

DEPARTMENT OF HEALTH AND SOCIAL SERVICES
DIVISION OF MEDICAID AND MEDICAL ASSISTANCE
Statutory Authority: 31 Delaware Code, Section 512 (31 Del.C. §512)

PROPOSED

PUBLIC NOTICE

Covered Outpatient Drugs for the Categorically Needy – Nonprescription Drug Products

In compliance with the State's Administrative Procedures Act (APA - Title 29, Chapter 101 of the Delaware Code), 42 U.S.C., §1902(a)(13)(A) of the Social Security Act, 42 CFR §447.205, and under the authority of Title 31 of the Delaware Code, Chapter 5, Section 512, Delaware Health and Social Services (DHSS) / Division of Medicaid and Medical Assistance (DMMA) is proposing to amend the Delaware Title XIX Medicaid State Plan regarding Covered Outpatient Drugs for the Categorically Needy, specifically, *to clarify covered non-prescription drug products*.

Any person who wishes to make written suggestions, compilations of data, testimony, briefs or other written materials concerning the proposed new regulations must submit same to Kimberly Xavier, Planning, Policy and Quality Unit, Division of Medicaid and Medical Assistance, 1901 North DuPont Highway, P.O. Box 906, New Castle, Delaware 19720-0906, by email at Kimberly.xavier@state.de.us, or by fax to 302-255-4425 by August 31, 2016.

The action concerning the determination of whether to adopt the proposed regulation will be based upon the results of Department and Division staff analysis and the consideration of the comments and written materials filed by other interested persons.

SUMMARY OF PROPOSAL

The purpose of this notice is to advise the public that Delaware Health and Social Services (DHSS)/Division of Medicaid and Medical Assistance (DMMA) is proposing to amend the Title XIX Medicaid State Plan regarding Covered Outpatient Drugs for the Categorically Needy, specifically, *to clarify covered non-prescription drug products*.

Statutory Authority

- 1927(d)(2) of the Social Security Act, *Limitations on coverage of drugs, drugs subject to exclusion*
- 1935(d)(2) of the Social Security Act, *Coverage of certain excludable drugs*
- Center for Medicaid and CHIP Services (CMCS) Informational Bulletin 060116, *Medicaid Benefits Available for the Prevention, Detection and Response to the Zika Virus*
- Del.C., Title 29, Ch. 101, §10119, *Administrative Procedures, Emergency Regulations*

Background

Zika is a virus that is spread to people primarily through the bite of an infected, day-time active Aedes species mosquito. The Zika virus can also be sexually transmitted from a man to his partner(s) regardless of gender. The Centers for Disease Control and Prevention (CDC) urges that men at risk of or with recent Zika virus infection use condoms or abstain from sex to prevent transmission. The most common symptoms of Zika infection are fever, rash, joint pain, and conjunctivitis (red eyes). In past outbreaks, the illness has usually been mild with symptoms lasting for several days to a week after being bitten by an infected mosquito. People usually don't get sick enough to go to the hospital and they very rarely die of Zika infection. For this reason, many people might not realize they have been infected.

Zika virus infection during pregnancy can lead to serious health consequences. The CDC has stated that Zika virus can be passed from a pregnant woman to her fetus, and infection during pregnancy has been linked to a serious birth defect of the brain called microcephaly, which involves incomplete brain development, and other severe brain defects. Other problems have been detected in fetuses and infants infected with Zika virus, such as defects of the eye, hearing deficits, and impaired growth. A mother infected with the Zika virus near the time of delivery can pass on the virus to her newborn around the time of birth. Zika has also been linked to Guillain-Barré syndrome (GBS), a rare disorder that can cause muscle weakness and paralysis for a few weeks to several months. Most people fully recover from GBS, but some have permanent damage.

The Center for Medicaid and CHIP (CMCS) Services issued a CMCS Informational Bulletin 060116 on June 1, 2016 to inform Medicaid agencies and interested stakeholders about how Medicaid services and authorities can help states and territories prevent, detect, and respond to the Zika virus, including efforts to prevent the transmission and address health risks to beneficiaries from the Zika virus. Since there is no vaccine available for Zika, the major means of prevention currently available are mosquito control, protection against mosquito bites, and contraception for women of childbearing age who do not wish to become pregnant.

Mosquito repellents that are applied to the skin can aid in preventing infection of the Zika virus. CDC recommends

people use Environmental Protection Agency (EPA)-registered insect repellents. As a general matter, over the counter insect repellents would not be covered by Medicaid. However, state Medicaid programs may choose to cover mosquito repellents when prescribed by an authorized health professional and these products would be eligible for Federal Financial Participation (FFP) under such circumstances.

Summary of Proposal

Purpose

To amend the Medicaid State plan to allow DMMA to provide nonprescription drugs, such as mosquito repellent as a preventative measure to protect Medicaid beneficiaries against the Zika virus, when guidance is issued from CMCS.

Summary of Proposed Changes

Effective for services provided on and after July 1, 2016, Delaware Health and Social Services/Division of Medicaid and Medical Assistance (DMMA) proposes to amend Attachment 3.1.A.1 Page 2, 2a, and 2b of the Medicaid State Plan to ensure coverage of nonprescription drugs, such as mosquito repellent as a preventative measure to protect Medicaid beneficiaries against the Zika virus, when guidance is issued from CMCS.

The agency's proposal involves no change in the definition of those eligible to receive pharmaceutical services.

Public Notice

In accordance with the *federal* public notice requirements established at Section 1902(a)(13)(A) of the Social Security Act and 42 CFR 447.205 and the *state* public notice requirements of Title 29, Chapter 101 of the Delaware Code, Delaware Health and Social Services (DHSS)/Division of Medicaid and Medical Assistance (DMMA) gives public notice and provides an open comment period for thirty (30) days to allow all stakeholders an opportunity to provide input to the coverage of outpatient drugs for the categorically needy. Comments must be received by 4:30 p.m. on August 31, 2016.

CMS Review and Approval

The provisions of this draft state plan amendment (SPA) are subject to the Centers for Medicare and Medicaid Services (CMS) review and approval. The draft SPA page(s) may undergo further revisions before and after submittal to CMS based upon public comment and/or CMS feedback. The final version may be subject to significant change.

Provider Manual Update

Also, upon CMS approval, the applicable Delaware Medical Assistance Program (DMAP) Provider Policy Specific Manuals will be updated. Manual updates, revised pages or additions to the provider manual are issued, as required, for new policy, policy clarification, and/or revisions to the DMAP program. Provider billing guidelines or instructions to incorporate any new requirement may also be issued. A newsletter system is utilized to distribute new or revised manual material and to provide any other pertinent information regarding manual updates.

Fiscal Impact

The cost of including an Over the Counter (OTC) product to the drug benefit is evaluated based on cost of a legend product to the OTC. Products in this category will only be added if the coverage of the product will reduce the legend drug costs or is anticipated to reduce other medical costs. As an example, the cost of the 'drug' to prevent or reduce the chance of a mosquito bite will be under \$25 per prescription. DMMA does not anticipate a significant number of practitioners and clients utilizing their drug benefit for this coverage. The cost of product will be offset by the avoidance of the Zika laboratory test that has an estimated cost of \$200. The coverage of insect repellents that lead to the prevention of even one situation where the fetus is negatively impacted eliminates the financial risk to the program.

DMMA PROPOSED REGULATION #16-020

REVISION:

Attachment 3.1.A.1

Page 2

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

STATE: DELAWARE

LIMITATIONS ON AMOUNT, DURATION, AND SCOPE OF MEDICAL AND REMEDIAL CARE AND SERVICES

PROVIDED TO THE CATEGORICALLY NEEDY

Pursuant to 1927(d)(2) and 1935(d)(2) of the Social Security Act, the Medicaid Agency provides coverage for the following excluded or otherwise restricted drugs or classes of drugs, or their medical uses to all Medicaid recipients, including full benefit dual eligible beneficiaries under the Medicare Prescription Drug Benefit - Part D.

The following excluded drugs are covered:

- (a) 1.) Agents when used for anorexia, weight loss, and weight gain. Products in these categories require prior authorization; see specific drug categories below:
 - a.) Megestrol Acetate,
 - b.) Somatropin, and
 - c.) Lipase Inhibitor
- (b) Agents when used to promote fertility; see specific drug categories below:
- (c) Agents when used for cosmetic purposes or hair growth; see specific drug categories below:
- (d) Agents when used for the symptomatic relief cough and colds; see specific drug categories below:
- (e) Prescription vitamins and mineral products, except prenatal vitamins and fluoride; see specific drug categories below:
- (f) Nonprescription drugs; see specific drug categories below.

2.) Nonprescription drugs, prescription vitamins and mineral products (except prenatal vitamins and fluoride), and other over-the-counter products, such as agents used for the symptomatic relief of cough and colds, as listed in the Delaware Medicaid and Medical Assistance (DMMA) Pharmacy Provider Manual Appendix A - Covered Over-the-Counter Drugs.

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

STATE: DELAWARE

~~MEDICAID PROGRAM: REQUIREMENTS RELATING TO PAYMENT FOR COVERED
OUTPATIENT DRUGS FOR THE CATEGORICALLY NEEDY~~

~~Citation (s)~~

~~Provision (s)~~

~~1927(d)(2) and 1935(d)(2)~~

~~(g) covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee (see specific drug categories below)~~

~~(The Medicaid agency lists specific category of drugs below)~~

~~(a) Agents when used for anorexia, weight loss, weight gain: Megestrol Acetate, Somatropin, Lipase Inhibitor. Products in these categories require prior authorization.~~

~~(d) Agents when used for the symptomatic relief cough and colds: Antihistamines, Antitussive, Decongestants, and Expectorants.~~

~~(e) Prescription vitamins and mineral products, except prenatal vitamins and fluoride: Single entity vitamins, Multiple vitamins w/ minerals, Nicotinic acid, Calcium salts, and Dialysis replacement products~~

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

STATE: DELAWARE

MEDICAID PROGRAM: REQUIREMENTS RELATING TO PAYMENT FOR COVERED-
OUTPATIENT DRUGS FOR THE CATEGORICALLY NEEDY

Citation (s)

Provision (s)

1927(d)(2) and 1935(d)(2)

CONTINUED

~~(f) Nonprescription drugs: Analgesic oral and rectal; Heartburn; Antiflatulents; Antidiarrheal; Antinauseants; Cough & Cold, oral; Cough & Cold, topical; Contraceptive Drugs; Laxatives & Stool Softeners; Lice Control Preparations; Nasal Drug Preparations; Nicotine Cessation Preparations; Ophthalmic Drug Preparations; Topical Anesthetics; Topical Antibacterials; Topical/Vaginal Fungicidals; and, Digestive Enzymes.~~

~~— No excluded drugs are covered.~~

20 DE Reg. 91 (08/01/16) (Prop.)