the treatment of HIV
    - Cathalene Teahan, RN, MSN, GA Aids Coalition – include all single tablet regimens on all formularies
    - Dr. Bryan D. Blake, Medical Director, Family First Healthcare – place Hysingla on the GA Medicaid formulary
    - Dr. Aimee Widner, Interventional Spine and Pain Management provider – add Hysingla to the formulary

Disclosure forms were completed by Viva Boyett, Tammy Kinney, Kim Jones, Dr. Todd Estroff, Dr. Zan Cook, Dr. Kathleen McKie, Lisa Feng, Dr. Jeffery English, Dr. Yvonne Carter, Cathalene Teahan, Dr. Byran D. Blake, and Dr. Aimee Widner and were reviewed by the Department.

Manufacturers' Forum

Afzal "Fez" Mistry, Pharm.D., noted the one page summaries from the Manufacturer's Forum were sent electronically to DURB members for review. There were no questions or comments.

The next forum will be held on Thursday, August 11, 2016 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
Cystic Fibrosis, Oral Respiratory	*Orkambi*	Afzal Mistry, Pharm.D.
Antidiabetics, Long-Acting Insulin	*Tresiba*	Afzal Mistry, Pharm.D.
Pulmonary Hypertension, Oral	*Uptravi*	Afzal Mistry, Pharm.D.
Irritable Bowel Syndrome, Diarrhea	*Viberzi*	Afzal Mistry, Pharm.D.

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

- Orkambi – no reason or insights provided on why there was the development of cataracts; pivitol drug retarding the progression of the pulmonary disease; highlights the receptors involved
- Tresiba – longer half-life (dosed daily); may have reduction in meal time insulin
- Uptravi – good addition to the armamentarium; haven't seen used first line yet
- Viberzi – Schedule IV due to abuse potential noted in package insert but no additional studies regarding this; no duration of action

Therapeutic Class Reviews

Clinical information for the following therapeutic classes was presented for discussion by Dr. Afzal "Fez" Mistry. The complete detailed therapeutic class review was provided in the Therapeutic Class Review section of the DUR Board binder.

Therapeutic Class Name
Multiple Sclerosis Agents

- There were no questions of comments from the Board.

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. Afzal "Fez" Mistry. The following therapeutic categories had updates:

Drug Class/Name
Antidiabetics, Insulin
Antidiabetics, Non-insulin
Antipsychotics, Atypical

Antivirals, Antiretrovirals
Bronchodilators, Anticholinergics
Gastrointestinal, Irritable Bowel Syndrome Agents
Opioids, Long-Acting Analgesics
Pulmonary Hypertension Agents

There were no questions or comments from the Board.

Acknowledgements
The following pharmacy students/residents were acknowledged: Shaily Doshi (UGA), Belinda Li (UGA), Kirby Welston, Pharm.D. (UGA), Kyle Starling (Mercer), and Colleen Cooley (PCOM).

DCH Decisions
DCH Decisions from the March 2016 DUR Board meeting were provided in the DCH Decision section of the DUR Board binder.

Future Agenda Items
There were no future agenda items noted.

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

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

  Tuesday, September 13, 2016
  Tuesday, December 13, 2016

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

  Thursday, August 11, 2016
  Thursday, November 10, 2016

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

Adjournment of Open Session
The DUR Board voted to close the open meeting pursuant to the Open Meeting Act of Georgia Section 50-14-1 – 50-14-6 and pursuant to Federal Law Section 1396R-8B3D. The individuals recorded in attendance with the Board members were from the Department of Community

Health, Goold Health Services, NorthStar HealthCare Consulting, and OptumRx. Pharmacy students/residents, Shaily Doshi (UGA), Belinda Li (UGA), Kirby. Welston, Pharm.D (UGA), Kyle Starling (Mercer), and Colleen Cooley (PCOM)., attended the closed session with Board members. A motion was made byJ. Russell May, Pharm.D., and seconded by Burton L. Lesnick, M.D., FAAP , to adjourn the open session and approve the closed session. There was a unanimous vote approving the closed session. The Chairman, Gurinder J.S. Doad, M.D., adjourned the open session at approximately 11:30 am, at which time members took a break then reconvened for the executive (closed) session.

Executive Session
The Executive Session was held from 11:43am to 1:09pm.

Reconvening of Open Session
The DUR Board reconvened for the open session at 1:14pm.

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 A.

New Drugs and Supplemental Rebate Classes

Cystic Fibrosis, Oral Respiratory Agents
The DUR Board recommended ***Preferred*** status with ***Prior Authorization*** for ***Orkambi (Oral) Tablet***.

Antidiabetics, Long-Acting Insulin Analogs
The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Tresiba (Subcutaneous) Injection***.

Pulmonary Hypertension Drugs
The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Uptravi (Oral) Tablet*** and ***Non-Preferred*** status with ***Prior Authorization and Grandfathering*** for ***Adcirca (Oral) Tablet, Remodulin (Subcutaneous/Intravenous) Injection*** and ***Tracleer (Oral) Tablet***.

Gastrointestinal, Irritable Bowel Syndrome Agents
The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Viberzi (Oral) Tablet.***

Multiple Sclerosis Agents
The DUR Board recommended ***Preferred*** status with ***Prior Authorization*** for ***Aubagio (Oral) Tablet, Betaseron (Subcutaneous) Injection,*** and ***Gilenya (Oral) Tablet*** and ***Non-Preferred*** status with ***Prior Authorization*** for ***Extavia (Subcutaneous) Injection***.

Anaphylaxis, Epinephrine Pens
The DUR Board recommended ***Preferred*** status for ***Epinephrine (Subcutaneous/Intramuscular) Injection***.

Antidepressants
The DUR Board recommended ***No Changes*** in the class.

Antidiabetics, GLP-1 Receptor Agonists
The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization and Grandfathering*** for ***Tanzeum (Subcutaneous) Injection***.

Antivirals, Antiretrovirals
The DUR Board recommended ***Preferred*** status for ***Descovy (Oral) Tablet*** and ***Non-Preferred*** status with ***Prior Authorization and Grandfathering*** for ***Aptivus (Oral) Capsule*** and ***Solution, Complera (Oral) Tablet, Crixivan (Oral) Capsule, Fuzeon (Subcutaneous) Injection, Intelence (Oral) Tablet, Invirase (Oral) Tablet*** and ***Capsule, Lexiva (Oral) Tablet*** and ***Suspension, Selzentry (Oral) Tablet, Stribild (Oral) Tablet, and Vitekta (Oral) Tablet***. The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization and Grandfathering*** for ***Triumeq (Oral) Tablet*** with the Board willing to give it a strong recommendation as a preferred agent if Triumeq's manufacturer presents a competitive supplemental rebate offer.

Antipsychotics, Atypical
The DUR Board recommended ***Preferred*** status with ***Prior Authorization*** for ***Clozapine (Oral) Tablet*** and ***Non-Preferred*** status with ***Prior Authorization*** for ***Rexulti (Oral) Tablet***.

Antipsychotics, Long-Acting Injectables
The DUR Board recommended ***Preferred*** status with ***Prior Authorization*** for ***all agents in the class***.

Bronchodilators, Anticholinergics
The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Spiriva Respimat (Inhalation) Solution***.

Bronchodilators, Steroid-Sympathomimetic Combinations
The DUR Board recommended ***Preferred*** status for ***Dulera (Inhalation) Aerosol***.

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

Multivitamins, Prenatal
The DUR Board recommended ***Preferred*** status with ***$30 maximum reimbursement*** for ***all Prenatal Vitamins with DHA***.

Opioids, Long-Acting Analgesics
The DUR Board recommended ***Preferred*** status for ***Embeda (Oral) Capsule***.

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 Doad adjourned the meeting at 1:27pm.

THESE MINUTES ARE HEREBY APPROVED AND ADOPTED, THIS THE _____ DAY OF _____, 2016.

_____

Gurinder J.S. Doad, M.D., Chair

Children's Hospital of Georgia

GEORGIA REGENTS

Augusta University
Department of Pediatrics
Division of Pediatric Pulmonology

1120 15th Street, BG 1104
Augusta, GA 30912
t. (706) 721-2635
f. (706) 721-8512
www.gru.edu

May 24, 2016

DCH Pharmacy Unit

2 Peachtree Street

Atlanta, GA 30303

Dear Members of the Drug Utilization Review Board,

We are writing to request insurance coverage for 1) all approved inhaled antibiotics for the treatment of cystic fibrosis (CF) and continued coverage for 2) lumacaftor/ivacaftor (Orkambi™) and 3) ivacaftor (Kalydeco®).

CF is the most common life-threatening genetic disease in the U.S., affecting approximately 30,000 individuals. In CF, a genetic mutation leads to the production of an abnormal CF Conductance Transmembrane Regulator (CFTR). The CFTR protein regulates the hydration and salt balance resulting in thick secretions in all of the mucous secreting glands of the body. Specifically, this affects the airways, pancreatic ducts, hepato-biliary system, reproductive system and sweat glands leading to multi-system organ dysfunction. As a result, most people with CF experience ongoing and progressively life-threatening lung infections and pancreatic insufficiency. However, over the last few decades, improvements in care have increased the median predicted survival age of individuals with CF to 40 years of age (Cystic Fibrosis Foundation Patient Registry 2013 Annual Data Report, 2014). However, a steady and unpredictable decline in lung function significantly impacts the daily lives of people with CF.

CF patients require treatment for pulmonary infections that can lead to a decline in lung function. Up to 80 percent of young adults with CF and more than half of all patients with the disease have cultured positive for *P. aeruginosa*, an organism that leads to persistent, significant declines in lung function (Mogayzel, et al., 2013). Regardless of mutation, pulmonary infection with *P. aeruginosa* in CF patients is associated with increased morbidity and mortality (Konstan, Wagener, Pasta, Millar, & Morgan, 2013). Suppressing infection through chronic use of inhaled antibiotics has been shown to preserve or improve lung function, improve quality of life and decrease the rate of costly pulmonary exacerbations in individuals with CF (Sanders, Bittner, Rosenfield, Hoffman, Redding, & Goss, 2010) (Bowman, 2002) (Saiman & Siegel, 2004). Delaying the progression of lung disease is the best way to improve quality and length of life, and is therefore a major focus of care of the individual with CF.

Access to all available inhaled antibiotic therapies is important to combat persistent lung infections, especially as antibiotic options are limited due to resistance in this intensely treated population. Further, drug toxicity and the time required to inhale each drug in addition to each patient's treatment regimen also contribute to the need for multiple treatment options. Furthermore, treatment

Children's Hospital of Georgia

GEORGIA REGENTS

Georgia Regents University
Department of Pediatrics
Section of Pediatric Pulmonology

1446 Harper Street
Augusta, GA 30912
t. (706) 721-2635
f. (706) 721-8512
www.gru.org

with an inhaled antibiotic on a continuous daily basis, as prescribed, in a patient with moderate or severe impairment of lung function can minimize their risk of exacerbations. To this end many patients may start their "on month" early or require continuous treatment with no off month. This helps preserve lung function, decrease the need for IV therapy and hospitalizations, and improve quality of life. As providers with decades of combined experience treating CF patients, we request the ability to prescribe the best treatment given the patient's care regimen and health needs.

Orkambi is the only FDA-approved medication that improves the function of CFTR for individuals with two copies of the F508del mutation while Kalydeco improves function for patients with mutations including G551D, G178R, S549N, S549R, G551S, G1244E, S1251N, S1255P, G1349D, and R117H. People with cystic fibrosis have a fundamental medical need for increased CFTR protein function. In clinical trials, Orkambi and Kalydeco were shown to improve airway surface liquid properties, reduce airway obstruction, and improve issues in non-respiratory organ systems. Evidence shows improvements in lung function (FEV_1), and BMI, two health indicators in CF, while also showing a decrease in pulmonary exacerbations. These are significant and important improvements for those with CF. Decline in lung function is characteristic of CF so the earlier a patient begins treatment with a modulator, the more potential the patient has for benefits throughout his or her life.

Please make all inhaled antibiotics therapies available for people with CF as prescribed by their physician and continue to cover Orkambi for all CF patients age 12 years and older with two copies of the F508del mutation and Kalydeco for all CF patients age 2 years and older with an on-label mutation.

I thank you for your time and consideration,

Kathleen T. McKie, MD

Co-Director, Augusta University CF Center

CYSTIC FIBROSIS FOUNDATION
ADDING TOMORROWS

March 11, 2016

Peter D'Alba RPh
Pharmacy Director
DCH Pharmacy Unit
2 Peachtree Street
Atlanta, GA 30303

Dear Mr. D'Alba and Members of the Drug Utilization Review Board:

On behalf of patients and families with cystic fibrosis (CF) living in Georgia, we write to urge Georgia Medicaid to include all FDA-approved pancreatic enzyme products and all FDA-approved inhaled antibiotics for the treatment of CF on the preferred drug list (PDL).

About the CF Foundation
Cystic fibrosis is caused by genetic mutations that result in the malfunction of a protein known as the cystic fibrosis transmembrane conductance regulator (*CFTR*). Decreased CFTR function causes irreversible damage and the associated symptoms of cystic fibrosis and leads to early death, usually by respiratory failure. As the world's leader in the search for a cure for CF and an organization dedicated to ensuring access to high quality, specialized CF care, the Cystic Fibrosis Foundation accredits 120 care centers, including 4 in Georgia, and 55 affiliate programs nationally that provide multidisciplinary, patient-centered care in accordance with systematically reviewed, data-driven, clinical practice guidelines. Treatment options for this rare, life-threatening disease are limited.

About Pancreatic Enzyme Replacement Therapy
Open access to pancreatic enzymes is critical, as approximately 90 percent of CF patients have pancreatic insufficiency. These patients require lifelong pancreatic enzyme replacement therapy (PERT) with each meal and snack to prevent abdominal distress and malabsorption of calories and nutrients. This is a life-sustaining therapy — nutritional status is closely linked to pulmonary function and survival.

Although the drug substance is the same, the dissolution properties of the PERTs are not identical. The differences in enteric coating, coating process, and size of each FDA-approved product affects a patient's ability to absorb nutrients. The degree of acidification of the GI tract in each CF patient also varies, causing some patients to have a better clinical response to one product over another. Failure of pancreatic enzyme therapy may be due to patient and product differences that can only be determined by an experienced clinician who has close follow up with each patient. We urge the DUR Board to make all pancreatic enzyme products available to CF patients.

CYSTIC FIBROSIS FOUNDATION
NATIONAL OFFICE
6931 ARLINGTON ROAD
BETHESDA, MD 20814
TEL: 800.FIGHT.CF
FAX: 301.951.6378
WEB: WWW.CFF.ORG

About Inhaled Antibiotic Therapies

Inhaled antibiotics are used to improve respiratory symptoms in people with cystic fibrosis who have *Pseudomonas aeruginosa*, a bacterium that colonizes in the lungs and is associated with increased morbidity and mortality in people with this disease. Use of CF specific antibiotics has been shown to decrease *P. aeruginosa* in sputum and improve lung function and quality of life.[1]

Due to increasing antibiotic resistance in this intensely treated population, antibiotic options are limited. Each FDA-approved inhaled antibiotic therapy represents an important component to the CF treatment arsenal. Further, some patients are not tolerant of one or more therapies due to drug toxicity or difficulty administering the product. Therefore, providers should have discretion to prescribe the most effective CF-specific inhaled antibiotic for individual patients.

For many patients, continuous alternating therapy with several antibiotics is vital to suppressing *P. aeruginosa* and other pathogens and maintaining lung function. Continuous alternating therapy entails the use of a second inhaled antibiotic during the off-month for Cayston®; Cayston® can only be used for a 28-day course before the patient must be off the drug for another 28 days. This period without an inhaled antibiotic treatment can lead to pulmonary exacerbations and a decline in lung function. Access to a tobramycin product allows patients on Cayston® to have FDA-approved alternatives during the 28-day off-regimen period to prevent a decline in health status during this period. Alternating or combining these antibiotic therapies may be helpful in suppressing chronic infection.

Policy Recommendations

Limiting patient choice for enzymes and inhaled antibiotics can greatly impact the health of people with cystic fibrosis who require pancreatic enzymes and inhaled antibiotics for optimal treatment. These therapies are an important part of standard CF care.

We urge you to provide access to all pancreatic enzyme and inhaled antibiotic therapies for people with cystic fibrosis as prescribed by their physician.

Please contact Jackie Erdo, MPH, Manager of Access Policy and Innovation, at jerdo@cff.org or 301.841.2628 with any further questions. We look forward to working with you on this important issue.

Sincerely,

Bruce C. Marshall, MD
Senior Vice President of Clinical Affairs

Lisa Feng, MPH
Senior Director, Access Policy & Innovation

---

[1] Retsch-Bogart GZ, Quittner AL, Gibson RL, Oermann CM, McCoy KS, Montgomery AB, Cooper PJ. Efficacy and safety of inhaled aztreonam lysine for airway *Pseudomonas* in cystic fibrosis. *Chest* 2009;135:1223-32.

2. Ramsey BW, Pepe MS, Quan JM, Otto KL, Montgomery AB, Williams-Warren J, Vasiljev KM, Borowitz D, Bowman CM, Marshall BC, *et al.* Intermittent administration of inhaled tobramycin in patients with cystic fibrosis. Cystic Fibrosis Inhaled Tobramycin Study Group. *N Engl J Med* 1999;340:23-30.

3. Quittner AL, Buu A. Effects of tobramycin solution for inhalation on global ratings of quality of life in patients with cystic fibrosis and *Pseudomonas aeruginosa* infection. *Pediatr Pulmonol* 2002;33:269-276.

CYSTIC FIBROSIS FOUNDATION
NATIONAL OFFICE
6931 ARLINGTON ROAD
BETHESDA, MD 20814
TEL: 800.FIGHT.CF
FAX: 301.951.6378
WEB: WWW.CFF.ORG

MSCA

THE MULTIPLE SCLEROSIS CENTER OF ATLANTA

WILLIAM H. STUART, M.D. ROBERT W. GILBERT JR., M.D. ELLIS V. HEDAYA, M.D.
DOUGLAS S. STUART, M.D. CHRISTOPHER S. RUSSELL, M.D. JEFFREY B. ENGLISH, M.D.
ANDREI I SERBANESCU, M.D. LAWRENCE G. SEIDEN, M.D. DAVID P. WILLIAMS, M.D.
BEVERLY BAKER-NEWSHOLME, MSN, RN, APRN, BC EILEEN M. GALLAGHER, MSN, RN, CNP

May 25, 2016

To whom it may concern,

I am writing a letter of medical necessity for access to all medications for patients with multiple sclerosis. Multiple sclerosis is a disease that affects predominantly women in the early stages of life, peaking at ages 20s and 40s. This is a potentially disabling disease. Also, the disease changes rapidly and disability can occur quickly. Unfortunately, there is no cure. Unfortunately also, we never know which medication will work best in individual patients. Delay in initiation of therapy or switching therapy when somebody is having breakthrough disease puts the patient at risk for permanent disability.

Medications for multiple sclerosis come in the form of shots into the skin or muscle, intravenous preparations, and oral therapies. Not only are the mechanisms of action vastly different, side effects and patient tolerance to mode of administration are also keys in compliance. Many studies show noncompliance as high as 80% with preparations in individual patients. Therefore, we need access to all medications of different forms of administration as well as medications within each class. Even the oral therapies have vastly different side effects and patient intolerance can still be extremely high.

As an expert and multiple sclerosis, I stand with the MS healthcare provider community stating that formularies for multiple sclerosis need to be non-restricted for the reasons mentioned above.

Sincerely,

Jeffrey B. English, M.D.

Director of Clinical Research

Multiple Sclerosis Center of Atlanta

THE PALISADES BUILDING 3200 DOWNWOOD CIRCLE, SUITE 550 ATLANTA, GEORGIA 30327 (404) 351-0205
DIPLOMATES: AMERICAN BOARD OF PSYCHIATRY AND NEUROLOGY

My name is Yvonne Carter, and I am writing as an advocate for the quality care of persons living with HIV in Georgia. I am a Board Certified Infectious Diseases Specialist, with more than ten years experience in treating HIV and AIDS. As a provider based in a county health department, I serve populations at high risk of noncompliance due to social issues, transportation, and medication costs. It is essential that we are able to provide patients with treatment options that are suitable for their lifestyle, comorbidities, and financial limitations. With this in mind, I am asking that Medicaid include all the new, safe, and effective options for the treatment of HIV to be included in their formulary, with unrestricted, open access to each. This would include Genvoya, Odefsey, Evotaz, and Prezcobix. Restricting access to medications that could be the best option for an individual patient would not only be detrimental to an individual's health, but also that of the community. I thank you for the opportunity to voice my concerns, and ask that you continue to work towards improving the health of all communities.

Thank you,

Yvonne L. Carter, MD, MPH
Medical Director, Capstone Health
Cobb & Douglas Public Health

TO: Members of the GA Medicaid Drug Utilization Review Board
FROM: Georgia AIDS Coalition
DATE: May 23, 2016

The Georgia AIDS Coalition is nonprofit organization that focuses on public policy, advocacy and education. We are primarily dedicated to ensuring that people living with HIV, hepatitis, TB and STI's have access to quality and affordable health care.

We ask that you include all Single Tablet Regimens (STRs) on all formularies for patients with HIV so as not to tie the hands of clinicians when treating these patients. We have grave concerns about patients' ability to adhere to medication protocols that do not include single dose tablets. The impact that lack of adherence will have on viral load not only for the individual patients but, ultimately on the community at large is a grave concern as well.

STRs are included in the HIV treatment regimens recommended by the Department of Health and Human Services and International Antiviral Society-USA.(1,2) By helping to keep people healthy and reducing transmission rates, STRs reduce overall healthcare costs. (3) STRs significantly reduce daily pill burden, further improving treatment adherence and thus management of HIV. (3-5) Individuals taking STRs demonstrate improved health outcomes and are less likely to transmit HIV to others. (6) Most Single Tablet Regimens are no more expensive than their component parts and can be of greater value when the individual and public health benefits of treatment adherence are considered.

Advances in HIV care and treatment have transformed HIV/AIDS from a deadly disease to a manageable chronic health condition for most patients who are successfully engaged in treatment of their disease. The HIV standard of care in the United States is to offer treatment to all individuals testing positive; failure to suppress the virus causes irreparable and costly harm to individuals' immune system and undermines HIV public health prevention efforts.

Again, we ask that you include all Single Tablet Regimens (STRs) on all formularies for patients with HIV so as not to tie the hands of clinicians when treating these patients.

Thank you for your consideration,

Cathalene Teahan

Cathalene Teahan, R.N., M.S.N.
Georgia AIDS Coalition
President of the Board

FAMILY FIRST HEALTHCARE, PC
939 THORNTON ROAD
LITHIA SPRINGS, GA 30122
770-948-5400 office 770-948-4930 fax

February 2, 2016

To Whom It May Concern:

I am writing this letter in regards to your February 11, 2016 meeting to place Hysingla ER on the Georgia State Medicaid formulary. I am a Primary Care Physician practicing in Lithia Springs, GA. I take care of many people who suffer with Chronic Pain daily. They are tolerating Hydrocodone, but require high dosages and multiple tablets daily. There are patients who are potentially misusing their medications as well as those who truly need longer acting control, request more tablets as their treatment goal. Having a long acting abuse deterrent option will truly help to control their pain and reduce diversion/abuse of these medications.

Feel free to contact my office directly with any questions.

Yours in good health,

B. David Blake, MD
Medical Director

Hello,

I am an interventional spine and pain management provider in the state of Georgia. I would ask that you consider adding Hysingla (extended release, abuse-deterrent, hydrocodone) to the formulary. I have used this medication with several patients that find in beneficial for around-the-clock pain control. It keeps them from waking up at night to take pain medication. It also has a better side-effect profile clinically than other long-acting narcotics such as morphine, fentanyl, methadone and oxycontin.

Appreciate your consideration,

Dr. Aimee Widner

Drug Utilization Review Board

Motions - Votes - **New Drugs**

June 16, 2016

New Drug	Drug	PDL Status	Motion - Recommendations	Additional Comments	
Cystic Fibrosis, Oral Respiratory Agents	Orkambi (Oral) Tablet	PPA	**PPA**		
Board Members - Present (Strike out, when absent)	**Motion** Maker (√)	**Seconded** By (√)	**VOTES** YES (√)	NO (√)	ABSTAIN (√)
1 Avery, Mia, Pharm.D.			√		
2 Duraski, Rod, M.D.			√		
3 Doad, Gurinder J.S., M.D.- **Chair**			√		
4 Fincher, Deborah W., M.S., R.Ph. - **Vice**			√		
5 Fowler, M. Celeste, Pharm.D.			√		
6 Graham, Yolanda, M.D.			√		
7 Harris, Mary, Ph.D.			√		
8 Lesnick, Burton, M.D.	√		√		
9 Lorys, Robyn Pharm.D.			√		
10 May, J. Russell (Rusty)		√	√		
11 Rollins, Brent L., R.Ph., Ph.D.			√		
12 Shervette III, Robert E., M.D.			√		
13 Toth, Danny, R.Ph.			√		
		TOTAL	**13**	**0**	**0**
Board Members - Absent					
1 Collins, Douglas, M.D.					
2 Miller, Osgood (Drew) A. R.Ph.					

Drug Utilization Review Board

Motions - Votes - **New Drugs**

June 16, 2016

New Drug	Drug	PDL Status	Motion - Recommendations	Additional Comments	
Antidiabetics, Long-Acting Insulin Analogs	Tresiba (Subcutaneous) Injection	NPPA	**NPPA**		
Board Members - Present (Strike out, when absent)	**Motion** Maker (√)	**Seconded** By (√)	**VOTES** YES (√)	NO (√)	ABSTAIN (√)
1 Avery, Mia, Pharm.D.		√	√		
2 Duraski, Rod, M.D.			√		
3 Doad, Gurinder J.S., M.D.- **Chair**			√		
4 Fincher, Deborah W., M.S., R.Ph. - **Vice**			√		
5 Fowler, M. Celeste, Pharm.D.			√		
6 Graham, Yolanda, M.D.			√		
7 Harris, Mary, Ph.D.			√		
8 Lesnick, Burton, M.D.			√		
9 Lorys, Robyn Pharm.D.	√		√		
10 May, J. Russell (Rusty)			√		
11 Rollins, Brent L., R.Ph., Ph.D.			√		
12 Shervette III, Robert E., M.D.			√		
13 Toth, Danny, R.Ph.			√		
		TOTAL	**13**	**0**	**0**
Board Members - Absent					
1 Collins, Douglas, M.D.					
2 Miller, Osgood (Drew) A. R.Ph.					

Drug Utilization Review Board

Motions - Votes - **New Drugs**

June 16, 2016

New Drug	Drug	PDL Status	Motion - Recommendations	Additional Comments
Pulmonary Hypertension Drugs	Uptravi (Oral) Tablet	NPPA	**NPPA**	
	Adcirca (Oral) Tablet	PPA	**NPPA** - With Grandfathering	Not A New Drug
	Remodulin (Subcutaneous/Intravenous)	P	**NPPA** - With Grandfathering	Not A New Drug
	Tracleer (Oral) Tablet	P	**NPPA** - With Grandfathering	Not A New Drug

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Duraski, Rod, M.D.			√		
3	Doad, Gurinder J.S., M.D.- **Chair**			√		
4	Fincher, Deborah W., M.S., R.Ph. - **Vice**			√		
5	Fowler, M. Celeste, Pharm.D.			√		
6	Graham, Yolanda, M.D.			√		
7	Harris, Mary, Ph.D.			√		
8	Lesnick, Burton, M.D.	√		√		
9	Lorys, Robyn Pharm.D.		√	√		
10	May, J. Russell (Rusty)			√		
11	Rollins, Brent L., R.Ph., Ph.D.			√		
12	Shervette III, Robert E., M.D.			√		
13	Toth, Danny, R.Ph.			√		
			TOTAL	13	0	0

	Board Members - Absent
1	Collins, Douglas, M.D.
2	Miller, Osgood (Drew) A. R.Ph.

Drug Utilization Review Board

Motions - Votes - **New Drugs**

June 16, 2016

New Drug	Drug	PDL Status	Motion - Recommendations	Additional Comments	
Gastrointestinal, Irritable Bowel Syndrome Agents	Viberzi (Oral) Tablet	NPPA	**NPPA**		
Board Members - Present (Strike out, when absent)	**Motion** Maker (√)	**Seconded** By (√)	**VOTES** YES (√)	NO (√)	ABSTAIN (√)
1 Avery, Mia, Pharm.D.	√		√		
2 Duraski, Rod, M.D.			√		
3 Doad, Gurinder J.S., M.D.- **Chair**			√		
4 Fincher, Deborah W., M.S., R.Ph. - **Vice**			√		
5 Fowler, M. Celeste, Pharm.D.			√		
6 Graham, Yolanda, M.D.			√		
7 Harris, Mary, Ph.D.			√		
8 Lesnick, Burton, M.D.		√	√		
9 Lorys, Robyn Pharm.D.			√		
10 May, J. Russell (Rusty)			√		
11 Rollins, Brent L., R.Ph., Ph.D.			√		
12 Shervette III, Robert E., M.D.			√		
13 Toth, Danny, R.Ph.			√		
		TOTAL	**13**	**0**	**0**
Board Members - Absent					
1 Collins, Douglas, M.D.					
2 Miller, Osgood (Drew) A. R.Ph.					

Drug Utilization Review Board

Motions - Votes - **Therapeutic Class Review**

June 16, 2016

Therapeutic Class Review	Drug	PDL Status	Motion - Recommendations	Additional Comments
Multiple Sclerosis Agents	Aubagio (Oral) Tablet	NPPA	**PPA**	
	Betaseron (Subcutaneous) Injection	NPPA	**PPA**	
	Gilenya (Oral) Tablet	NPPA	**PPA**	
	Extavia (Subcutaneous) Injection	PPA	**NPPA**	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.		√	√		
2	Duraski, Rod, M.D.			√		
3	Doad, Gurinder J.S., M.D.- **Chair**			√		
4	Fincher, Deborah W., M.S., R.Ph. - **Vice**			√		
5	Fowler, M. Celeste, Pharm.D.			√		
6	Graham, Yolanda, M.D.			√		
7	Harris, Mary, Ph.D.			√		
8	Lesnick, Burton, M.D.			√		
9	Lorys, Robyn Pharm.D.				√	
10	May, J. Russell (Rusty)	√		√		
11	Rollins, Brent L., R.Ph., Ph.D.			√		
12	Shervette III, Robert E., M.D.			√		
13	Toth, Danny, R.Ph.			√		
			TOTAL	12	1	0

	Board Members - Absent
1	Collins, Douglas, M.D.
2	Miller, Osgood (Drew) A. R.Ph.

Drug Utilization Review Board

Motions - Votes - SR Class Review

June 16, 2016

Supplemental Rebate Class	Drug	PDL Status	Motion - Recommendations	Additional Comments
Anaphylaxis, Epinephrine Pens	Epinephrine (Subcutaneous/Intramuscular) Injection	NPPA	P	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Duraski, Rod, M.D.			√		
3	Doad, Gurinder J.S., M.D.- **Chair**			√		
4	Fincher, Deborah W., M.S., R.Ph. - **Vice**			√		
5	Fowler, M. Celeste, Pharm.D.			√		
6	Graham, Yolanda, M.D.			√		
7	Harris, Mary, Ph.D.			√		
8	Lesnick, Burton, M.D.		√	√		
9	Lorys, Robyn Pharm.D.			√		
10	May, J. Russell (Rusty)	√		√		
11	Rollins, Brent L., R.Ph., Ph.D.			√		
12	Shervette III, Robert E., M.D.			√		
13	Toth, Danny, R.Ph.			√		
			TOTAL	13	0	0

	Board Members - Absent
1	Collins, Douglas, M.D.
2	Miller, Osgood (Drew) A. R.Ph.

Drug Utilization Review Board

Motions - Votes - **SR Class Review**

June 16, 2016

Supplemental Rebate Class	Recommendation
Antidepressants	No PDL changes for the drugs in this class

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Duraski, Rod, M.D.			√		
3	Doad, Gurinder J.S., M.D.- **Chair**			√		
4	Fincher, Deborah W., M.S., R.Ph. - **Vice**			√		
5	Fowler, M. Celeste, Pharm.D.			√		
6	Graham, Yolanda, M.D.			√		
7	Harris, Mary, Ph.D.			√		
8	Lesnick, Burton, M.D.			√		
9	Lorys, Robyn Pharm.D.			√		
10	May, J. Russell (Rusty)			√		
11	Rollins, Brent L., R.Ph., Ph.D.		√	√		
12	Shervette III, Robert E., M.D.			√		
13	Toth, Danny, R.Ph.	√		√		
			TOTAL	13	0	0

	Board Members - Absent
1	Collins, Douglas, M.D.
2	Miller, Osgood (Drew) A. R.Ph.

Drug Utilization Review Board

Motions - Votes - **SR Class Review**

June 16, 2016

Supplemental Rebate Class	Drug	PDL Status	Motion - Recommendations	Additional Comments
Antidiabetics, GLP-1 Receptor Agonists	Tanzeum (Subcutaneous) Injection	PPA	**NPPA** - With Grandfathering	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.	√		√		
2	Duraski, Rod, M.D.			√		
3	Doad, Gurinder J.S., M.D.- **Chair**			√		
4	Fincher, Deborah W., M.S., R.Ph. - **Vice**		√	√		
5	Fowler, M. Celeste, Pharm.D.			√		
6	Graham, Yolanda, M.D.			√		
7	Harris, Mary, Ph.D.			√		
8	Lesnick, Burton, M.D.			√		
9	Lorys, Robyn Pharm.D.			√		
10	May, J. Russell (Rusty)			√		
11	Rollins, Brent L., R.Ph., Ph.D.			√		
12	Shervette III, Robert E., M.D.			√		
13	Toth, Danny, R.Ph.			√		
			TOTAL	13	0	0

	Board Members - Absent
1	Collins, Douglas, M.D.
2	Miller, Osgood (Drew) A. R.Ph.

Drug Utilization Review Board

Motions - Votes - **SR Class Review**

June 16, 2016

Supplemental Rebate Class	Drug	PDL Status	Motion - Recommendations	Additional Comments
Antivirals, Antiretrovirals	Descovy (Oral) Tablet	NPPA	**P**	The Board will strongly consider recommending Preferred status for Trimeq (Oral) Tablet when the manufacturer offers a competitive supplemental rebate.
	Aptivus (Oral) Capsule & Solution	PPA	**NPPA** with Grandfathering	
	Complera (Oral) Tablet	PPA	**NPPA** with Grandfathering	
	Crixivan (Oral) Capsule	P	**NPPA** with Grandfathering	
	Fuzeon (Subcutaneous) Injection	PPA	**NPPA** with Grandfathering	
	Intelence (Oral) Tablet	PPA	**NPPA** with Grandfathering	
	Invirase (Oral) Tablet & Capsule	P	**NPPA** with Grandfathering	
	Lexiva (Oral) Tablet & Suspension	P	**NPPA** with Grandfathering	
	Selzentry (Oral) Tablet	PPA	**NPPA** with Grandfathering	
	Stribild (Oral) Tablet	P	**NPPA** with Grandfathering	
	Triumeq (Oral) Tablet	P	**NPPA** with Grandfathering	
	Vitekta (Oral) Tablet	PPA	**NPPA** with Grandfathering	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Duraski, Rod, M.D.			√		
3	Doad, Gurinder J.S., M.D.- **Chair**			√		
4	Fincher, Deborah W., M.S., R.Ph. - **Vice**			√		
5	Fowler, M. Celeste, Pharm.D.			√		
6	Graham, Yolanda, M.D.			√		
7	Harris, Mary, Ph.D.			√		
8	Lesnick, Burton, M.D.			√		
9	Lorys, Robyn Pharm.D.		√	√		
10	May, J. Russell (Rusty)			√		
11	Rollins, Brent L., R.Ph., Ph.D.	√		√		
12	Shervette III, Robert E., M.D.			√		
13	Toth, Danny, R.Ph.			√		
			TOTAL	13	0	0

	Board Members - Absent
1	Collins, Douglas, M.D.
2	Miller, Osgood (Drew) A. R.Ph.

Drug Utilization Review Board

Motions - Votes - **SR Class Review**

June 16, 2016

Supplemental Rebate Class	Drug	PDL Status	Motion - Recommendations	Additional Comments
Antipsychotics, Atypical	Clozapine (Oral) Tablet	NPPA	**PPA**	
	Rexulti (Oral) Tablet	NPPA	**NPPA**	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Duraski, Rod, M.D.			√		
3	Doad, Gurinder J.S., M.D.- **Chair**			√		
4	Fincher, Deborah W., M.S., R.Ph. - **Vice**			√		
5	Fowler, M. Celeste, Pharm.D.			√		
6	Graham, Yolanda, M.D.	√		√		
7	Harris, Mary, Ph.D.			√		
8	Lesnick, Burton, M.D.			√		
9	Lorys, Robyn Pharm.D.			√		
10	May, J. Russell (Rusty)			√		
11	Rollins, Brent L., R.Ph., Ph.D.			√		
12	Shervette III, Robert E., M.D.			√		
13	Toth, Danny, R.Ph.		√	√		
			TOTAL	13	0	0

	Board Members - Absent
1	Collins, Douglas, M.D.
2	Miller, Osgood (Drew) A. R.Ph.

Drug Utilization Review Board

Motions - Votes - **SR Class Review**

June 16, 2016

Supplemental Rebate Class	Recommendation
Antipsychotics, Long-Acting Injectables	Preferred Status with Prior Authorization for all drugs in this class.

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Duraski, Rod, M.D.			√		
3	Doad, Gurinder J.S., M.D.- **Chair**			√		
4	Fincher, Deborah W., M.S., R.Ph. - **Vice**			√		
5	Fowler, M. Celeste, Pharm.D.			√		
6	Graham, Yolanda, M.D.	√		√		
7	Harris, Mary, Ph.D.			√		
8	Lesnick, Burton, M.D.			√		
9	Lorys, Robyn Pharm.D.			√		
10	May, J. Russell (Rusty)			√		
11	Rollins, Brent L., R.Ph., Ph.D.			√		
12	Shervette III, Robert E., M.D.			√		
13	Toth, Danny, R.Ph.		√	√		
			TOTAL	13	0	0

	Board Members - Absent
1	Collins, Douglas, M.D.
2	Miller, Osgood (Drew) A. R.Ph.

Drug Utilization Review Board

Motions - Votes - **SR Class Review**

June 16, 2016

Supplemental Rebate Class	Drug	PDL Status	Motion - Recommendations	Additional Comments
Bronchodilators, Anticholinergics	Spiriva Respimat (Inhalation) Solution	P	**NPPA**	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Duraski, Rod, M.D.		√	√		
3	Doad, Gurinder J.S., M.D.- **Chair**			√		
4	Fincher, Deborah W., M.S., R.Ph. - **Vice**			√		
5	Fowler, M. Celeste, Pharm.D.			√		
6	Graham, Yolanda, M.D.			√		
7	Harris, Mary, Ph.D.			√		
8	Lesnick, Burton, M.D.			√		
9	Lorys, Robyn Pharm.D.	√		√		
10	May, J. Russell (Rusty)			√		
11	Rollins, Brent L., R.Ph., Ph.D.			√		
12	Shervette III, Robert E., M.D.			√		
13	Toth, Danny, R.Ph.			√		
			TOTAL	**13**	**0**	**0**

	Board Members - Absent
1	Collins, Douglas, M.D.
2	Miller, Osgood (Drew) A. R.Ph.

Drug Utilization Review Board

Motions - Votes - **SR Class Review**

June 16, 2016

Supplemental Rebate Class	Drug	PDL Status	Motion - Recommendations	Additional Comments
Bronchodilators, Steroid-Sympathomimetic Combinations	Dulera (Inhalation) Aerosol	NPPA	**P**	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.		√	√		
2	Duraski, Rod, M.D.			√		
3	Doad, Gurinder J.S., M.D.- **Chair**			√		
4	Fincher, Deborah W., M.S., R.Ph. - **Vice**			√		
5	Fowler, M. Celeste, Pharm.D.			√		
6	Graham, Yolanda, M.D.			√		
7	Harris, Mary, Ph.D.			√		
8	Lesnick, Burton, M.D.	√		√		
9	Lorys, Robyn Pharm.D.			√		
10	May, J. Russell (Rusty)			√		
11	Rollins, Brent L., R.Ph., Ph.D.			√		
12	Shervette III, Robert E., M.D.			√		
13	Toth, Danny, R.Ph.			√		
			TOTAL	13	0	0

	Board Members - Absent
1	Collins, Douglas, M.D.
2	Miller, Osgood (Drew) A. R.Ph.

Drug Utilization Review Board

Motions - Votes - **SR Class Review**

June 16, 2016

Supplemental Rebate Class	Drug	PDL Status	Motion - Recommendations	Additional Comments
Corticosteroids, Oral	Dexpak (Oral) Tablet	P	**NPPA**	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.	√		√		
2	Duraski, Rod, M.D.			√		
3	Doad, Gurinder J.S., M.D.- **Chair**			√		
4	Fincher, Deborah W., M.S., R.Ph. - **Vice**			√		
5	Fowler, M. Celeste, Pharm.D.			√		
6	Graham, Yolanda, M.D.			√		
7	Harris, Mary, Ph.D.			√		
8	Lesnick, Burton, M.D.			√		
9	Lorys, Robyn Pharm.D.			√		
10	May, J. Russell (Rusty)		√	√		
11	Rollins, Brent L., R.Ph., Ph.D.			√		
12	Shervette III, Robert E., M.D.			√		
13	Toth, Danny, R.Ph.			√		
			TOTAL	**13**	**0**	**0**

	Board Members - Absent
1	Collins, Douglas, M.D.
2	Miller, Osgood (Drew) A. R.Ph.

Supplemental Rebate Class	Recommendation
Multivitamins, Prenatal DHA	Preferred status with $30 maximum reimbursement for all Prenatal Vitamins with DHA

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Duraski, Rod, M.D.			√		
3	Doad, Gurinder J.S., M.D.- **Chair**			√		
4	Fincher, Deborah W., M.S., R.Ph. - **Vice**	√		√		
5	Fowler, M. Celeste, Pharm.D.			√		
6	Graham, Yolanda, M.D.			√		
7	Harris, Mary, Ph.D.			√		
8	Lesnick, Burton, M.D.			√		
9	Lorys, Robyn Pharm.D.			√		
10	May, J. Russell (Rusty)			√		
11	Rollins, Brent L., R.Ph., Ph.D.		√	√		
12	Shervette III, Robert E., M.D.			√		
13	Toth, Danny, R.Ph.			√		
			TOTAL	13	0	0

	Board Members - Absent
1	Collins, Douglas, M.D.
2	Miller, Osgood (Drew) A. R.Ph.

Drug Utilization Review Board

Motions - Votes - **SR Class Review**

June 16, 2016

Supplemental Rebate Class	Drug	PDL Status	Motion - Recommendations	Additional Comments
Opioids, Long-Acting Analgesics	Embeda (Oral) Capsule	NPPA	**P**	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Duraski, Rod, M.D.			√		
3	Doad, Gurinder J.S., M.D.- **Chair**			√		
4	Fincher, Deborah W., M.S., R.Ph. - **Vice**			√		
5	Fowler, M. Celeste, Pharm.D.			√		
6	Graham, Yolanda, M.D.			√		
7	Harris, Mary, Ph.D.			√		
8	Lesnick, Burton, M.D.		√	√		
9	Lorys, Robyn Pharm.D.			√		
10	May, J. Russell (Rusty)	√		√		
11	Rollins, Brent L., R.Ph., Ph.D.			√		
12	Shervette III, Robert E., M.D.			√		
13	Toth, Danny, R.Ph.			√		
			TOTAL	**13**	**0**	**0**

	Board Members - Absent
1	Collins, Douglas, M.D.
2	Miller, Osgood (Drew) A. R.Ph.

Important Update
DCH Decision Document

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

EFFECTIVE July 1, 2016 (see chart below)

DCH rebate vendor Goold Health Systems (GHS) has reviewed SFY2017 supplemental rebate offers with DCH and reviewed the below drug categories at the June 2016 DURB meeting. The PDL decisions or PDL changes for new drugs or categories reviewed during the June DURB meeting are outlined below. Those drugs highlighted in red indicate a change from current PDL status. For a full listing of our PDL, go to www.dch.georgia.gov/pharmacy and select the "preferred product list" option.

ONLY DRUGS with Supplemental Rebate Offer or reviewed during the March DURB as either new to market or a change in PDL status are listed	PREFERRED AGENTS	NON-PREFERRED AGENTS
ALLERGEN IMMUNOTHERAPY - SUBLINGUAL		
		GRASTEK
		RAGWITEK
ANAPHYLAXIS EPINEPHRINE PENS		
	EPIPEN, JR	
	EPINEPHRINE (INJECTION) AUTO INJCT	
ANDROGENS-ANABOLIC		
	ANDROGEL	
ANTIDEMENTIA AGENTS		
	EXELON	NAMENDA XR
		NAMZARIC
ANTIDEPRESSANTS		
	TRINTELLIX	FETZIMA
		VIIBRYD
ANTIDIABETICS – INSULIN		
	HUMALOG KWIKPEN U-100	HUMALOG KWIKPEN U-200
	HUMALOG MIX 50/50 KWIKPEN	
	HUMALOG MIX 75/25 KWIKPEN	
	HUMULIN 70/30 KWIKPEN	
	HUMULIN 70/30 PEN	
	HUMULIN N KWIKPEN	
	HUMULIN N U-100 PEN	
	HUMULIN R U-500 KWIKPEN	

ONLY DRUGS with Supplemental Rebate Offer or reviewed during the March DURB as either new to market or a change in PDL status are listed	PREFERRED AGENTS	NON-PREFERRED AGENTS
ANTIDIABETICS - INSULIN ANALOG LONG ACTING		
		TRESIBA
ANTIDIABETICS - NON-INSULIN DPPIV		
	JENTADUETO	JANUMET , XR
	TRADJENTA	JANUVIA
ANTIDIABETICS NININSULIN- GLP-1RA		
	BYDUREON	TANZEUM
		VICTOZA
ANTIDIABETICS - NON-INSULIN SGLT		
		INVOKAMET
		JARDIANCE
		SYNJARDY
ANTIPSYCHOTICS, ORAL		
	CLOZAPINE	REXULTI
	LATUDA	SAPHRIS
ANTIPSYCHOTICS, LAI		
	ABILIFY MAINTENA	
	ARISTADA	
	INVEGA SUSTENNA	
	INVEGA TRINZA	
	RISPERDAL CONSTA	
	ZYPREXA RELPREVV	
ANTIVIRALS, ANTIRETROVIRALS		
	DESCOVY	APTIVUS
	EVOTAZ	COMPLERA
	GENVOYA	CRIXIVAN
	NORVIR	FUZEON
	PREZCOBIX	INTELENCE
	TRIUMEQ	INVIRASE
		LEXIVA
		ODEFSEY
		SELZENTRY
		STRIBILD
		VITEKTA
BRONCHODIL, ANTICHOLINERGICS		
	SPIRIVA INH	ANORO ELLIPTA
	COMBIVENT RESPIMAT	INCRUSE ELLIPTA
		SPIRIVA RESPIMAT
		STIOLTO RESPIMAT
BRONCHODIL, STEROID INHALANTS		
	AEROSPAN	
BRONCHODIL,SYMPATH STER		
	DULERA HFA	BREO ELLIPTA
CALCIUM REGULATORS		
		ALENDRONATE SOL 70/75ML
		BINOSTO

ONLY DRUGS with Supplemental Rebate Offer or reviewed during the March DURB as either new to market or a change in PDL status are listed	PREFERRED AGENTS	NON-PREFERRED AGENTS
CEPHALOSPORINS, 3RD GENERATION ORAL		
	SUPRAX CAP 400 MG	SUPRAX CHEW TABS
CORTICOSTEROIDS, ORAL		
	PREDNISOLONE SODIUM PHOSPHATE (ORAL) SOLUTION 25 MG/5 ML	DEXPAK
CYSTIC FIBROSIS, ORAL RESPIRATORY AGENTS		
	ORKAMBI	
GI- CONSTIPATION – IBS/OIC		
		LINZESS
		MOVANTIK
GI -IRRITABLE BOWEL SYNDROME -D		
		VIBERZI
HEMATAPOIETIC,GROWTH FACTOR		
	PROCRIT	ARANESP
HYPNOTICS		
		BELSOMRA
MIGRAINE PRODUCTS		
	RELPAX	
MS AGENTS		
	AUBAGIO	COPAXONE 40 MG/ML SYRINGE
	BETASERON	EXTAVIA
	GILENYA	PLEGRIDY
	TECFIDERA	
MULTIVITAMINS, PRENATAL DHA		
	PRENATAL DHA, all products	
OPIOID ABUSE, ANALGESICS		
	SUBOXONE	BUNAVAIL
		ZUBSOLV
OPIOID LONG ACTING ANALGESICS		
	BUTRANS	HYSINGLA ER
	EMBEDA	OXYCONTIN ER
		ZOHYDRO ER
OPIOID-NSAID COMBINATIONS		
	IBUDONE	
OTIC ANTI-INFECTIVES		
	CIPRODEX	
PLATELET AGGREGATION INHIBITORS		
	BRILINTA	ZONTIVITY
PULMONARY HYPERTENSION DRUGS, ORAL		
	LETAIRIS	ADCIRCA
		ORENITRAM ER
		TRACLEER
		REMODULIN

ONLY DRUGS with Supplemental Rebate Offer or reviewed during the March DURB as either new to market or a change in PDL status are listed	PREFERRED AGENTS	NON-PREFERRED AGENTS
		UPTRAVI
SMOKING DETERRENTS		
		CHANTIX
URINARY ANTISPASMODICS		
	TOVIAZ	MYRBETRIQ
	VESICARE	

GEORGIA DEPARTMENT OF COMMUNITY HEALTH

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

On behalf of the Georgia Department of Community Health (DCH) and in service to the Georgia Medicaid Fee-for-Service (FFS) Drug Utilization Review Board (DURB), NorthStar HealthCare Consulting (NHC), in conjunction with OptumRx, announces the Manufacturers' Forum occurring on Thursday, November 10, 2016.

Date: **Thursday, November 10, 2016 from 9am-5pm EST**

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

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

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

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

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

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

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

Ongoing Opportunity:

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

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

Presentation Opportunity:

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

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

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

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

Opportunity to Appeal to GDCH:

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

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

2016

Upcoming Meetings

Drug Utilization Review Board Meeting

2 Peachtree Street, N.W.

5th Floor Board Room

Atlanta, Georgia 30303

Tuesday, December 13, 2016: 9:30am – 1:30pm

Manufacturers' Forum

NorthStar HealthCare Consulting

1121 Alderman Drive

Suite 112

Alpharetta, Georgia 30005

Thursday, November 10, 2016: 9:00am – 5:00pm

This page intentionally left blank

Drug Utilization Review Board

Board Member	Credentials	Specialty/Area of Expertise	Company Name
Gurinder J.S. Doad, Chair	M.D., Ph.D.	Family Practice	Southwest Georgia Family Medicine and Mercer University School of Medicine
Deborah W. Fincher, Vice-Chair	R.Ph., M.S.	HIV/AIDS Pharmacy	Pride Medical Pharmacy
Mia Avery	Pharm.D.	Oncology Pharmacy	Emory University Hospital Winship Cancer Institute
Douglas C. Collins	M.D.	Hematology/Oncology	Metro Hematology-Oncology, PC
Rod M. Duraski	M.D., FACP, MBA	Internal Medicine	West Georgia Health
M. Celeste Fowler	Pharm.D., HCMBA	Hospital Pharmacy	Piedmont Henry Hospital
Yolanda P. Graham	M.D.	Child and Adolescent Psychiatry	Devereux Georgia Treatment Network
Mary S. Harris	Ph.D.	Health Care Information/Education Research	BioTechnical Communications, Inc
Burton L. Lesnick	M.D., FAAP	Pediatrics/Pediatric Pulmonology	Children's Healthcare of Atlanta
Robyn Lorys	Pharm.D.	Managed Care	Peach State Health Plan
J. Russell May	Pharm.D.	Academia - Professor	University of Georgia College of Pharmacy
Drew A. Miller	R.Ph.	Retail Pharmacy	Wynn's Pharmacy
Brent L. Rollins	R.Ph., Ph.D.	Academia - Professor	Philadelphia College of Osteopathic Medicine School of Pharmacy
Robert E. Shervette, III	M.D.	Child and Adolescent Psychiatry	Ogeechee Behavioral Health Services
Danny A. Toth	R.Ph.	Pharmacy Benefit Plans	Timber Ridge Consultants, LLC