DUR Board Meeting
September 3, 2014
Pioneer Room
State Capitol

North Dakota Medicaid
DUR Board Meeting Agenda
Pioneer Room
State Capitol
600 East Blvd. Avenue
Bismarck, ND
September 3, 2014
1pm

1. Administrative items
    - Travel vouchers
    - Introduction of new members

2. Old business

• Review and approval of minutes of 06/14 meeting	Chair
• Budget update	Brendan
• Second review of Northera	Brendan
• Second review of oral allergen extracts	Brendan
• Updated AAP Guidelines-Synagis	Brendan
• Update on NDQuits protocol	Health Department

3. New business

• Hepatitis C treatment and compliance	HID
• Review of benzodiazepine utilization	HID
• Review of testosterone products	HID
• Review of phosphate binders	HID
• Review of Zontivity	HID
• Review of Evzio	HID
• Criteria recommendations	HID
• Upcoming meeting date/agenda	Chair

4. Adjourn — Chair

Please remember to silence all cellular phones during the meeting.

Drug Utilization Review (DUR) Meeting Minutes
June 2, 2014

Members Present: Norman Byers, John Savageau, Jeffrey Hostetter, Peter Woodrow, Carrie Sorenson, Russ Sobotta, Tanya Schmidt, Steve Irsfeld, Michael Booth, Cheryl Huber, Gary Betting, Leann Ness

Members Absent: Todd Twogood, Carlotta McCleary, James Carlson

Medicaid Pharmacy Department: Brendan Joyce

J. Savageau called the meeting to order at 1:00 p.m. Chair J. Savageau asked for a motion to approve the minutes from the March meeting. T. Schmidt moved that the minutes be approved, and N. Byers seconded the motion. Chair J. Savageau called for a voice vote to approve the minutes. The motion passed with no audible dissent.

Cathflo Second Review
A motion and second were made at the March meeting to place Cathflo on prior authorization. The topic was brought up for a second review. There was no public comment. After discussion, Chair J. Savageau called for a voice vote to approve the motion. The motion passed with no audible dissent. The form will be labeled "Alteplase."

Intranasal Cyanocobalamin Products Second Review
A motion and second were made at the March meeting to place intranasal cyanocobalamin products on prior authorization. The topic was brought up for a second review. There was no public comment. After discussion, Chair J. Savageau called for a voice vote to approve the motion. The motion passed with no audible dissent.

Luzu Second Review
A motion and second were made at the March meeting to place Luzu on prior authorization. The topic was brought up for a second review. There was no public comment. After discussion, Chair J. Savageau called for a voice vote to approve the motion. The motion passed with no audible dissent.

Noxafil Second Review
A motion and second were made at the March meeting to place Noxafil on prior authorization. The topic was brought up for a second review. There was no public comment. After discussion, Chair J. Savageau called for a voice vote to approve the motion. The motion passed with no audible dissent.

Bethkis Second Review
A motion and second were made at the March meeting to place Bethkis on prior authorization. The topic was brought up for a second review. There was no public comment. After discussion, Chair J. Savageau called for a voice vote to approve the motion. The motion passed with no audible dissent.

Name Brand Narcotics
B. Joyce discussed with the board changing the name of the form to "Narcotics PA." All narcotics will require a prior authorization except generic MS Contin. In the future, PDMP reports may be required from prescribers when requesting a narcotic.

Medicaid Expansion Drug Coverage
Michael Crandell, Chief Medical Officer of Sanford Health Plan, spoke with the committee about Medicaid expansion in North Dakota.

Cayston Review
B. Joyce reviewed Cayston information with the board. There was no public comment. P. Woodrow made a motion to place Cayston on prior authorization. J. Hostetter seconded the motion. This topic will be reviewed at the next meeting.

Procysbi Review
B. Joyce reviewed Procysbi information with the board. There was no public comment. The committee agreed that Procysbi should be included in the >$3,000 prior authorization.

Ravicti Review
B. Joyce reviewed Ravicti information with the board. There was no public comment. Ravicti is also >$3,000. The board agreed that the state should PA all high cost medications $3,000 and over and report back to the board on drugs that were added.

Gastrointestinal Agents Review
B. Joyce reviewed gastrointestinal agents with the board. There was no public comment. This topic was tabled.

Myalept Review
B. Joyce reviewed Myalept information with the board. There was no public comment. This topic was tabled.

Northera Review
B. Joyce reviewed Northera information with the board. There was no public comment. M. Booth made a motion to place Northera on prior authorization. C. Sorenson seconded the motion. This topic will be reviewed at the next meeting.

Oral Allergen Extracts Review
B. Joyce reviewed oral allergen extracts with the board. There was no public comment. M. Booth made a motion to place oral allergen extracts on prior authorization. J. Hostetter seconded the motion. This topic will be reviewed at the next meeting.

Criteria Recommendations
The recommended RDUR criteria enclosed in the packet were developed from product information provided by the manufacturers and usually are consistent with new indications, new drugs added, new warnings, etc. These proposed criteria will be added to the current set of criteria and will be used in future DUR cycles. J. Hostetter asked that criterion #36 dealing with high doses of statins and diabetes be brought back to the next meeting. J. Hostetter moved to approve the new criteria (without #36) and P. Woodrow seconded the motion. Chair J. Savageau called for a voice vote. The motion passed with no audible dissent.

The next DUR board meeting will be held September 3, in Bismarck. N. Byers made a motion to adjourn the meeting. J. Hostetter seconded. The motion passed with no audible dissent. J. Savageau adjourned the meeting.

NORTHERA
PA FORM

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving a new prescription for Northera must meet the following criteria:

- **Patient must have an FDA approved indication.**

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number	
Physician Name			
Physician Medicaid Provider Number	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage: □ NORTHERA	**Diagnosis for this Request:**		
□ *I confirm that I have considered a generic or other alternative and that the requested drug is expected to result in the successful medical management of the recipient.*			
Prescriber Signature		Date	

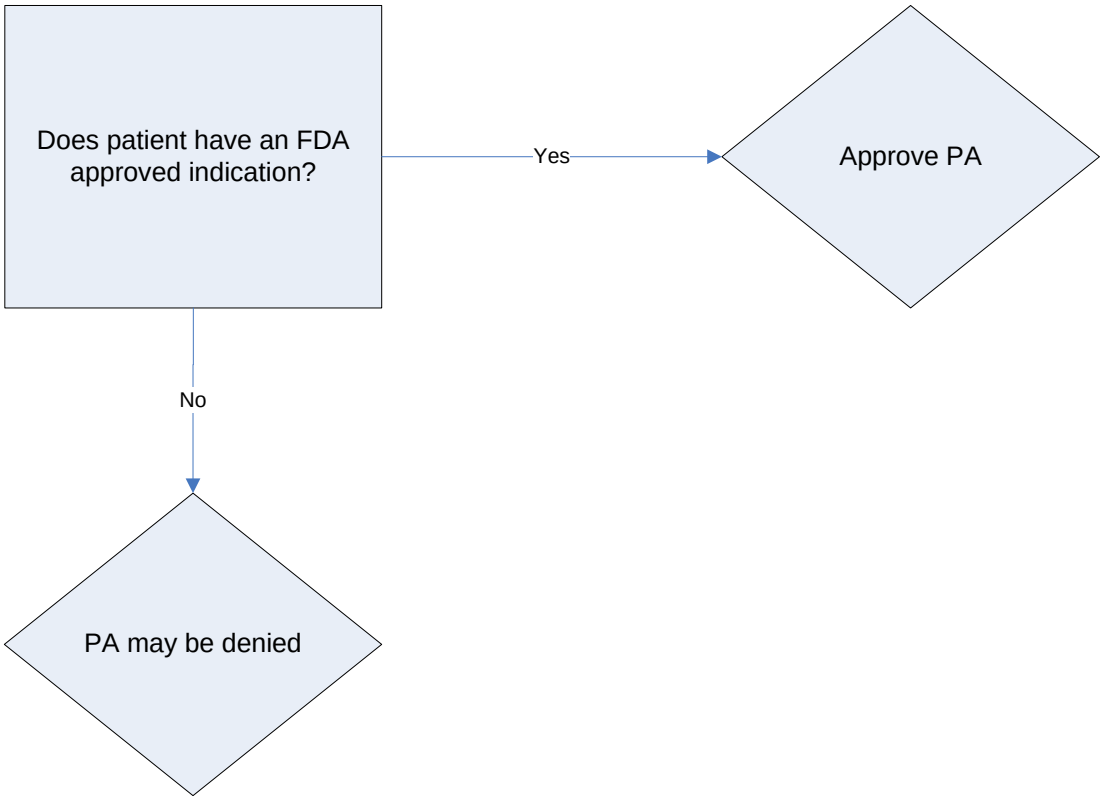
Part II: TO BE COMPLETED BY PHARMACY

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

North Dakota Department of Human Services
Northera Prior Authorization Algorithm



ORAL ALLERGEN EXTRACTS
PA FORM

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving a new prescription for oral allergen extracts must meet the following criteria:

- **Patient must have the FDA approved indication for the drug requested.**
- **Diagnosis confirmed by positive skin test or *in vitro* testing for pollen-specific IgE antibodies.**
- **History of failure, contraindication, or intolerance to two of the following: oral antihistamine, intranasal antihistamine, intranasal corticosteroid, or leukotriene inhibitors.**
- **History of failure or intolerance to subcutaneous allergen immunotherapy (allergy shots).**
- **Patient must not have severe, unstable, or uncontrolled asthma.**

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number	
Physician Name			
Physician Medicaid Provider Number	Telephone Number	Fax Number	
Address	City	State	Zip Code

Requested Drug:	**Diagnosis for this Request:**	**History of Failure:**
□ GRASTEK	□ GRASS POLLEN-INDUCED ALLERGIC RHINITIS	**1.**
□ ORALAIR	□ RAGWEED POLLEN-INDUCED ALLERGIC RHINITIS	**2.**
□ RAGWITEK		**3.**

□ *I confirm that I have considered a generic or other alternative and that the requested drug is expected to result in the successful medical management of the recipient.*

Prescriber Signature	Date

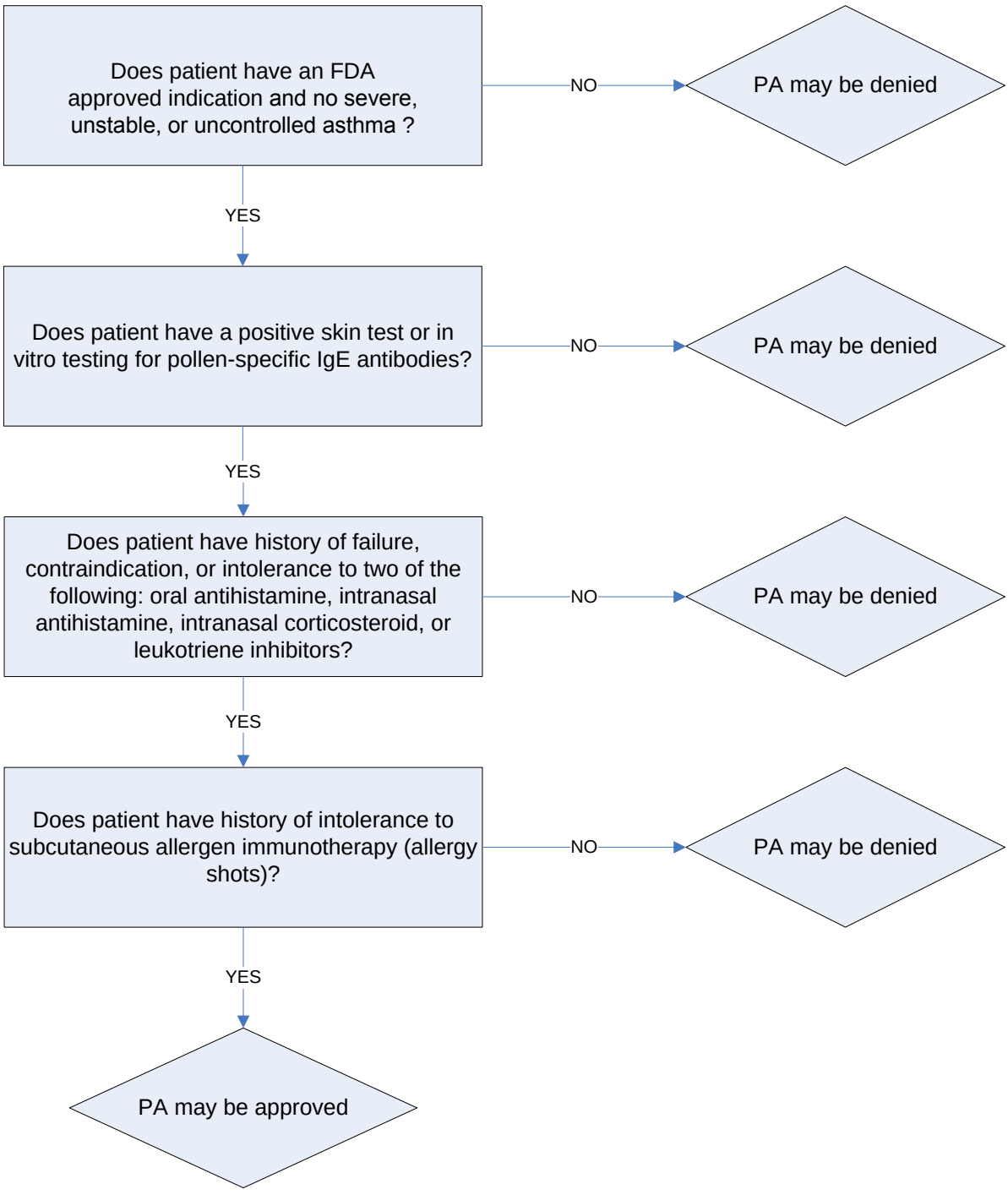
Part II: TO BE COMPLETED BY PHARMACY

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

North Dakota Department of Human Services
Oral Allergen Extracts Prior Authorization Algorithm



PEDIATRICS®
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Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection

COMMITTEE ON INFECTIOUS DISEASES AND BRONCHIOLITIS GUIDELINES COMMITTEE

Pediatrics; originally published online July 28, 2014;
DOI: 10.1542/peds.2014-1665

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN™

POLICY STATEMENT

Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection

COMMITTEE ON INFECTIOUS DISEASES AND BRONCHIOLITIS GUIDELINES COMMITTEE

KEY WORDS
RSV, respiratory syncytial virus, palivizumab, bronchiolitis, infants and young children, chronic lung disease, congenital heart disease

ABBREVIATIONS
AAP—American Academy of Pediatrics
CHD—congenital heart disease
CLD—chronic lung disease
COID—Committee on Infectious Diseases
RSV—respiratory syncytial virus

(Continued on last page)

abstract

FREE

Palivizumab was licensed in June 1998 by the Food and Drug Administration for the reduction of serious lower respiratory tract infection caused by respiratory syncytial virus (RSV) in children at increased risk of severe disease. Since that time, the American Academy of Pediatrics has updated its guidance for the use of palivizumab 4 times as additional data became available to provide a better understanding of infants and young children at greatest risk of hospitalization attributable to RSV infection. The updated recommendations in this policy statement reflect new information regarding the seasonality of RSV circulation, palivizumab pharmacokinetics, the changing incidence of bronchiolitis hospitalizations, the effect of gestational age and other risk factors on RSV hospitalization rates, the mortality of children hospitalized with RSV infection, the effect of prophylaxis on wheezing, and palivizumab-resistant RSV isolates. This policy statement updates and replaces the recommendations found in the 2012 *Red Book*. *Pediatrics* 2014;134:415–420

Policy statements from the American Academy of Pediatrics (AAP) are designed to provide updated guidance for child health care topics, with an emphasis on evidence-based recommendations whenever possible. Policy statements are reviewed at least every 3 years and updated when appropriate. In following this procedure, the AAP Committee on Infectious Diseases (COID) has undertaken a systematic review of all recent and older peer-reviewed literature relating to the burden of respiratory syncytial virus (RSV) disease in infants and children, focusing on publications that delineate children at greatest risk of serious RSV disease and studies that define pharmacokinetics, safety, and efficacy. Detailed input regarding this guidance has been solicited from 21 committees, councils, sections, and advisory groups within the AAP, as well as organizations outside the AAP. Outside groups include the American College of Chest Physicians, American College of Emergency Physicians, American Thoracic Society, Emergency Nurses Association, National Association of Neonatal Nurses, National Association of Neonatal Nurse Practitioners, and Society of Hospital

Medicine. In addition, this review includes all data presented to the COID by the manufacturer of palivizumab.

As part of this deliberative review of palivizumab use, the COID judged the quality of the available data, as well as the impact of palivizumab prophylaxis to reach a unanimous consensus on guidance for the use of palivizumab in the United States. Cost was considered during deliberations by the COID and Bronchiolitis Guideline Committee, but the final guidance as presented here is driven by the limited clinical benefit derived from palivizumab prophylaxis.[1–3]

As detailed in the accompanying technical report,[4] the benefit resulting from this drug is limited. Palivizumab prophylaxis has limited effect on RSV hospitalizations on a population basis, no measurable effect on mortality, and a minimal effect on subsequent wheezing.

This policy statement updates and replaces the most recent AAP recommendations for the use of palivizumab prophylaxis published in 2012 in the 29th edition of the *Red Book*.[5] This policy statement offers specific guidance for the use of palivizumab on the basis of available evidence, as well as expert opinion. A detailed discussion of the foundation of the updated guidance for each category as well as the references for each section may be found in the accompanying technical report,[4] and AAP guidelines for the diagnosis and management of bronchiolitis, which were published in 2006[6] (for which a revision is forthcoming).

The palivizumab package insert states: "Synagis is indicated for the prevention of serious lower respiratory tract disease caused by RSV in children at high risk of RSV disease."[7] In the absence of a specific definition of "high risk" by the US Food and Drug Administration, the AAP has endeavored to provide pediatricians and other health care providers with more precise guidance for determining who is at increased risk since palivizumab was first licensed.[5,8–11]

The informed opinion of the COID and the Bronchiolitis Guidelines Committee, as well as others participating in the current statement, is that palivizumab use should be restricted to the populations detailed below.

PRETERM INFANTS WITHOUT CHRONIC LUNG DISEASE OF PREMATURITY OR CONGENITAL HEART DISEASE

Palivizumab prophylaxis may be administered to infants born before 29 weeks, 0 days' gestation who are younger than 12 months at the start of the RSV season. For infants born during the RSV season, fewer than 5 monthly doses will be needed.

Available data for infants born at 29 weeks, 0 days' gestation or later do not identify a clear gestational age cutoff for which the benefits of prophylaxis are clear. For this reason, infants born at 29 weeks, 0 days' gestation or later are not universally recommended to receive palivizumab prophylaxis. Infants 29 weeks, 0 days' gestation or later may qualify to receive prophylaxis on the basis of congenital heart disease (CHD), chronic lung disease (CLD), or another condition.

Palivizumab prophylaxis is not recommended in the second year of life on the basis of a history of prematurity alone.

Some experts believe that on the basis of the data quantifying a small increase in risk of hospitalization, even for infants born earlier than 29 weeks, 0 days' gestation, palivizumab prophylaxis is not justified.

PRETERM INFANTS WITH CLD

Prophylaxis may be considered during the RSV season during the first year of life for preterm infants who develop CLD of prematurity defined as gestational age <32 weeks, 0 days and a requirement for >21% oxygen for at least the first 28 days after birth.

During the second year of life, consideration of palivizumab prophylaxis is recommended only for infants who satisfy this definition of CLD of prematurity and continue to require medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) during the 6-month period before the start of the second RSV season. For infants with CLD who do not continue to require medical support in the second year of life prophylaxis is not recommended.

INFANTS WITH HEMODYNAMICALLY SIGNIFICANT CHD

Certain children who are 12 months or younger with hemodynamically significant CHD may benefit from palivizumab prophylaxis. Children with hemodynamically significant CHD who are most likely to benefit from immunoprophylaxis include infants with acyanotic heart disease who are receiving medication to control congestive heart failure and will require cardiac surgical procedures and infants with moderate to severe pulmonary hypertension.

Decisions regarding palivizumab prophylaxis for infants with cyanotic heart defects in the first year of life may be made in consultation with a pediatric cardiologist.

These recommendations apply to qualifying infants in the first year of life who are born within 12 months of onset of the RSV season.

The following groups of infants with CHD are not at increased risk of RSV infection and generally should not receive immunoprophylaxis:

- Infants and children with hemodynamically insignificant heart disease (eg, secundum atrial septal

defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus)

- Infants with lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure
- Infants with mild cardiomyopathy who are not receiving medical therapy for the condition
- Children in the second year of life

Because a mean decrease in palivizumab serum concentration of 58% was observed after surgical procedures that involve cardiopulmonary bypass, for children who are receiving prophylaxis and who continue to require prophylaxis after a surgical procedure, a postoperative dose of palivizumab (15 mg/kg) should be considered after cardiac bypass or at the conclusion of extracorporeal membrane oxygenation for infants and children younger than 24 months.

Children younger than 2 years who undergo cardiac transplantation during the RSV season may be considered for palivizumab prophylaxis.

CHILDREN WITH ANATOMIC PULMONARY ABNORMALITIES OR NEUROMUSCULAR DISORDER

No prospective studies or population-based data are available to define the risk of RSV hospitalization in children with pulmonary abnormalities or neuromuscular disease. Infants with neuromuscular disease or congenital anomaly that impairs the ability to clear secretions from the upper airway because of ineffective cough are known to be at risk for a prolonged hospitalization related to lower respiratory tract infection and, therefore, may be considered for prophylaxis during the first year of life.

IMMUNOCOMPROMISED CHILDREN

No population based data are available on the incidence of RSV hospitalization in children who undergo solid organ or hematopoietic stem cell transplantation. Severe and even fatal disease attributable to RSV is recognized in children receiving chemotherapy or who are immunocompromised because of other conditions, but the efficacy of prophylaxis in this cohort is not known. Prophylaxis may be considered for children younger than 24 months of age who are profoundly immunocompromised during the RSV season.

CHILDREN WITH DOWN SYNDROME

Limited data suggest a slight increase in RSV hospitalization rates among children with Down syndrome. However, data are insufficient to justify a recommendation for routine use of prophylaxis in children with Down syndrome unless qualifying heart disease, CLD, airway clearance issues, or prematurity (<29 weeks, 0 days' gestation) is present.

CHILDREN WITH CYSTIC FIBROSIS

Routine use of palivizumab prophylaxis in patients with cystic fibrosis, including neonates diagnosed with cystic fibrosis by newborn screening, is not recommended unless other indications are present. An infant with cystic fibrosis with clinical evidence of CLD and/or nutritional compromise in the first year of life may be considered for prophylaxis. Continued use of palivizumab prophylaxis in the second year may be considered for infants with manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest radiography or chest computed tomography that persist when stable) or weight for length less than the 10th percentile.

RECOMMENDATIONS FOR TIMING OF PROPHYLAXIS FOR ALASKA NATIVE AND AMERICAN INDIAN INFANTS

On the basis of the epidemiology of RSV in Alaska, particularly in remote regions where the burden of RSV disease is significantly greater than the general US population, the selection of Alaska Native infants eligible for prophylaxis may differ from the remainder of the United States. Clinicians may wish to use RSV surveillance data generated by the state of Alaska to assist in determining onset and end of the RSV season for qualifying infants.

Limited information is available concerning the burden of RSV disease among American Indian populations. However, special consideration may be prudent for Navajo and White Mountain Apache infants in the first year of life.

DISCONTINUATION OF PALIVIZUMAB PROPHYLAXIS AMONG CHILDREN WHO EXPERIENCE BREAKTHROUGH RSV HOSPITALIZATION

If any infant or young child receiving monthly palivizumab prophylaxis experiences a breakthrough RSV hospitalization, monthly prophylaxis should be discontinued because of the extremely low likelihood of a second RSV hospitalization in the same season (<0.5%).

USE OF PALIVIZUMAB IN THE SECOND YEAR OF LIFE

Hospitalization rates attributable to RSV decrease during the second RSV season for all children. A second season of palivizumab prophylaxis is recommended only for preterm infants born at <32 weeks, 0 days' gestation who required at least 28 days of oxygen after birth and who continue to require

supplemental oxygen, chronic systemic corticosteroid therapy, or bronchodilator therapy within 6 months of the start of the second RSV season.

LACK OF THERAPEUTIC EFFICACY OF PALIVIZUMAB

Passive antibody administration is not effective in treatment of RSV disease and is not approved or recommended for this indication.

PREVENTION OF HEALTH CARE-ASSOCIATED RSV DISEASE

No rigorous data exist to support palivizumab use in controlling outbreaks of health care-associated disease, and palivizumab use is not recommended for this purpose. Infants in a neonatal unit who qualify for prophylaxis because of CLD, prematurity, or CHD may receive the first dose 48 to 72 hours before discharge to home or promptly after discharge.

Strict adherence to infection-control practices is the basis for reducing health care-associated RSV disease.

RSV SEASONALITY

Because 5 monthly doses of palivizumab at 15 mg/kg per dose will provide more than 6 months (>24 weeks) of serum palivizumab concentrations above the desired level for most children, administration of more than 5 monthly doses is not recommended within the continental United States. For qualifying infants who require 5 doses, a dose beginning in November and continuation for a total of 5 monthly doses will provide protection for most infants through April and is recommended for most areas of the United States. If prophylaxis is initiated in October, the fifth and final dose should be administered in February, which will provide protection for most infants through March. If prophylaxis is initiated in December, the fifth and final dose should be administered in April, which will provide protection for most infants through May.

Variation in the onset and offset of the RSV season in different regions of Florida may affect the timing of palivizumab administration. Data from the Florida Department of Health may be used to determine the appropriate timing for administration of the first dose of palivizumab for qualifying infants. Despite varying onset and offset dates of the RSV season in different regions of Florida, a maximum of 5 monthly doses of palivizumab should be adequate for qualifying infants for most RSV seasons in Florida.

Sporadic RSV infections occur throughout the year in most geographic locations. During times of low RSV prevalence (regardless of proportion of positive results), prophylaxis with palivizumab provides the least benefit because of the large number of children who must receive prophylaxis to prevent 1 RSV hospitalization.

EFFECT OF PALIVIZUMAB PROPHYLAXIS ON SUBSEQUENT WHEEZING

Prophylaxis is not recommended for primary asthma prevention or to reduce subsequent episodes of wheezing.

SUMMARY OF GUIDANCE

- In the first year of life, palivizumab prophylaxis is recommended for infants born before 29 weeks, 0 days' gestation.
- Palivizumab prophylaxis is not recommended for otherwise healthy infants born at or after 29 weeks, 0 days' gestation.
- In the first year of life, palivizumab prophylaxis is recommended for preterm infants with CLD of prematurity, defined as birth at <32 weeks, 0 days' gestation and a requirement for >21% oxygen for at least 28 days after birth.
- Clinicians may administer palivizumab prophylaxis in the first year of life to certain infants with hemodynamically significant heart disease.
- Clinicians may administer up to a maximum of 5 monthly doses of palivizumab (15 mg/kg per dose) during the RSV season to infants who qualify for prophylaxis in the first year of life. Qualifying infants born during the RSV season may require fewer doses. For example, infants born in January would receive their last dose in March.
- Palivizumab prophylaxis is not recommended in the second year of life except for children who required at least 28 days of supplemental oxygen after birth and who continue to require medical intervention (supplemental oxygen, chronic corticosteroid, or diuretic therapy).
- Monthly prophylaxis should be discontinued in any child who experiences a breakthrough RSV hospitalization.
- Children with pulmonary abnormality or neuromuscular disease that impairs the ability to clear secretions from the upper airways may be considered for prophylaxis in the first year of life.
- Children younger than 24 months who will be profoundly immunocompromised during the RSV season may be considered for prophylaxis.
- Insufficient data are available to recommend palivizumab prophylaxis for children with cystic fibrosis or Down syndrome.
- The burden of RSV disease and costs associated with transport from remote locations may result in a broader use of palivizumab for RSV prevention in Alaska Native

populations and possibly in selected other American Indian populations.

- Palivizumab prophylaxis is not recommended for prevention of health care-associated RSV disease.

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PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection

COMMITTEE ON INFECTIOUS DISEASES AND BRONCHIOLITIS GUIDELINES COMMITTEE

Pediatrics; originally published online July 28, 2014;
DOI: 10.1542/peds.2014-1665

HEALTH INFORMATION DESIGNS

SYNAGIS WEB BASED FORM

For questions regarding this Prior Authorization Call 701-328-4023

Prior Authorization Vendor for ND Medicaid

Note:

- Synagis season will be October 19th through April 21st
- Based on the 2009 American Academy of Pediatrics *Policy Statement – Modified Recommendations for Use of Palivizumab for Prevention of Respiratory Syncytial Virus Infections**, a maximum of 5 or 3 doses will be allowed during the Synagis season determined by gestational age.
- Providers will choose when to start dosing Synagis based on prevalence of RSV in the community

TO BE COMPLETED BY PRESCRIBER

Recipient Medicaid ID Number	Recipient Date of Birth	Prescriber NPI	Prescriber Fax Number

Diagnosis (qualification for Synagis)

___ Prematurity

≤28 weeks, 6 days gestational age – Synagis allowed if younger than 12 months of age at start of RSV season (max of 5 doses)

29-31 weeks, 6 days gestational age – Synagis allowed if younger than 6 months of age at start of RSV season (max of 5 doses)

32-34 weeks, 6 days gestational age – Synagis allowed during RSV season up to 6 months of life (max of 3 doses)

Gestational Age (e.g. 32 weeks, 4 days)

Weeks _____ **Days** _____

Risk Factor(s) (for those 32-34 weeks, 6 days)

___ Daycare attendance

___ Sibling younger than 5 years of age

___ Chronic Lung Disease of Prematurity (CLD)

Must be less than 24 months of age and receive medical therapy within six months before start of RSV season

___ Supplemental Oxygen

___ Bronchodilator

___ Diuretic

___ Chronic corticosteroid therapy

___ Congenital Heart Disease (CHD)

Must be less than 24 months of age and requiring medical therapy for CHD

Medical Therapy Required _____

___ Neuromuscular disease

___ Congenital abnormalities of the airways

***Accessed online at http://aappolicy.aappublications.org/cgi/reprint/pediatrics;124/6/1694.pdf.**

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Gestational Age (e.g. 32 weeks, 4 days)

Weeks _____ **Days** _____

~~Risk Factor(s) (for those 32-34 weeks, 6 days)~~

___ ~~Daycare attendance~~

___ ~~Sibling younger than 5 years of age~~

___ Chronic Lung Disease of Prematurity (CLD) – gestational age <32 weeks, 0 days and a requirement for >21% oxygen for at least the first 28 days of birth.

Must be less than 24 months of age and receive medical therapy within six months before start of RSV season

___ Supplemental Oxygen

___ ~~Bronchodilator~~

___ Diuretic

___ Chronic corticosteroid therapy

___ Congenital Heart Disease (CHD)

Must be less than 12 months of age and requiring medical therapy for hemodynamically significant CHD

Medical Therapy Required _____

*children less than 24 months who undergo cardiac transplantation during RSV season may be considered for prophylaxis.

___ Neuromuscular disease (may be considered for prophylaxis during the first year of life)

___ Congenital abnormalities of the airways (may be considered for prophylaxis during the first year of life)

___ Profoundly Immunocompromised children (children <24 months may be considered for prophylaxis during the RSV season)

***Accessed online at http://aappolicy.aappublications.org/cgi/reprint/pediatrics;124/6/1694.pdf.**

NORTH DAKOTA
DEPARTMENT of HEALTH

COMMUNITY HEALTH SECTION
600 East Boulevard Avenue, Dept. 301
Bismarck, N.D. 58505-0200
www.ndhealth.gov
TTY 800.366.6888

Memorandum

To: North Dakota Medicaid Drug Utilization Review Board

From: Krista Fremming, Tobacco Program Director

Date: 8/5/2014

Re: Training Protocol for Rehabilitative Services providers

The steps below outline a proposed process for the Department of Health to provide training and distribution of prior authorization forms to Medicaid rehabilitative services providers. The purpose of the new process is to expand tobacco dependence treatment coverage options for ND Medicaid members by providing a way for FDA-approved tobacco cessation medications to be covered through ND Medicaid when the member participates in face to face or group counseling through a rehabilitative services provider.

Currently, ND Medicaid members who wish to use tobacco cessation medications are required to enroll in phone counseling provided by NDQuits. The new proposed process (below) will allow coverage for medications when participating in face to face or group counseling, which will encourage more successful quit attempts by ND Medicaid members.

1. DoH develops a webinar that will be housed on the NDQuits website for rehab providers (and others) that will include the basics of brief cessation interventions, motivational interviewing, neurobiology of nicotine and pharmacology.
2. After providers complete the webinar, they will be prompted to take a test to demonstrate their knowledge. The test results will be forwarded to DoH Tobacco program staff for documentation and certification of pass/fail.
3. Providers who successfully pass the webinar post-test will be provided with the current ND Medicaid prior authorization form for cessation medications as well as a template enrollment letter in counseling services. The DoH will coordinate the distribution of the PA forms and enrollment letter templates.
4. Providers will be required to complete the webinar or another approved tobacco cessation training (minimum of 2 hours in length) at least every 2 years to maintain their eligibility to receive the Medicaid cessation medications forms. The DoH will track and remind providers who are getting close to having their eligibility expire.

For any questions on the proposed process or tobacco cessation activity in North Dakota, please contact Krista at 701.328.2315 or kfremming@nd.gov.

PL Detail-Document **#300204**
−This PL Detail-Document gives subscribers additional insight related to the Recommendations published in−
PHARMACIST'S LETTER / PRESCRIBER'S LETTER
February 2014

Comparison of Hepatitis C Drugs

For years, peginterferon alpha plus ribavirin was the only treatment for hepatitis C. Now protease inhibitors (boceprevir, telaprevir, simeprevir) and a polymerase inhibitor (sofosbuvir) are available **for use with peginterferon alpha and ribavirin** to improve efficacy for genotype 1 infections. Sofosbuvir is also indicated for genotypes 2, 3, and 4, and can be used without peginterferon alpha in some patients. The newest agents (simeprevir, sofosbuvir) have convenient dosing regimens, fewer drugs interactions, and seem to be better tolerated than boceprevir and telaprevir. The following chart compares hepatitis C drugs in regard to dosing, common adverse effects, contraindicated drugs, safety monitoring, and cost. Patient assistance programs are also listed. Information in the chart is from U.S. product labeling unless otherwise noted. Information from Canadian labeling is included when it differs significantly (e.g., more conservative) from U.S. labeling.

Abbreviations: ALT = alanine aminotransferase; CBC = complete blood count; LFTs = liver function tests

Adult Dosing[a]	**Common Adverse Effects**[a]	**Drug Interactions**	**Safety Monitoring**[a]	**Cost**[b]
PROTEASE INHIBITORS				
Boceprevir (*Victrelis*; *Victrelis Triple* [Canada] kit includes ribavirin and peginterferon alpha-2b): For genotype 1 infections. Must use with peginterferon alpha and ribavirin.				
800 mg three times daily (every 7 to 9 hours) with food starting on week five of peginterferon alpha plus weight-based ribavirin. For patients with compensated cirrhosis, treatment is continued for 44 more weeks (48 weeks total treatment duration). For patients without cirrhosis, total treatment duration 28 to 48 weeks, depending on viral response and response history.	Over 35% of patients when used with peginterferon and ribavirin: fatigue, anemia (over 40% of patients need erythropoiesis-stimulating agent), nausea, headache, dysgeusia.	• CYP3A substrate and strong inhibitor. • P-glycoprotein substrate and inhibitor. **Contraindicated Drugs**: alfuzosin, amiodarone (Canada), carbamazepine, cisapride, drospirenone, ergots, lovastatin, midazolam (oral), pimozide, phenobarbital, phenytoin, propafenone (Canada), quinidine (Canada), rifampin, sildenafil (*Revatio*), simvastatin, St. John's wort, tadalafil (*Adcirca*), triazolam (Boceprevir interacts with many other drugs. See U.S. MedGuide and product labeling for a complete list of all interacting drugs, dosing adjustments, and monitoring).	Check CBC at baseline and at weeks two, four, eight, and 12, and as clinically indicated. Decreased white blood cell, neutrophil, or platelet count may require peginterferon dosage decrease or treatment discontinuation. Reductions in hemoglobin may require peginterferon and/or ribavirin dose reduction or treatment discontinuation. If peginterferon or ribavirin is discontinued, boceprevir must also be discontinued.	U.S.: $40,120.32 for 24 weeks or $73,553.92 for 44 weeks Canada: $26,460 for 24 weeks or $48,510 for 44 weeks Patient assistance programs: U.S.: http://www.merck.com/merckhelps/act-program/ Canada: 866-872-5773 (Merck Care)

More. . .

Adult Dosing[a]	**Common Adverse Effects**[a]	**Drug Interactions**	**Safety Monitoring**[a]	**Cost**[b]
Simeprevir (*Olysio* [U.S.], *Galexos* [Canada]): For genotype 1 infections. Must use with peginterferon alpha and ribavirin. Dosed once daily. Has fewer drug interactions and appears better tolerated than telaprevir or boceprevir. May cause rash and sun sensitivity, especially in patients of East Asian ancestry. Check the virus for a specific genetic mutation before using *Olysio*. About 35% of patients are infected with a virus containing a Q80K polymorphism that makes *Olysio* less effective, but doesn't change susceptibility to other antivirals. Caution should be exercised when using *Olysio* in severely sulfa-allergic patients; contains a sulfonamide moiety.				
150 mg once daily with food plus peginterferon alfa plus ribavirin* for 12 weeks. This is followed by an additional 12 to 36 weeks of peginterferon alfa plus ribavirin,* based on viral response and response history (24 to 48 weeks total treatment duration). *Ribavirin dose: 1000 mg divided twice daily (e.g., 400 mg qAM, 600 mg qPM) if <75 kg, or 1200 mg divided twice daily if ≥75 kg.[1]	Over 20% of patients when used with peginterferon and ribavirin: rash (including photosensitivity), itching, nausea	• CYP3A substrate and weak intestinal CYP3A4 inhibitor. • Weak CYP1A2 inhibitor. • P-glycoprotein inhibitor. • Inhibits an organic anion transporter protein (OATP1B1). No contraindicated drugs. (See product labeling for a complete list of all interacting drugs, dosing adjustments, and monitoring).	See monitoring as for peginterferon alpha and ribavirin. If peginterferon or ribavirin is discontinued, simeprevir must also be discontinued.	*Olysio* (U.S.): $66,360 for 12 weeks *Galexos* (Canada): $39,422.40 for 12 weeks Patient assistance program for *Olysio*: http://www.olysio.com/support/financial-assistance *Galexos* program not available at press time. Contact Janssen Medical Information at 800-567-3331.

Adult Dosing[a]	**Common Adverse Effects**[a]	**Drug Interactions**	**Safety Monitoring**[a]	**Cost**[b]
Telaprevir (*Incivek*): For genotype 1 infections. Must use with peginterferon alpha and ribavirin.				
1125 mg twice daily (every 10 to 14 hours) with food (not low fat), plus peginterferon alfa plus weight-based ribavirin for 12 weeks. This is followed by an additional 12 to 36 weeks of peginterferon alfa plus ribavirin, based on viral response and response history (24 to 48 weeks total treatment duration).	Over 35% of patients when used with peginterferon and ribavirin: rash (discontinue all treatment components if progressive or severe), fatigue, itching, nausea, anemia	• Strong CYP3A inhibitor. • CYP3A substrate. • P-glycoprotein substrate and inhibitor. • Inhibits organic anion transporter proteins OATP1B1 and OATP2B1. **Contraindicated Drugs**: alfuzosin, amiodarone (Canada), atorvastatin (U.S.), carbamazepine, cisapride, eletriptan (Canada), eplerenone (Canada), ergots, flecainide (Canada), lovastatin, midazolam (oral), phenobarbital, phenytoin, pimozide, propafenone (Canada), quinidine (Canada), rifampin, sildenafil (*Revatio*), simvastatin, St. John's wort, tadalafil (*Adcirca*)(U.S.), triazolam, vardenafil (Canada) (Telaprevir interacts with many other drugs. See U.S. MedGuide and product labeling for a complete list of all interacting drugs, dosing adjustments, and monitoring).	Check CBC, blood chemistry, LFTs, TSH, and lipids (Canada) at baseline, at weeks two, four, eight, and 12, and as clinically indicated. Decreased white blood cell, neutrophil, or platelet count may require peginterferon dosage decrease or treatment discontinuation. Reductions in hemoglobin may require peginterferon and/or ribavirin dose reduction or treatment discontinuation. If peginterferon or ribavirin is discontinued, telaprevir must also be discontinued.	U.S.: $66,155.10 for 12 weeks Canada: $36,716.40 for 12 weeks Patient assistance program: U.S.: www.incivek.com/help-paying-for-incivek Canada: 877-574-4298 (*Incivek* Care)

More. . .

Adult Dosing[a]	Common Adverse Effects[a]	Drug Interactions	Safety Monitoring[a]	Cost[b]
POLYMERASE INHIBITOR				
Sofosbuvir (*Sovaldi*): For genotype 1 and 4 infections, with peginterferon alpha and ribavirin. For genotypes 2 and 3, must use with ribavirin. For genotype 1 infections, use with only ribavirin can be considered if peginterferon cannot be used. Seems better tolerated than the protease inhibitors, and usually requires a shorter treatment duration. Indicated for patients co-infected with HIV. Sofosbuvir plus ribavirin can be used for up to 48 weeks pre-liver transplant to prevent reinfection (U.S.).				
Genotypes 1 and 4: 400 mg once daily with or without food plus ribavirin* and peginterferon alfa for 12 weeks. (For **genotype 1**, use with only ribavirin* can be considered if peginterferon cannot be used [U.S.]). **Genotypes 2 and 3**: 400 mg once daily with or without food plus ribavirin* for 12 weeks for genotype 2, or 24 weeks for genotype 3 (16 to 24 weeks, Canada). *Ribavirin dose: 1000 mg divided twice daily (e.g., 400 mg qAM, 600 mg qPM) if <75 kg, or 1200 mg divided twice daily if ≥75 kg.	Over 20% of patients when used with peginterferon and ribavirin: fatigue, headache, nausea, insomnia, anemia	• P-glycoprotein substrate. • BCRP (breast cancer resistance protein) drug transporter substrate. No contraindicated drugs. (See product labeling for a complete list of all interacting drugs, dosing adjustments, and monitoring).	See monitoring as for peginterferon alpha and ribavirin. If the other agents used with sofosbuvir are discontinued, sofosbuvir must also be discontinued.	U.S.: $84,000 for 12 weeks Canada: price not available at press time. Patient assistance programs: U.S: www.mysupportpath.com Canada: 866-207-4267 (Momentum Support Program)

Adult Dosing[a]	Common Adverse Effects[a]	Drug Interactions	Safety Monitoring[a]	Cost[b]
INTERFERONS				
Peginterferon alfa-2a (*Pegasys*; *Pegasys RBV* kit [Canada] includes ribavirin [*Copegus*]): For use with ribavirin. For genotype 1 infections, add a protease inhibitor or polymerase inhibitor to improve efficacy.				
180 mcg subcutaneously once weekly for 12 to 48 weeks, depending on antiviral regimen, patient history, and response. Reduce dose to 135 mcg once weekly if CrCl <30 mL/min. (Canada: reduce dose to 135 mcg once weekly in hemodialysis patients).	Over 35% of patients when used with ribavirin: fatigue, weakness, fever, myalgia, headache	• CYP1A2 inhibitor. No contraindicated drugs. (See product labeling for a complete list of all interacting drugs, dosing adjustments, and monitoring).	Check CBC at baseline, at weeks two and four, and periodically. Check blood chemistry and LFTs at baseline, at week four, and periodically. In clinical trials, CBC, blood chemistry, and LFTs were checked at weeks one, two, four, six, and eight. Thyroid function should be checked at baseline. In clinical trials, it was checked every 12 weeks. Dose reduction or discontinuation may be required in the event of reduced neutrophil or platelet count, or elevated ALT. Patients with cardiac disease should have a baseline EKG. Monitor for depression/suicidal ideation. Dose reduction (U.S. only) or discontinuation may be indicated.	U.S.: $21,595.56 for 28 weeks Canada: $11,970.28 (*Pegasys*) or $11,637.92 (*Pegasys RBV* kit) for 28 weeks Patient assistance programs: U.S.: http://www.genentech-access.com/pegasys/hcp/find-patient-assistance Canada: 888-748-8926 (Pegassist)

Adult Dosing[a]	Common Adverse Effects[a]	Drug Interactions	Safety Monitoring[a]	Cost[b]
Peginterferon alfa-2b (*PegIntron* [U.S.]; *Pegetron* kit [Canada] includes ribavirin): For use with ribavirin. For genotype 1 infections, add a protease inhibitor or polymerase inhibitor to improve efficacy.				
1.5 mcg/kg subcutaneously once weekly for 12 to 48 weeks, depending on antiviral regimen, patient history, and response. Reduce dose by 25% if CrCl is 30 to 50 mL/min. Reduce dose by 50% if CrCl 10 to 29 mL/min. (Canada: contraindicated if CrCl <50 mL/min).	Over 35% of patients when used with ribavirin: injection site reaction, fatigue, weakness, headache, rigors, fever, nausea, myalgia, insomnia, mood instability, hair loss	• May induce CYP2C8/9. • May increase or decrease CYP2D6 activity. No contraindicated drugs. (See product labeling for a complete list of all interacting drugs, dosing adjustments, and monitoring).	Check CBC, blood chemistry, and LFTs at baseline and periodically (Canada: at baseline, weeks two and four, then periodically). In clinical trials, these tests were measured at weeks 2, 4, 8, and 12, then every six weeks, and as clinically indicated. Check thyroid function at baseline. In clinical trials, TSH was checked every 12 weeks. Decreased white blood cell, neutrophil, or platelet count or hemoglobin may require dosage decrease or treatment discontinuation. Discontinue treatment if liver or renal function deteriorates. Patients with cardiac disease should have a baseline EKG. Monitor for depression/suicidal ideation. Dose reduction (U.S. only) or discontinuation may be indicated.	U.S.: $21,699.16 for 120 mcg for 28 weeks Canada: $12,585.02 (*Pegetron* 120 mcg kit) for 28 weeks Patient assistance programs (U.S.): http://www.merck.com/merckhelps/act-program/ (ACT Program) Canada: 866-872-5773 (Merck Care)

Adult Dosing[a]	Common Adverse Effects[a]	Drug Interactions	Safety Monitoring[a]	Cost[b]
NUCLEOSIDE ANALOGUE				
Ribavirin (*Copegus*, *Rebetol*, *Ribasphere* tablets and capsules [U.S.]; *Pegetron* kit [Canada] includes peginterferon alpha-2b, *Pegasys RBV* kit [Canada] includes Peginterferon): For use with peginterferon alpha. For genotype 1 infections, add a protease inhibitor or polymerase inhibitor to improve efficacy.				
Duration is 12 to 48 weeks depending on genotype, antiviral regimen, patient history, and response. ***Copegus*, *Ribasphere* tablets [U.S.]** (indicated for use with peginterferon alpha-2a)**:**[c] Genotype 2 or 3: 400 mg twice daily Genotypes 1 and 4: weight <75 kg, 400 mg qAM and 600 mg qPM. Weight ≥75 kg, 600 mg twice daily. For CrCl 30 to 50 mL/min., reduce dose to alternating 200 mg/400 mg once daily. For patients with CrCl <30 mL/min., reduce dose to 200 mg once daily (U.S.). *Continued…*	Over 35% of patients when used with peginterferon: fatigue, weakness, fever, myalgia, headache, rigors, nausea, insomnia, mood instability, alopecia	• Contraindicated with didanosine (Canada, not recommended). (See product labeling for a complete list of all interacting drugs, dosing adjustments, and monitoring).	Pregnancy test at baseline, then monthly during treatment and for six months after discontinuation. Patients with cardiac disease should have a baseline EKG. Check CBC at baseline, at weeks two and four, then periodically. Check blood chemistry and LFTs at baseline, (week two [*Pegetron*], week four [*Copegus*, *Pegasys RBV*, *Pegetron*]), then periodically. Check thyroid function at baseline. In clinical trials of *Copegus*/*Pegasys*, CBC, blood chemistry, and LFTs were checked at weeks one, two, four, six, and eight, then every four to six weeks and as clinically indicated. TSH was checked every 12 weeks. Reductions in hemoglobin may require ribavirin dose reduction or treatment discontinuation.	U.S.: $21,016.66 (*Copegus*) for 600 mg twice daily for 28 weeks $8,653.68 (*Rebetol*) or $3,831.80 (*Ribasphere*) for 1000 mg divided twice daily for 28 weeks Canada: $12,585.02 (*Pegetron* 120 mcg kit) or $11,637.92 (*Pegasys RBV* kit) for 1000 mg divided twice daily for 28 weeks Patient assistance program for *Rebetol*: http://www.merck.com/merckhelps/act-program/ (ACT program) Canada: for *Pegetron*, 866-872-

More. . .

Adult Dosing[a]	**Common Adverse Effects**[a]	**Drug Interactions**	**Safety Monitoring**[a]	**Cost**[b]
Ribavirin, continued ***Rebetol* [U.S], *Ribasphere* capsules [U.S.], *Pegetron* kit [Canada]** (indicated for use with peginterferon alpha-2b):[c] 800 to 1400 mg (divided twice daily), depending on weight. Contraindicated if CrCl <50 mL/min.				5773; for *Pegasys*, 877-734-2897

The following product labeling was used in the preparation of this chart: *Victrelis* (September 2013), *Pegasys* (July 2013), *PegIntron* (November 2013), *Copegus* (February 2013), *Rebetol* (November 2013), *Ribasphere* tablets (December 2013), *Ribasphere* capsules (October 2012), *Olysio* (November 2013), *Sovaldi* (December 2013), *Incivek* (October 2013), *Victrelis* Canada (May 2013), *Pegasys* Canada (August 2013), *Pegetron* (March 2013), *Pegasys RBV* (August 2013), *Galexos* (November 2013), *Sovaldi* Canada (December 2013), *Incivek* Canada (December 2013)

a. See product labeling for dose reduction and other management recommendations in the event of moderate to severe clinical adverse reactions or laboratory abnormalities.
b. U.S. cost is wholesale average cost (WAC). Canadian cost is wholesale price.
c. Although each ribavirin product/dose is indicated for use with a specific peginterferon alpha product, some experts use the ribavirin dose used in the clinical trials for each specific protease or polymerase inhibitor, regardless of the peginterferon product used.

Project Leader in preparation of this PL Detail-Document: *Melanie Cupp, Pharm.D., BCPS*

References

1. Fried MW, Buti M, Dore GJ, et al. Once-daily simeprevir (TMC435) with pegylated interferon and ribavirin in treatment-naïve genotype 1 hepatitis C: the randomized PILLAR study. *Hepatology* 2013;58:1918-29.

Cite this document as follows: PL Detail-Document, Comparison of Hepatitis C Drugs. Pharmacist's Letter/Prescriber's Letter. February 2014.

PHARMACIST'S LETTER *Evidence and Recommendations You Can Trust…* PRESCRIBER'S LETTER

3120 West March Lane, Stockton, CA 95219 ~ TEL (209) 472-2240 ~ FAX (209) 472-2249

ND Medicaid - Agents Used to Treat Hep C Utilization			
01/01/14 - 05/31/14			
Label Name	**Rx Num**	**Total Reimb Amt**	**Avg Cost per Script**
RIBAVIRIN 200 MG TABLET	14	$1,409.99	$100.71
PEGINTRON REDIPEN 120	2	$6,178.16	$3,089.08
PEGASYS 180 MCG/0.5 ML	9	$27,678.06	$3,075.34
SOVALDI 400 MG TABLET	9	$227,867.22	$25,318.58
8 recipients/4 prescribers (infectious disease specialists/gastroenterologist/NP/internist)			
Sovaldi Recipient	**Doses**	**Pegasys**	**Ribavirin**
1	3	yes	yes
2	2	yes	yes
3	2	no	yes
4	1	no	no
5	1	yes	yes

SOVALDI PA FORM

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving a new prescription for Sovaldi must meet the following criteria:

- Patient must be ≥ 18 years old.
- Must have a diagnosis of chronic hepatitis C (genotypes 1, 2, 3, or 4) with compensated liver disease.
- Liver biopsy showing fibrosis corresponding to a Metavir score of greater than or equal to 2 or Ishak score of greater than or equal to 3 or other accepted test demonstrating liver fibrosis.
- Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist.
- Must be used in combination with ribavirin or in combination with pegylated interferon and ribavirin **(must not be used as monotherapy).**
- Female patients must have a negative pregnancy test within 30 days prior to initiation of therapy and monthly during treatment.
- Absence of renal impairment (eGFR must be >30mL/min/1.73m^2) and absence of end stage renal disease (ESRD).
- Documentation showing that patient is drug and alcohol free for the past 12 months.

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name		Recipient Date of Birth	Recipient Medicaid ID Number	
Physician Name		Specialist involved in therapy		
Physician Medicaid Provider Number		Telephone Number	Fax Number	
Address		City	State	Zip Code
Requested Drug □ **Sovaldi** Dosage _____	**Documented liver fibrosis**	**Diagnosis for this request** **Genotype** **Pegylated interferon dose** **Ribavirin dose**	**Patient is drug and alcohol free for past 12 months** □ YES □ NO **Negative pregnancy test in the past 30 days** □ YES □ NO	**eGFR**
Physician Signature			Date	

Part II: TO BE COMPLETED BY PHARMACY

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

OLYSIO PA FORM

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving a new prescription for Olysio must meet the following criteria:

- Patient must be ≥ 18 years old.
- Must have a diagnosis of chronic hepatitis C, genotype 1, with compensated liver disease.
- Liver biopsy showing fibrosis corresponding to a Metavir score of greater than or equal to 2 or Ishak score of greater than or equal to 3 or other accepted test demonstrating liver fibrosis.
- Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist.
- Must be used in combination with pegylated interferon and ribavirin **(must not be used as monotherapy).**
- Female patients must have a negative pregnancy test within 30 days prior to initiation of therapy and monthly during treatment.
- Documentation showing that patient is drug and alcohol free for the past 12 months.
- Alternative therapy should be considered for patients infected with HCV genotype 1a containing the Q80K polymorphism.

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name		Recipient Date of Birth	Recipient Medicaid ID Number
Physician Name		Specialist involved in therapy	
Physician Medicaid Provider Number		Telephone Number	Fax Number
Address		City	State / Zip Code
Requested Drug □ **Olysio** Dosage _____	**Documented liver fibrosis** **Presence of Q80K polymorphism?** □ YES □ NO	**Diagnosis for this request** **Genotype** **Pegylated interferon dose** **Ribavirin dose**	**Patient is drug and alcohol free for past 12 months** □ YES □ NO **Negative pregnancy test in the past 30 days** □ YES □ NO
Physician Signature			Date

Part II: TO BE COMPLETED BY PHARMACY

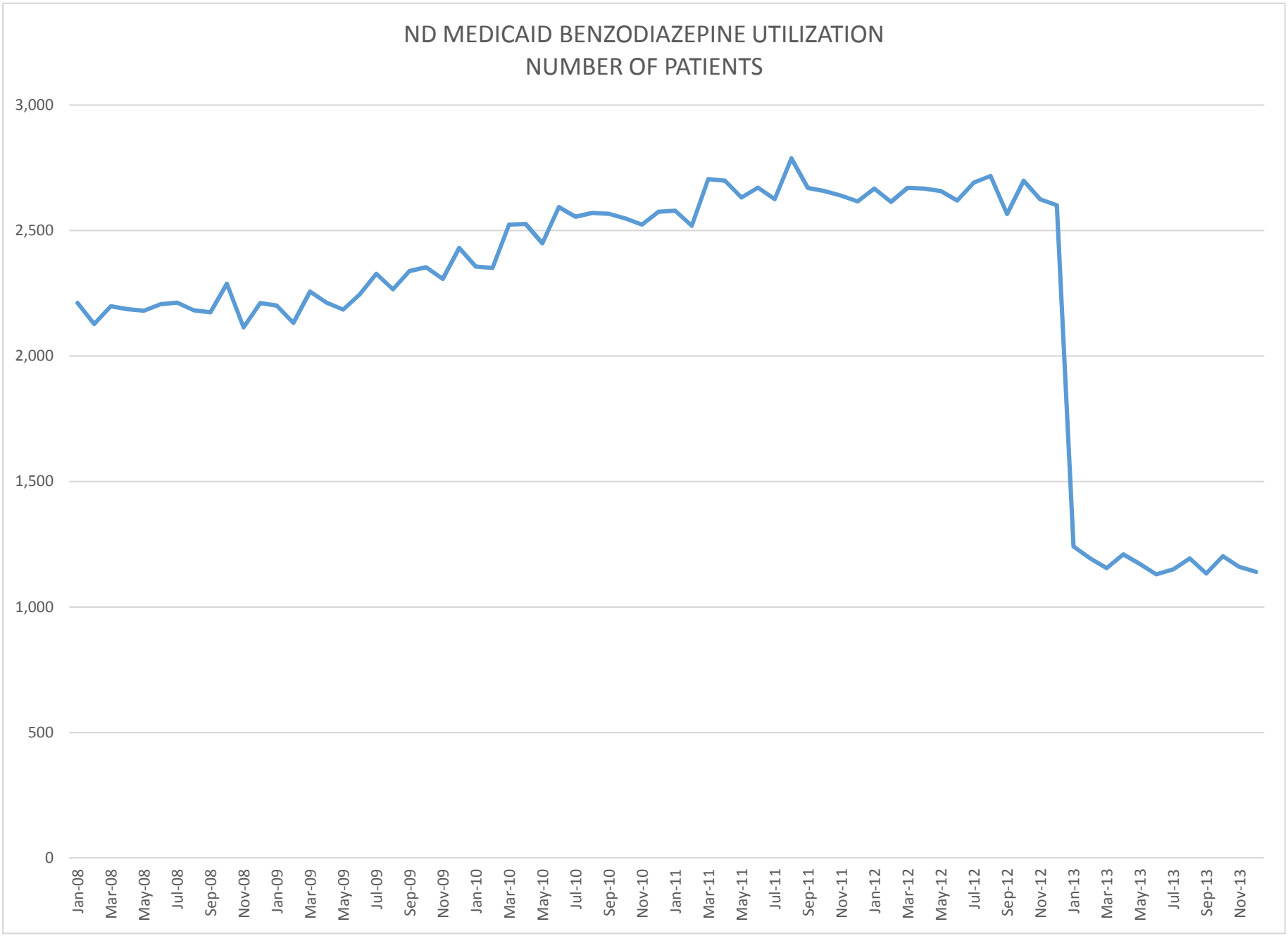
PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

ND Medicaid Benzodiazepine Utilization			
06/01/13 - 05/31/14			
Label Name	**Rx Num**	**Total Reimb Amt**	**Average Cost per Script**
ALPRAZOLAM 0.25 MG TABLET	631	$4,575.18	$7.25
ALPRAZOLAM 0.5 MG TABLET	1598	$11,264.32	$7.05
ALPRAZOLAM 1 MG TABLET	1515	$11,706.03	$7.73
ALPRAZOLAM 2 MG TABLET	181	$2,603.02	$14.38
ALPRAZOLAM ER 0.5 MG TABLET	6	$92.75	$15.46
ALPRAZOLAM ER 1 MG TABLET	9	$158.41	$17.60
ALPRAZOLAM ER 2 MG TABLET	15	$523.31	$34.89
ALPRAZOLAM ER 3 MG TABLET	13	$386.00	$29.69
ALPRAZOLAM XR 0.5 MG TABLET	1	$16.69	$16.69
ALPRAZOLAM XR 1 MG TABLET	6	$118.50	$19.75
ALPRAZOLAM XR 2 MG TABLET	15	$428.68	$28.58
ALPRAZOLAM XR 3 MG TABLET	1	$34.78	$34.78
ATIVAN 0.5 MG TABLET	3	$5.39	$1.80
CHLORDIAZEPOXIDE 10 MG CAPSULE	12	$122.78	$10.23
CHLORDIAZEPOXIDE 25 MG CAPSULE	26	$273.79	$10.53
CHLORDIAZEPOXIDE 5 MG CAPSULE	2	$21.80	$10.90
CLONAZEPAM 0.125 MG DIS TAB	32	$137.15	$4.29
CLONAZEPAM 0.25 MG ODT	41	$114.40	$2.79
CLONAZEPAM 0.5 MG DIS TABLET	49	$410.16	$8.37
CLONAZEPAM 0.5 MG TABLET	2478	$18,188.70	$7.34
CLONAZEPAM 1 MG DIS TABLET	5	$33.20	$6.64
CLONAZEPAM 1 MG TABLET	2541	$20,966.77	$8.25
CLONAZEPAM 2 MG TABLET	384	$3,121.88	$8.13
CLORAZEPATE 3.75 MG TABLET	60	$680.06	$11.33
CLORAZEPATE 7.5 MG TABLET	48	$448.33	$9.34
DIASTAT 2.5 MG PEDI SYSTEM	7	$1,618.75	$231.25
DIASTAT ACUDIAL 12.5-15-20 MG	4	$832.27	$208.07
DIASTAT ACUDIAL 5-7.5-10 MG KT	54	$13,811.67	$255.77
DIAZEPAM 10 MG RECTAL GEL SYST	104	$21,588.96	$207.59
DIAZEPAM 10 MG TABLET	330	$2,602.70	$7.89
DIAZEPAM 2 MG TABLET	129	$738.42	$5.72
DIAZEPAM 2.5 MG RECTAL GEL SYS	30	$6,581.88	$219.40
DIAZEPAM 20 MG RECTAL GEL SYST	9	$2,220.84	$246.76
DIAZEPAM 5 MG TABLET	682	$4,655.63	$6.83
DIAZEPAM 5 MG/5 ML SOLUTION	180	$3,885.52	$21.59
ESTAZOLAM 1 MG TABLET	2	$62.44	$31.22
ESTAZOLAM 2 MG TABLET	6	$82.81	$13.80
FLURAZEPAM 15 MG CAPSULE	5	$60.10	$12.02
FLURAZEPAM 30 MG CAPSULE	22	$207.02	$9.41
LORAZEPAM 0.5 MG TABLET	1706	$12,281.59	$7.20
LORAZEPAM 1 MG TABLET	2646	$19,062.81	$7.20
LORAZEPAM 2 MG TABLET	341	$3,617.22	$10.61
LORAZEPAM 2 MG/ML ORAL CONCENT	150	$6,324.80	$42.17
MIDAZOLAM HCL 10 MG/2 ML VIAL	1	$6.27	$6.27

ND Medicaid Benzodiazepine Utilization			
06/01/13 - 05/31/14			
Label Name	**Rx Num**	**Total Reimb Amt**	**Average Cost per Script**
MIDAZOLAM HCL 2 MG/ML SYRUP	2	$16.72	$8.36
MIDAZOLAM HCL 5 MG/ML VIAL	2	$20.70	$10.35
ONFI 10 MG TABLET	44	$15,473.24	$351.66
ONFI 2.5 MG/ML SUSPENSION	22	$6,568.44	$298.57
ONFI 20 MG TABLET	22	$12,549.97	$570.45
ONFI 5 MG TABLET	8	$675.39	$84.42
OXAZEPAM 15 MG CAPSULE	3	$48.99	$16.33
TEMAZEPAM 15 MG CAPSULE	175	$1,516.85	$8.67
TEMAZEPAM 22.5 MG CAPSULE	11	$304.17	$27.65
TEMAZEPAM 30 MG CAPSULE	276	$2,436.51	$8.83
TEMAZEPAM 7.5 MG CAPSULE	1	$170.60	$170.60
TRIAZOLAM 0.25 MG TABLET	52	$922.82	$17.75
XANAX 0.5 MG TABLET	1	$2.07	$2.07
3,193 recipients	**16704**	**$217,380.25**	


ND MEDICAID BENZODIAZEPINE UTILIZATION
NUMBER OF PATIENTS
3,000
2,500
2,000
1,500
1,000
500
0
Jan-08
Mar-08
May-08
Jul-08
Sep-08
Nov-08
Jan-09
Mar-09
May-09
Jul-09
Sep-09
Nov-09
Jan-10
Mar-10
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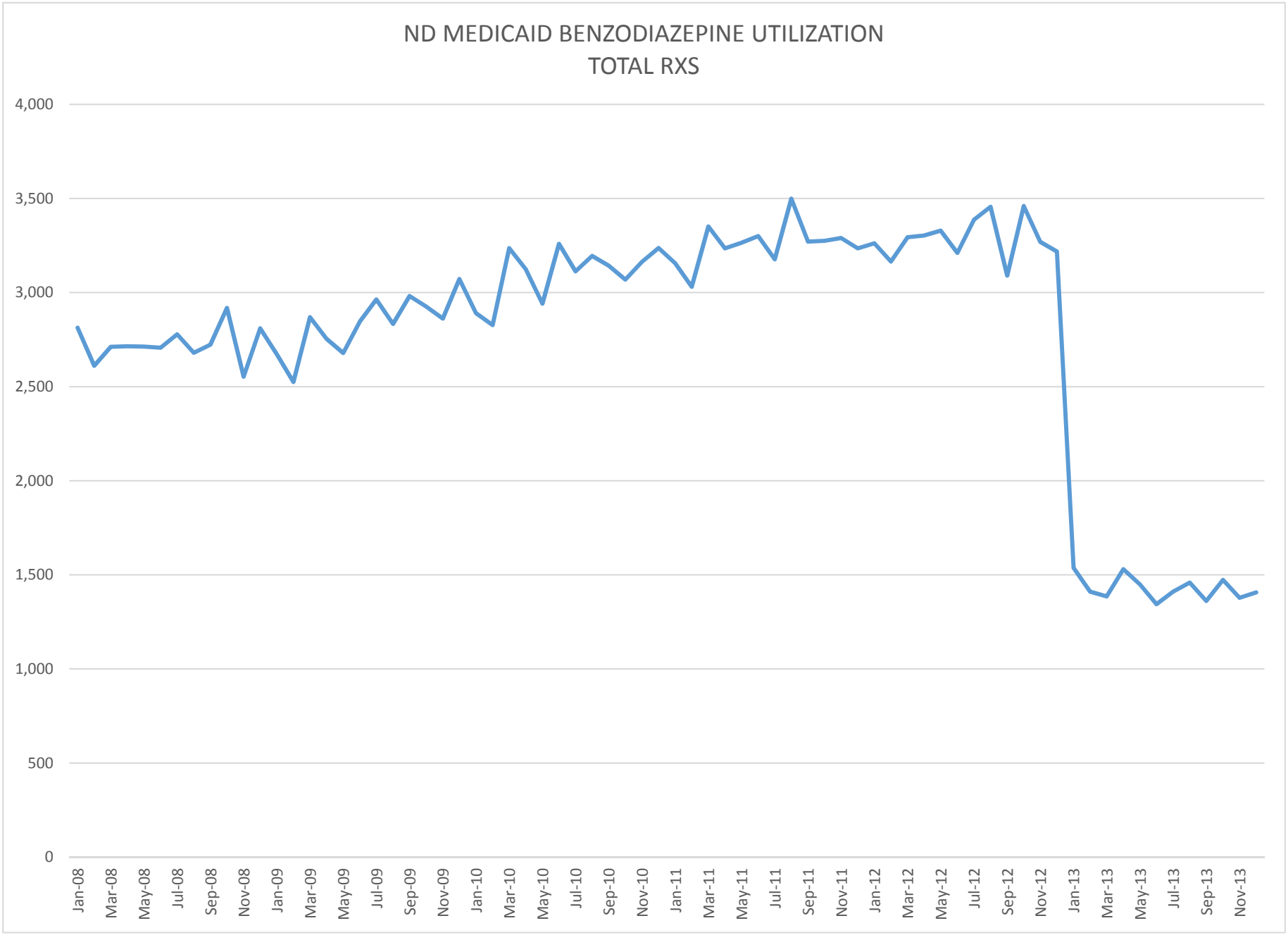
ND MEDICAID BENZODIAZEPINE UTILIZATION
TOTAL RXS
4,000
3,500
3,000
2,500
2,000
1,500
1,000
500
0
Jan-08
Mar-08
May-08
Jul-08
Sep-08
Nov-08
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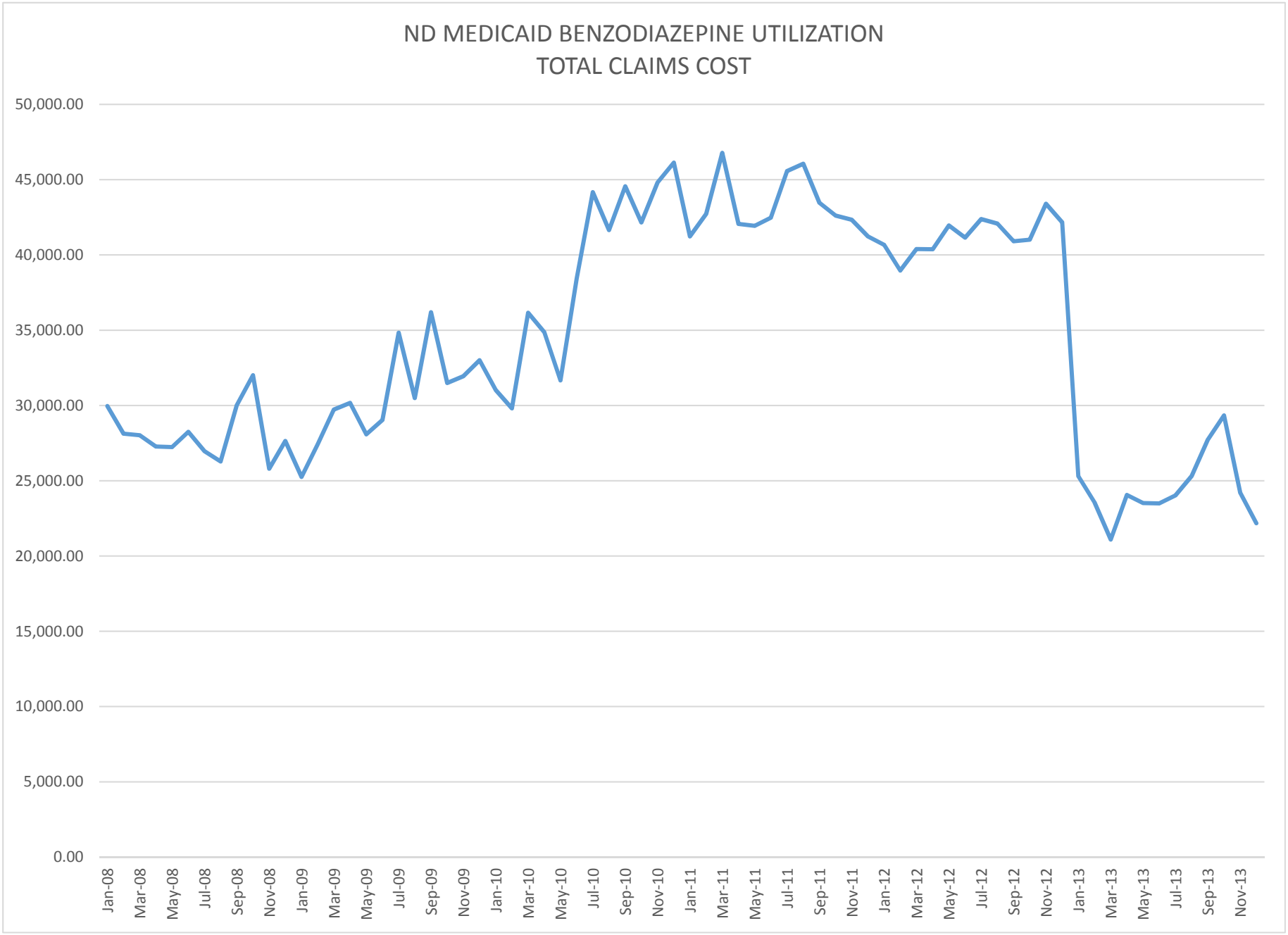
Nov-13


ND MEDICAID BENZODIAZEPINE UTILIZATION
TOTAL CLAIMS COST
50,000.00
45,000.00
40,000.00
35,000.00
30,000.00
25,000.00
20,000.00
15,000.00
10,000.00
5,000.00
0.00
Jan-08
Mar-08
May-08
Jul-08
Sep-08
Nov-08
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Nov-13

PRODUCT DETAILS OF TRANSDERMAL ANDROGENS

INDICATIONS AND USE: Transdermal androgens are indicated for the management of male hypogonadism. Hypogonadism is a defect of the reproductive system which results in a lack of function of the gonads (testes). It can be categorized by the level of the reproductive system that is defective. Primary hypogonadism results from a defect of the gonads while secondary hypogonadism (hypogonadotropic hypogonadism) results from defects in the hypothalamus or pituitary.

DOSAGE FORMS: Transdermal androgens are available as patches, gels, and solutions.

ADMINISTRATION:

- AndroGel 1% – initial, 50 mg once daily in the morning; maintenance, 50 to 100 mg/day.
- AndroGel 1.62% – initial, 40.5 mg applied topically once daily in the morning; maintenance, 20.25 to 81 mg/day.
- Androderm – initial, 4 mg/day applied nightly for 24 hours; maintenance, 2 to 6 mg/day applied at night.
- Fortesta – initial, 40 mg applied once daily in the morning; maintenance, 10 to 70 mg/day.
- Testim – initial, 5 g once daily; maintenance, 5 to 10 g/day.
- Axiron – initial, 60 mg applied once daily in the morning; maintenance, 30 to 120 mg/day.
- Vogelxo – initial, 50 mg applied topically once daily; maintenance 50 to 100 mg/day.

SPECIAL POPULATIONS:

- Safety and efficacy in patients younger than 18 years have not been established.

WARNINGS AND PRECAUTIONS:

- Black Box Warning – Virilization has been reported in children who were secondarily exposed to transdermal testosterone. Ensure that children avoid contact with unwashed or unclothed application sites in men using transdermal testosterone.
- Monitor patients with benign prostatic hyperplasia (BPH) for worsening signs and symptoms.
- Venous thromboembolism (VTE), including deep vein thrombosis (DVT) and pulmonary embolism (PE) have been reported in patients using testosterone products.
- Exogenous administration of androgens may lead to azoospermia.
- Edema, with or without congestive heart failure, may be a complication in patients with preexisting cardiac, renal, or hepatic disease.
- Sleep apnea may occur in those with risk factors.
- Monitor serum testosterone, prostate specific antigen (PSA), hematocrit, hemoglobin, liver function, and lipid concentrations periodically.

ADVERSE REACTIONS: Most common adverse reactions (incidences ≥ 5%) are acne, application site reaction, abnormal lab tests, and prostatic disorders.

PATIENT COUNSELING INFORMATION:

- Men with known or suspected carcinoma of the breast or prostrate should not use testosterone gel.
- Know signs and symptoms of secondary exposure in children and women.
- Wash hands with soap and water after application.
- Cover the application site with clothing after the gel has dried.
- Wash the application site thoroughly with soap and water prior to any situation where skin-to-skin contact of the application site with another person is anticipated.
- Testosterone gel is an alcohol-based product and is flammable; therefore, avoid fire, flame, or smoking until the gel has dried.
- Be aware of the potential adverse reactions with androgens: changes in urinary habits, breathing disturbances, too frequent or persistent erections of the penis, nausea, vomiting, changes in skin color, or ankle swelling.
- Wait 2 hours before swimming or washing following application.

UTILIZATION:

ND Medicaid Testosterone Utilization			
06/01/13 - 05/31-14			
Label Name	**Rx Num**	**Total Reimb Amt**	**Avg Cost per Script**
ANDROGEL 1% GEL PUMP	10	$3,968.45	$396.85
ANDROGEL 1%(2.5G) GEL PACKET	4	$5,326.42	$1,331.61
ANDROGEL 1%(5G) GEL PACKET	2	$844.38	$422.19
ANDROGEL 1.62% GEL PUMP	31	$14,585.16	$470.49
ANDROGEL 1.62%(2.5G) GEL PCKT	5	$1,921.45	$384.29
AXIRON 30 MG/ACTUATION SOLN	3	$1,278.27	$426.09
DEPO-TESTOSTERONE 200 MG/ML	19	$843.26	$44.38
METHITEST 10 MG TABLET	3	$118.05	$39.35
TESTIM 1% (50MG) GEL	3	$1,204.77	$401.59
TESTOSTERON CYP 2,000 MG/10 ML	20	$1,402.90	$70.15
26 recipients	**100**	**$31,493.11**	

References:

1. Vogelxo [package insert]. Maple Grove, MN: Upsher-Smith Laboratories, Inc.; June 2014.
2. Axiron [package insert]. Indianapolis, IN: Lilly USA, LLC: June 2014.
3. Fortesta [package insert]. Malvern, PA: Endo Pharmaceuticals, Inc.; June 2014.
4. Androderm [package insert]. Parsippany, NY: Watson; November 2013.
5. Androgel [package insert]. North Chicago, IL: AbbVie, Inc.; June 2014.
6. Testim [package insert]. Chesterbrook, PA: Auxilium Pharmaceuticals, Inc.; June 2014.

PRODUCT DETAILS OF PHOSPHATE BINDERS

INDICATIONS AND USE: The mainstay of therapy for patients with chronic kidney disease (CKD) unable to excrete phosphate is dietary restriction of phosphate. However, high concentrations of phosphorous are found in many foods including dairy products, nuts, and meat. Consequently, most patients with chronic kidney disease (CKD) will require a phosphate-binding medication. Maintaining serum phosphorus levels of 2.7 to 4.6 mg/dL in patients who are not receiving dialysis and 3.5 to 5.5 mg/dL in those receiving dialysis is generally considered a clinically acceptable outcome of treatment with phosphate binders.

Drug	Indication
Calcium acetate (Phoslo, Eliphos, others)	To reduce serum phosphate in patients with end-stage renal disease (ESRD).
Lanthanum carbonate (Fosrenol)	To reduce serum phosphate in patients with end-stage renal disease (ESRD).
Sevelamer hydrochloride (Renagel)	Control of serum phosphorous levels in patients with CKD on dialysis.
Sevelamer carbonate (Renvela)	Control of serum phosphorous levels in patients with CKD on dialysis.
Sucroferric oxyhydroxide (Velphoro)	Control of serum phosphorous levels in patients with CKD on dialysis.

DOSAGE FORMS: Phosphate binders are available in capsules, solution, tablets, suspension, and chewable tablets.

ADMINISTRATION:

- Calcium acetate – 1334 mg three times daily with meals
- Lanthanum carbonate – 500 mg three times daily with meals
- Sevelamer hydrochloride – 800 to 1600 mg three times daily with meals
- Sevelamer carbonate – 800 to 1600 mg three times daily with meals
- Sucroferric oxyhydroxide – 500 mg three times daily with meals.

SPECIAL POPULATIONS:

- Safety and efficacy have not been established in pediatric patients.
- Pregnancy category B (sucroferric oxyhydroxide)
- Pregnancy category C (sevelamer, lanthanum, calcium acetate)

WARNINGS AND PRECAUTIONS:

- Patients with peritonitis during peritoneal dialysis, significant gastric or hepatic disorders, following major gastrointestinal surgery, or with a history of hemochromatosis or other diseases with iron accumulation have not been included in clinical studies with sucroferric oxyhydroxide. Monitor effect and iron homeostasis.

- Serious cases of dysphagia, bowel obstruction, and perforation have been associated with sevelamer use, some requiring hospitalization and surgery.
- Chew or crush lanthanum carbonate completely to reduce the risk of serious adverse effects.
- Serious cases of gastrointestinal obstruction, ileus, and fecal impaction have been associated with lanthanum use, some requiring surgery or hospitalization. Risk factors include altered gastrointestinal anatomy, hypomotility disorders and concomitant medications.
- Lanthanum has radio-opaque properties and therefore may give the appearance typical of an imaging agent during abdominal X-ray procedures.
- Patients with end stage renal disease (ESRD) may develop hypercalcemia while treated with calcium. Monitor calcium levels regularly.

ADVERSE REACTIONS: Most common adverse reactions include discolored feces, diarrhea, hypercalcemia (calcium acetate), nausea, vomiting, and abdominal pain.

PATIENT COUNSELING INFORMATION:

- Take with or immediately after meals.
- Chew or crush completely before swallowing (lanthanum carbonate)
- Report new onset or worsening of existing constipation promptly to a physician.
- Tablets must be chewed and not swallowed whole (sucroferric oxyhydroxide)

UTILIZATION:

ND Medicaid Phosphate-Binder Utilization			
06/01/13 - 05/31/14			
Label Name	**Rx Num**	**Total Remb Amt**	**Avg Cost per Script**
CALCIUM ACETATE 667 MG CAPSULE	108	$10,215.64	$94.59
CALCIUM ACETATE 667 MG GELCAP	4	$403.49	$100.87
CALCIUM ACETATE 667 MG TABLET	6	$452.04	$75.34
FOSRENOL 1,000 MG TABLET CHEW	14	$11,177.29	$798.38
FOSRENOL 500 MG TABLET CHEW	3	$4,635.33	$1,545.11
RENAGEL 800 MG TABLET	15	$23,520.88	$1,568.06
RENVELA 0.8 GM POWDER PACKET	1	$346.20	$346.20
RENVELA 800 MG TABLET	79	$36,397.23	$460.72
36 recipients	**230**	**$87,148.10**	

References:

1. Velphoro [package insert]. Waltham, MA: Fresenius Medical Care North America; December 2013.
2. Renagel [package insert]. Cambridge, MA: Genzyme: May 2011.
3. Renvela [package insert]. Cambridge, MA: Genzyme; May 2011.
4. Fosrenol [package insert]. Wayne, PA: Shire US, Inc.; October 2012.

PRODUCT DETAILS OF ZONTIVITY (VORAPAXAR)

INDICATIONS AND USE: Zontivity is a protease-activated receptor-1 (PAR-1) antagonist indicated for the reduction of thrombotic cardiovascular events in patients with a history of myocardial infarction (MI) or with peripheral arterial disease (PAD). Zontivity has been shown to reduce the rate of a combined endpoint of cardiovascular death, MI, stroke, and urgent coronary revascularization.

DOSAGE FORMS: Zontivity is available as 2.08 mg tablets.

ADMINISTRATION: Take one tablet of Zontivity 2.08 mg orally once daily, with or without food. There is no experience with use of Zontivity alone as the only administered antiplatelet agent. Zontivity has been studied only as an addition to aspirin and/or clopidogrel. There is limited clinical experience with other antiplatelet drugs.

SPECIAL POPULATIONS:

- Zontivity is classified as pregnancy category B. There are no adequate and well-controlled studies of Zontivity use in pregnant women.
- It is unknown whether Zontivity or its metabolites are excreted in human milk, but it is actively secreted in milk of rats. Because many drugs are excreted in human milk, and because of the potential for serious adverse reactions in nursing infants from Zontivity, discontinue nursing or discontinue Zontivity.
- The safety and effectiveness of Zontivity in pediatric patients have not been established.
- Because older patients are generally at a higher risk of bleeding, consider patient age before initiating Zontivity.

WARNINGS AND PRECAUTIONS:

- Like other antiplatelet agents, Zontivity increases the risk of bleeding.
- Avoid use with strong CYP3A inhibitors or inducers.

ADVERSE REACTIONS:

- Black Box Warning-Do not use Zontivity in patients with a history of stroke, transient ischemic attack (TIA), intracranial hemorrhage (ICH), or active pathological bleeding.
- Bleeding, including life-threatening and fatal bleeding, is the most commonly reported adverse reaction.

PATIENT COUNSELING INFORMATION:

- Take medication exactly as prescribed.
- Do not discontinue Zontivity without discussing with the prescribing physician.
- Report any unanticipated, prolonged, or excessive bleeding, or blood in the stool or urine.
- Inform physicians and dentists of Zontivity use before surgery or dental procedures.

- List all prescription medications, over-the-counter medications, or dietary supplements they are taking or plan to take so that the physician knows about other treatments that may affect bleeding risk.

References:

1. Zontivity© [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; May 2014.

PRODUCT DETAILS OF EVZIO (NALOXONE HYDROCHLORIDE INJECTION)

INDICATIONS AND 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.

DOSAGE FORMS: Evzio is available as a 0.4mg/0.4mL naloxone hydrochloride solution in a pre-filled auto-injector.

ADMINISTRATION: Administer the initial dose of Evzio to adult or pediatric patients intramuscularly or subcutaneously into the anterolateral aspect of the thigh, through clothing if necessary, and seek emergency medical assistance. Administer Evzio as quickly as possible because prolonged respiratory depression may result in damage to the central nervous system or death. The requirement for repeat doses of Evzio depends upon the amount, type, and route of administration of the opioid being antagonized.

If the desired response is not obtained after 2 or 3 minutes, another Evzio dose may be administered. If there is still no response and additional doses are available, additional Evzio doses may be administered every 2 to 3 minutes until emergency medical assistance arrives. Additional supportive and/or resuscitative measures may be helpful while awaiting emergency medical assistance.

Reversal of respiratory depression by partial agonists or mixed agonist/antagonists, such as buprenorphine and pentazocine, may be incomplete or require higher doses of naloxone.

SPECIAL POPULATIONS:

- Evzio is classified as pregnancy category B. There are no adequate and well-controlled studies of Evzio in pregnant women.
- Exercise caution when Evzio is administered to a nursing woman.
- The safety and effectiveness of Evzio have been established in pediatric patients for known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression.
- Geriatric patients have a greater frequency of decreased hepatic, renal, or cardiac function and of concomitant disease or other drug therapy. Therefore, the systemic exposure of naloxone can be higher in these patients.

WARNINGS AND PRECAUTIONS:

- Due to the duration of action, keep the patient under continued surveillance and repeated doses of naloxone should be administered, as necessary, while awaiting emergency medical assistance.
- Other supportive and/or resuscitative measures may be helpful while awaiting emergency medical assistance.

- Reversal of respiratory depression by partial agonists or mixed agonists/ antagonists, such as buprenorphine and pentazocine, may be incomplete.
- Use in patients who are opioid dependent may precipitate acute abstinence syndrome.
- Patients with pre-existing cardiac disease or patients who have received medications with potential adverse cardiovascular effects should be monitored in an appropriate healthcare setting.
- In neonates, opioid withdrawal may be life-threatening if not recognized and properly treated.

ADVERSE REACTIONS: The following adverse reactions have been identified during use of naloxone hydrochloride in the post-operative setting: Hypotension, hypertension, ventricular tachycardia and fibrillation, dyspnea, pulmonary edema, and cardiac arrest. Death, coma, and encephalopathy have been reported as sequelae of these events. Excessive doses of naloxone hydrochloride in post-operative patients have resulted in significant reversal of analgesia and have caused agitation.

Abrupt reversal of opioid effects in persons who were physically dependent on opioids has precipitated signs and symptoms of opioid withdrawal including: body aches, fever, sweating, runny nose, sneezing, piloerection, yawning, weakness, shivering or trembling, nervousness, restlessness or irritability, diarrhea, nausea or vomiting, abdominal cramps, increased blood pressure, tachycardia. In the neonate, opioid withdrawal signs and symptoms also included: convulsions, excessive crying, hyperactive reflexes.

PATIENT COUNSELING INFORMATION:

- Become familiar with the Evzio instructions for use.
- Practice using the trainer before Evzio is needed.
- Each Evzio can only be used one time; however, the trainer (which is black and white) can be re-used for training purposes and its red safety guard can be removed and replaced.
- Make sure Evzio is present whenever persons may be intentionally or accidentally exposed to an opioid to treat serious opioid overdose (i.e., opioid emergencies).
- Instruct the patients and their family members or caregivers how to recognize the signs and symptoms of an opioid overdose requiring the use of Evzio.
- When in doubt, if a patient is unresponsive, and an opioid overdose is suspected, administer Evzio as quickly as possible because prolonged respiratory depression may result in damage to the central nervous system or death.
- Seek emergency medical assistance after administering the first dose of Evzio.

References:

1. Evzio [package insert]. Richmond, VA: Kaleo, Inc.; April 2014.

NORTH DAKOTA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
3RD QUARTER 2014

Criteria Recommendations ***Approved Rejected***

1. Eslicarbazepine / Overutilization _____ _____

Alert Message: The manufacturer's maximum recommended dose of Aptiom (eslicarbazepine) is 1200 mg once daily (after a minimum of one week at 800 mg once daily). This dosage is associated with an increase in adverse reactions.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Eslicarbazepine		CKD Stage 3, 4 & 5
		ESRD

Max Dose: 1200 mg/day

References:
Aptiom Prescribing Information, Nov. 2013, Sunovion.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

2. Eslicarbazepine / Overutilization – Moderate & Severe Renal Impairment _____ _____

Alert Message: The manufacturer's maximum recommended dose of Aptiom (eslicarbazepine) in patients with moderate to severe renal impairment is 600 mg once daily. These patients should be titrated starting at 200 mg once daily and after two weeks, increase dosage to 400 mg once daily, which is the recommended maintenance dosage.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Eslicarbazepine		CKD Stage 3, 4 & 5
		ESRD

Max Dose: 600 mg/day

References:
Aptiom Prescribing Information, Nov. 2013, Sunovion.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

3. Eslicarbazepine / Non-adherence _____ _____

Alert Message: Based on refill history, your patients may be under-utilizing Aptiom (eslicarbazepine). Non-adherence to the prescribed dosing regimen may result in sub-therapeutic effects, which may lead to decreased patient outcomes and additional healthcare costs.

Conflict Code: LR – Non-adherence
Drugs/Diseases

Util A	Util B	Util C
Eslicarbazepine		

References:
Aptiom Prescribing Information, Nov. 2013, Sunovion.
Faught E, Duh MS, Weiner JR., Nonadherence to Antiepileptic Drugs and Increased Mortality. Neurology. 2008; 71(20):1572-1578.
Faught ER, Weiner JR, Guerin A, et al. Impact of Nonadherence to Antiepileptic Drugs on Health Care Utilization and Costs: Findings from the RANSOM Study. Epilepsia 2009;50(3):501-509.

4. Eslicarbazepine / Therapeutic Appropriateness _____ _____

Alert Message: Aptiom (eslicarbazepine) can cause clinically significant, and in some cases, serious, life-threatening hyponatremia. Measurement of serum sodium and chloride levels should be considered during maintenance treatment with eslicarbazepine, particularly if the patient is receiving medications known to decrease serum sodium levels.

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Eslicarbazepine		

References:
Aptiom Prescribing Information, Nov. 2013, Sunovion.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

5. Eslicarbazepine / Therapeutic Appropriateness _____ _____

Alert Message: Serious dermatologic reactions including Steven-Johnson Syndrome (SJS) have been reported in association with Aptiom (eslicarbazepine) use. If a patient develops a dermatologic reaction while taking eslicarbazepine, discontinue eslicarbazepine, unless the reaction is clearly not drug-related.

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Eslicarbazepine		

References:
Aptiom Prescribing Information, Nov. 2013, Sunovion.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

6. Eslicarbazepine / Jaundice _____ _____

Alert Message: Aptiom (eslicarbazepine) can cause liver injury and baseline evaluations of liver laboratory tests are recommended. Eslicarbazepine should be discontinued in patients with jaundice or other evidence of significant liver injury (e.g., laboratory evidence).

Conflict Code: MC – Drug (Actual) Disease Precaution/Warning
Drugs/Diseases

Util A	Util B	Util C
Eslicarbazepine	Jaundice	

References:
Aptiom Prescribing Information, Nov. 2013, Sunovion.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

7. Eslicarbazepine / Oral Hormonal Contraceptives _____ _____

Alert Message: Concurrent use of Aptiom (eslicarbazepine) with oral hormonal contraceptives (OC) may result in decreased plasma levels of the OC and loss of contraceptive efficacy. Females of reproductive potential should use additional or alternative non-hormonal birth control.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases

Util A	Util B	Util C
Eslicarbazepine	Hormonal Oral Contraceptives	

Gender: Females
Age: 11-55 yoa

References:
Aptiom Prescribing Information, Nov. 2013, Sunovion.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

8. Eslicarbazepine / Warfarin _____ _____

Alert Message: Concurrent use of Aptiom (eslicarbazepine) with warfarin may result in decreased warfarin plasma concentrations. Patients receiving concurrent therapy with these agents should have INR monitored, particularly during eslicarbazepine initiation or upon discontinuation of concomitant therapy.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases

Util A	Util B	Util C
Eslicarbazepine	Warfarin	

References:
Aptiom Prescribing Information, Nov. 2013, Sunovion.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

9. Eslicarbazepine / Carbamazepine _____ _____

Alert Message: Concurrent use of Aptiom (eslicarbazepine) with carbamazepine may require dosage adjustment of one or both drugs, based on efficacy and tolerability. Both agents increase the clearance of the other. The agents are also chemically related and concomitant use has been shown to increase the incidence of adverse reactions.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases

Util A	Util B	Util C
Eslicarbazepine	Carbamazepine	

References:
Aptiom Prescribing Information, Nov. 2013, Sunovion.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

10. Eslicarbazepine / Phenytoin _____ _____

Alert Message: Concurrent use of Aptiom (eslicarbazepine) with phenytoin may require dosage adjustment of one or both agents. Phenytoin may induce eslicarbazepine metabolism decreasing plasma concentrations while eslicarbazepine may inhibit phenytoin metabolism increasing phenytoin concentrations. Phenytoin plasma concentrations should be monitored during concurrent therapy and dose adjustment made based on clinical response and serum levels.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases

Util A	Util B	Util C
Eslicarbazepine	Phenytoin	

References:
Aptiom Prescribing Information, Nov. 2013, Sunovion.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

11. Eslicarbazepine / Phenobarbital & Primidone _____ _____

Alert Message: Concurrent use of Aptiom (eslicarbazepine) with phenobarbital or primidone may require an increase in the eslicarbazepine dose. Phenobarbital and primidone may induce eslicarbazepine metabolism decreasing plasma concentrations.

Conflict Code: DD – Drug/Drug Interaction

Drugs/Diseases

Util A	Util B	Util C
Eslicarbazepine	Phenobarbital Primidone	

References:
Aptiom Prescribing Information, Nov. 2013, Sunovion.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

12. Eslicarbazepine / Simvastatin & Rosuvastatin _____ _____

Alert Message: Concurrent use of Aptiom (eslicarbazepine) with either simvastatin or rosuvastatin may result in decreased systemic exposure of the statin due to inhibition, by eslicarbazepine, of statin CYP3A4-mediated metabolism. Dose adjustment of simvastatin or rosuvastatin may be needed, if clinically significant changes in serum lipids are noted.

Conflict Code: DD – Drug/Drug Interaction

Drugs/Diseases

Util A	Util B	Util C
Eslicarbazepine	Simvastatin Rosuvastatin	

References:
Aptiom Prescribing Information, Nov. 2013, Sunovion.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

13. Eslicarbazepine / Oxcarbazepine _____ _____

Alert Message: Aptiom (eslicarbazepine) should not be taken as an adjunctive therapy with oxcarbazepine. Eslicarbazepine is a prodrug for the active metabolite of oxcarbazepine and concurrent use may result in increased active metabolite levels.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases

Util A	Util B	Util C
Eslicarbazepine	Oxcarbazepine	

References:
Aptiom Prescribing Information, Nov. 2013, Sunovion.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

14. Tolvaptan / Liver Disease _____ _____

Alert Message: Samsca (tolvaptan) can cause serious and potentially fatal liver injury. The use of tolvaptan should be avoided in patients with underlying liver disease, including cirrhosis, because the ability to recover from liver injury may be impaired.

Conflict Code: MC – Drug (Actual) Disease Precaution
Drugs/Diseases

Util A	Util B	Util C
Tolvaptan	Cirrhosis	
	Necrosis of Liver	
	Hepatitis	
	Liver Disorders	

References:
Clinical Pharmacology, 2014 Elsevier/Gold Standard.
Facts & Comparisons, 2014 Updates, Wolters Kluwer Healthcare.
Samsca Prescribing Information, Feb. 2014, Otsuka Pharmaceuticals Co., Ltd.

15. Tolvaptan / Therapeutic Appropriateness – Duration _____ _____

Alert Message: Samsca (tolvaptan) should not be administered for more than 30 days to minimize the risk of liver injury.

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Tolvaptan		

Day Supply: > 30 days

References:
Clinical Pharmacology, 2014 Elsevier/Gold Standard.
Facts & Comparisons, 2014 Updates, Wolters Kluwer Healthcare.
Samsca Prescribing Information, Feb. 2014, Otsuka Pharmaceuticals Co., Ltd.

16. ARBs / Lithium _____ _____

Alert Message: Concurrent use of lithium with an angiotensin II receptor antagonist (ARB) may result in substantially increased steady-state plasma lithium levels, sometimes resulting in lithium toxicity. If concurrent use is required, monitor lithium concentrations and adjust lithium dosage as needed.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases

Util A	Util B	Util C
Losartan	Lithium	
Valsartan		
Candesartan		
Eprosartan		
Irbesartan		
Olmesartan		
Telmisartan		
Azilsartan		

References:
Clinical Pharmacology, 2014 Elsevier/Gold Standard.
Facts & Comparisons, 2014 Updates, Wolters Kluwer Healthcare.

17. Econazole / Warfarin _____ _____

Alert Message: Concurrent use of econazole 1% cream or foam with warfarin has resulted in enhanced anticoagulant effect. Most cases reported product application with the use under occlusion, genital application or application to large body surface area which may increase the systemic absorption of econazole. If concomitant therapy is clinically indicated, monitor INR and/or prothrombin time especially for patients who apply econazole to large body surface area, or under occlusion.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases

Util A	Util B	Util C
Econazole	Warfarin	

References:
Clinical Pharmacology, 2014 Elsevier/Gold Standard.
Micromedex DrugDex Drug Evaluations, 2014 Truven Health Analytics, Inc.
Spectazole 1% Topical Cream Feb. 2014, Merz Pharmaceuticals LLC.
Facts & Comparisons, 2014 Updates, Wolters Kluwer Health.

18. Ketoconazole / Disopyramide _____ _____

Alert Message: Concurrent use of ketoconazole and disopyramide is contraindicated due to risk of serious cardiovascular adverse events including QT prolongation. Disopyramide is a CYP3A4 substrate and use with the potent CYP3A4 inhibitor ketoconazole may result in elevated disopyramide plasma concentrations and associated toxicity.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases

Util A	Util B	Util C
Ketoconazole	Disopyramide	

References:
Clinical Pharmacology, 2014 Elsevier/Gold Standard.
Nizoral Prescribing Information, Feb. 2014, Janssen Pharmaceuticals, Inc.

19. Ketoconazole / Colchicine _____ _____

Alert Message: Concurrent use of ketoconazole and colchicine is contraindicated due to risk of colchicine toxicity. Colchicine is a CYP3A4 substrate and use with the potent CYP3A4 inhibitor ketoconazole may result in elevated colchicine plasma concentrations and associated toxicity.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases

Util A	Util B	Util C
Ketoconazole	Colchicine	

References:
Clinical Pharmacology, 2014 Elsevier/Gold Standard.
Nizoral Prescribing Information, Feb. 2014, Janssen Pharmaceuticals, Inc.

20. Ketoconazole / Felodipine & Nisoldipine _____ _____

Alert Message: Concurrent use of ketoconazole with felodipine or nisoldipine is contraindicated due to risk of calcium channel blocker (CCB) negative inotropic effects. Felodipine and nisoldipine are CYP3A4 substrates and use with the potent CYP3A4 inhibitor ketoconazole may result in increased CCB plasma concentrations and risk of edema and congestive heart failure.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases

Util A	Util B	Util C
Ketoconazole	Nisoldipine Felodipine	

References:
Clinical Pharmacology, 2014 Elsevier/Gold Standard.
Nizoral Prescribing Information, Feb. 2014, Janssen Pharmaceuticals, Inc.

21. Dapagliflozin / Overutilization _____ _____

Alert Message: The manufacturer's maximum recommended dose of Farxiga (dapagliflozin) is 10 mg once daily.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Dapagliflozin		Renal Impairment

Max Dose: 10mg/day

References:
Farxiga Prescribing Information, Jan. 2014, Bristol-Myers Squibb.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

22. Dapagliflozin / Moderate Renal impairment _____ _____

Alert Message: Assessment of renal function is recommended prior to initiation of Farxiga (dapagliflozin) therapy and periodically thereafter. Dapagliflozin should not be initiated in patients with an eGFR less than 60 mL/min/1.73m^2 and should be discontinued when eGFR is persistently less than 60mL/ min/1.73m^2.

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Dapagliflozin		CKD Stage 1, 2 & 3

References:
Farxiga Prescribing Information, Jan. 2014, Bristol-Myers Squibb.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

23. Dapagliflozin / Severe Renal Impairment, ESRD & Dialysis _____ _____

Alert Message: Farxiga (dapagliflozin) is contraindicated in patients with severe renal impairment, end-stage renal disease, or on dialysis. Based on its mechanism of action, inhibition of SGLT2 in the proximal renal tubules, dapagliflozin is not expected to be effective in these patients.

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Dapagliflozin		CKD Stage 4, & 5 End-Stage Renal Disease Dialysis

References:
Farxiga Prescribing Information, Jan. 2014, Bristol-Myers Squibb.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

24. Dapagliflozin / Nonadherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Farxiga (dapagliflozin). Non-adherence to the prescribed dosing regimen may result in sub-therapeutic effects, which may lead to decreased patient outcomes and additional healthcare costs.

Conflict Code: LR - Nonadherence
Drugs/Diseases

Util A	Util B	Util C
Dapagliflozin		

References:
Farxiga Prescribing Information, Jan. 2014, Bristol-Myers Squibb.
Osterberg L, Blaschke T. Adherence to medication. N Engl J Med 2005;353:487-97.
Ho PM, Rumsfeld JS, Masoudi FA, et al., Effect of Medication Nonadherence in Diabetes Mellitus. Cardiology Review, April 2007.
Currie CJ, Peyrot M, Morgan CL, et al. The Impact of Treatment Noncompliance on Mortality in People With Type 2 Diabetes. Diabetes Care 35:1279-1284, June 2012.

25. Dapagliflozin / Hypotension _____ _____

Alert Message: Farxiga (dapagliflozin) causes osmotic diurese which can lead to volume depletion and hypotension, particularly in patients with impaired renal function, elderly patients or patients on loop diuretics. Monitor patients for signs and symptoms during therapy. Before initiating dapagliflozin in patients with one or more of these characteristics, volume status should be assessed and corrected.

Conflict Code: MC – Drug (Actual) Disease Precaution/Warning
Drugs/Diseases

Util A	Util B	Util C
Dapagliflozin	Hypotension	
	Hypovolemia	
	CKD Stage 3	
	Dehydration	

References:
Farxiga Prescribing Information, Jan. 2014, Bristol-Myers Squibb.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

26. Dapagliflozin / Loop Diuretics _____ _____

Alert Message: Farxiga (dapagliflozin) causes osmotic diurese which can lead to volume depletion and hypotension, particularly in patients with impaired renal function, elderly patients or patients on loop diuretics. Monitor patients for signs and symptoms during therapy. Before initiating dapagliflozin in patients with one or more of these characteristics, volume status should be assessed and corrected.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases

Util A	Util B	Util C
Dapagliflozin	Furosemide	
	Torsemide	
	Ethacrynate	
	Bumetanide	

References:
Farxiga Prescribing Information, Jan. 2014, Bristol-Myers Squibb.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

27. Dapagliflozin / Insulin & Insulin Secretagogues _____ _____

Alert Message: The concurrent use of Farxiga (dapagliflozin) with insulin and insulin secretagogues can increase the risk of hypoglycemia. A lower dose of insulin or insulin secretagogue may be required to minimize the risk of hypoglycemia when used in combination with dapagliflozin.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases

Util A	Util B	Util C
Dapagliflozin	Insulins	
	Sulfonylureas	

References:
Farxiga Prescribing Information, Jan. 2014, Bristol-Myers Squibb.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

28. Dapagliflozin / LDL-C Increases _____ _____

Alert Message: The use of Farxiga (dapagliflozin) can cause dose-related increases in LDL-C levels. Patients receiving dapagliflozin should have their LDL-C levels monitored and treated per standard of care.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Dapagliflozin	Hypercholesterolemia	

References:
Farxiga Prescribing Information, Jan. 2014, Bristol-Myers Squibb.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

29. Dapagliflozin / Bladder Cancer _____ _____

Alert Message: An imbalance in bladder cancers was observed in Farxiga (dapagliflozin) clinical trials. Dapagliflozin should not be used in patients with active bladder cancer and used with caution in patients with a prior history of bladder cancer.

Conflict Code: MC – Drug (Actual) Disease Precaution/Warning
Drugs/Diseases

Util A	Util B	Util C
Dapagliflozin		Neoplasm of Bladder
		History of Malignant Neoplasm of Bladder

References:
Farxiga Prescribing Information, Jan. 2014, Bristol-Myers Squibb.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

30. SGLT2 Inhibitors / Therapeutic Duplication _____ _____

Alert Message: Therapeutic duplication of sodium-glucose co-transporter 2 (SGLT2) inhibitors may be occurring.

Conflict Code: TD – Therapeutic Duplication
Drugs/Diseases

Util A	Util B	Util C
Dapagliflozin		
Canagliflozin		

References:
Farxiga Prescribing Information, Jan. 2014, Bristol-Myers Squibb.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

31. Ketoconazole / Methadone _____ _____

Alert Message: Concurrent use of ketoconazole and methadone is contraindicated due to risk of serious cardiovascular adverse events including QT prolongation and respiratory and/or CNS depression. Methadone is a CYP3A4 substrate and use with the potent CYP3A4 inhibitor ketoconazole may result in elevated methadone plasma concentrations.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases

Util A	Util B	Util C
Ketoconazole	Methadone	

References:
Clinical Pharmacology, 2014 Elsevier/Gold Standard.
Nizoral Prescribing Information, Feb. 2014, Janssen Pharmaceuticals, Inc.

32. Testosterone / Venous Thrombosis _____ _____

Alert Message: There have been postmarketing reports of venous thromboembolism (VTE), including deep vein thrombosis (DVT) and pulmonary embolism (PE), in patients using testosterone products. The risk of venous clots is unrelated to polycythemia that can occur with testosterone therapy. Evaluate patients who report symptoms of pain, edema, warmth, and erythema in the lower extremity for DVT and those who present with acute shortness of breath for PE. If a VTE is suspected, discontinue testosterone treatment and initiate appropriate management.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Testosterone		

References:
Natesto Prescribing Information, May 2014, Trimel BioPharma SRL.
Vogelxo Prescribing Information, June 2014, Upsher-Smith Laboratories, Inc.
FDA Drug Safety and Availability: Testosterone Products: FDA/CDER Statement – Risk of Venous Blood Clots. [6-20-2014].

TABLED CRITERIA

1. ASCVD Inferring Drugs / High-Intensity Statin Therapy (Negating) _____ _____

Alert Message: The ACC/AHA Blood Cholesterol Guidelines recommend the use of high-intensity statin therapy, which lowers LDL-C at least 50%, to reduce atherosclerotic cardiovascular risk in adults 75 years of age and younger who have clinical ASCVD (e.g., CHD, stroke, and PAD), unless contraindicated. Moderate-intensity statin therapy should be used as a second-line option if high-intensity statin therapy is not tolerated. Refer to the ACC/AHA guidelines for agents and dosage.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Negating if High-Intensity Therapy Present)**
Nitrates		Atorvastatin 40mg & 80 mg
Cilostazol		Rosuvastatin 20 mg, 40 mg & 80 mg
Clopidogrel		
Prasugrel		
Ticagrelor		
Ticlopidine		
Dipyridamole/Aspirin		

Age Range: ≤ 75 yoa

References:
Stone NJ, Robinson J, Lichtenstein AH, et.al., 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults, Jrnl Am Coll Cardiol (2013), doi:10.1016/j.jacc.2013.11.002.