
Table of Contents

State/Territory Name: Montana

State Plan Amendment (SPA) #: MT-15-0023

This file contains the following documents in the order listed:

- 1) Approval Letter
- 2) CMS 179 Form/Summary Form (with 179-like data)
- 3) Approved SPA Pages



Disabled & Elderly Health Programs Group

March 11, 2016,

Mary E. Dalton
State Medicaid Director
Montana Department of Public Health and Human Services
Attention: Mary Eve Kulawik
P. O. BOX 4210
Helena, MT, 59620

Dear Ms. Dalton:

We have reviewed Montana State Plan Amendment (SPA) 15-023 received in the Denver regional office on December 20, 2015. This amendment proposes to remove nonprescription bronchosaline and nonprescription pyridoxine from the excludable-but-covered nonprescription drugs section of the prescribed drugs pages. It further proposes that Montana will cover them, as well as nonprescription folic acid by placing them in a stand-alone section (Item 7) on the prescribed drugs pages.

We are pleased to inform you that the amendment is approved with an effective date of January 1, 2016. A copy of the CMS-179 form, as well as the pages approved for incorporation into the Montana state plan, will be forwarded by the Denver Regional Office. If you have any questions regarding this amendment, please contact Emeka Egwim, PharmD at (410) 786-1092.

Sincerely,

/s/

John Coster, PhD, RPh
Director
Division of Pharmacy

cc: Katie Hawkins, Pharmacy Program Manager, DPHHS, MT
Richard D. Allen, ARA, Denver Regional Office
Sophia Hinojosa, Denver Regional Office

MONTANA

Drugs covered by the Medicaid Program are subject to the following limitations:

1. Drugs must be prescribed by a physician or other licensed practitioner who is authorized by law to prescribe drugs and is recognized by the Medicaid program;
2. Maintenance medications may be dispensed in quantities sufficient for a 90-day supply or 100 units, whichever is greater. Other medications may not be dispensed in quantities greater than a 34-day supply except where manufacturer packaging cannot be reduced to a smaller quantity. The department posts a list of current drug classes which are considered maintenance medications on the department's web site at <http://medicaidprovider.hhs.mt.gov>.
3. Drugs are not covered if they:
 - a. Have been classified as "less than effective" by the Food and Drug Administration (FDA). (Drug Efficacy Study Implementation (DESI) drugs); or
 - b. Are produced by manufacturers who have not signed a rebate agreement with CMS.
4. Nursing facilities are responsible for providing over-the-counter laxatives, antacids, and aspirin to their residents as these items are included in the facility per diem rate determined by the Department.
5. Montana Medicaid will cover vaccines administered in an outpatient pharmacy setting.
6. The Department will reimburse for compounded nonrebtable Active Pharmaceutical Ingredient (API) bulk powders and excipients on the Department's maintained drug formulary.
7. The Department will cover nonprescription folic acid, pyridoxine, and bronchosaline.
8. Effective January 1, 2006, the Medicaid agency will not cover any Part D drug for full-benefit dual eligible individuals who are entitled to receive Medicare benefits under Part A or Part B.
9. 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) agents when used for anorexia, weight loss, weight gain. Weight gain agents are covered when medically necessary. Agents when used for anorexia and weight loss continue as excluded drugs.
- (b) agents when used to promote fertility
- (c) agents when used for cosmetic purposes or hair growth
- (d) agents when used for the symptomatic relief cough and colds
- (e) prescription vitamins and mineral products, except prenatal vitamins and fluoride

MONTANA

- (f) nonprescription drugs
aspirin, laxatives, antacids, head lice treatment, H2 antagonist GI products, proton pump inhibitors, non-sedating antihistamines, diphenhydramine, over-the-counter contraceptive drugs, ketotifen ophthalmic solution, doxylamine, steroid nasal sprays, benzoyl peroxide, and oxybutynin transdermal.
- (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

Services considered experimental are not a benefit of the Montana Medicaid Program.

Experimental services include:

1. All procedures and items, including prescribed drugs, considered experimental by the U.S. Department of Health and Human Services or any other appropriate federal agency.
2. All procedures and items, including prescribed drugs, provided as part of a control study, approved by the Department of Health and Human Services or any other appropriate federal agency to demonstrate whether the item, prescribed drug or procedure is safe and effective in curing/preventing, correcting or alleviating the effects of certain medical conditions.
3. All procedures and items, including prescribed drugs, which may be subject to question but are not covered in #1 and #2 above, will be evaluated by the Department's designated medical review organization.

MONTANA

Product Restrictions:

The Medicaid program restricts coverage of certain drug products through the operation of an outpatient drug formulary. The state utilizes the University of Montana, School of Pharmacy and Allied Health Sciences for literature research and the state Drug Utilization Review (DUR) Board as the formulary committee. Criteria used to include/exclude drugs from the formulary is based upon safety, efficacy and clinical outcomes as provided by the product labeling of the drug. Montana's formulary committee meets the formulary requirements that are specified in section 1927(d)(4) of the Social Security Act.

Prior Authorization:

Drugs may require prior authorization for the reimbursement of any covered outpatient drugs. Prior authorization is under the provisions of Section 1927(d)(5) of the Social Security Act. For drugs requiring prior authorization, an automated voice response system is used to meet the requirements for providing a response within 24 hours. Up to a 72-hour supply of medication requiring prior authorization may be dispensed in an emergency.

Preferred Drug List:

Certain designated therapeutic classes will be reviewed periodically to consider which products are clinically appropriate and most cost-effective. Those products within the therapeutic class that are not determined to be clinically superior and/or are not cost-effective will require prior authorization. The Department may maintain a Preferred Drug List containing the names of pharmaceutical drugs for which prior authorization will not be required under the medical assistance program. All other pharmaceutical drugs not on the Preferred Drug List, and determined by the Department to be in the same drug class and used for the treatment of the same medical condition as drug(s) placed on the Preferred Drug List, will require prior authorization.

The Department will appoint a Formulary Committee or utilize the drug utilization review committee in accordance with Federal law.

MONTANA

Supplemental Drug Rebate Programs:

The State is in compliance with section 1927(d)(4) of the Social Security Act. The State has the following policies for the Supplemental Rebate Program for the Medicaid population:

- CMS has authorized the State of Montana to enter into the Michigan Multi-State Pooling Agreement (MMSPA), also referred to as the National Medicaid Pooling Initiative (NMPI) for drugs provided to Medicaid beneficiaries. The NMPI Supplemental Rebate Agreement (SRA) and the Amendment to the SRA submitted to CMS on August 10, 2004 have been authorized for pharmaceutical manufacturers' existing agreements through their current expiration dates. The updated NMPI SRA submitted to CMS in October 2013 has been authorized for renewal and new agreements with pharmaceutical manufacturers for drugs provided to Medicaid beneficiaries.
- CMS has authorized Montana's collection of supplemental rebates through the NMPI.
- The prior authorization process complies with the requirements of Section 1927 of the Social Security Act and provides a turn-around response by either telephone or other telecommunications device within 24 hours of receipt of a prior authorization request. In emergency situations, providers may dispense a 72-hour supply of medication (except for those drugs that are excluded or restricted from coverage).
- Supplemental rebates received by the State in excess of those required under the National Drug Rebate Program will be shared with the Federal government on the same percentage basis as applied under the National Drug Rebate Agreement.
- All drugs covered by the National Drug Rebate Agreements remain available to Medicaid beneficiaries, although some may require prior authorization.
- All drugs covered by the program, irrespective of a supplemental rebate agreement, will comply with the provisions of the National Drug Rebate Agreement.
- The unit rebate amount is confidential and will not be disclosed except in accordance with §1927 (b)(3)(D) of the Act.

MONTANA

Drugs covered by the Medicaid Program are subject to the following limitations:

1. Drugs must be prescribed by a physician or other licensed practitioner who is authorized by law to prescribe drugs and is recognized by the Medicaid program;
2. Maintenance medications may be dispensed in quantities sufficient for a 90-day supply or 100 units, whichever is greater. Other medications may not be dispensed in quantities greater than a 34-day supply except where manufacturer packaging cannot be reduced to a smaller quantity. The department posts a list of current drug classes which are considered maintenance medications on the department's web site at <http://medicaidprovider.hhs.mt.gov>.
3. Drugs are not covered if they:
 - a. Have been classified as "less than effective" by the Food and Drug Administration (FDA). (Drug Efficacy Study Implementation (DESI) drugs); or
 - b. Are produced by manufacturers who have not signed a rebate agreement with CMS.
4. Nursing facilities are responsible for providing over-the-counter laxatives, antacids, and aspirin to their residents as these items are included in the facility per diem rate determined by the Department.
5. Montana Medicaid will cover vaccines administered in an outpatient pharmacy setting.
6. The Department will reimburse for compounded nonrebtable Active Pharmaceutical Ingredient (API) bulk powders and excipients on the Department's maintained drug formulary.
7. The Department will cover nonprescription folic acid, pyridoxine, and bronchosaline.
8. Effective January 1, 2006, the Medicaid agency will not cover any Part D drug for full-benefit dual eligible individuals who are entitled to receive Medicare benefits under Part A or Part B.
9. 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) agents when used for anorexia, weight loss, weight gain. Weight gain agents are covered when medically necessary. Agents when used for anorexia and weight loss continue as excluded drugs.
- (b) agents when used to promote fertility
- (c) agents when used for cosmetic purposes or hair growth
- (d) agents when used for the symptomatic relief cough and colds
- (e) prescription vitamins and mineral products, except prenatal vitamins and fluoride

MONTANA

- (f) nonprescription drugs
aspirin, laxatives, antacids, head lice treatment, H2 antagonist GI products, proton pump inhibitors, non-sedating antihistamines, diphenhydramine, over-the-counter contraceptive drugs, ketotifen ophthalmic solution, doxylamine, steroid nasal sprays, benzoyl peroxide, and oxybutynin transdermal.
- (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

Services considered experimental are not a benefit of the Montana Medicaid Program.

Experimental services include:

1. All procedures and items, including prescribed drugs, considered experimental by the U.S. Department of Health and Human Services or any other appropriate federal agency.
2. All procedures and items, including prescribed drugs, provided as part of a control study, approved by the Department of Health and Human Services or any other appropriate federal agency to demonstrate whether the item, prescribed drug or procedure is safe and effective in curing/preventing, correcting or alleviating the effects of certain medical conditions.
3. All procedures and items, including prescribed drugs, which may be subject to question but are not covered in #1 and #2 above, will be evaluated by the Department's designated medical review organization.

MONTANA

Product Restrictions:

The Medicaid program restricts coverage of certain drug products through the operation of an outpatient drug formulary. The state utilizes the University of Montana, School of Pharmacy and Allied Health Sciences for literature research and the state Drug Utilization Review (DUR) Board as the formulary committee. Criteria used to include/exclude drugs from the formulary is based upon safety, efficacy and clinical outcomes as provided by the product labeling of the drug. Montana's formulary committee meets the formulary requirements that are specified in section 1927(d)(4) of the Social Security Act.

Prior Authorization:

Drugs may require prior authorization for the reimbursement of any covered outpatient drugs. Prior authorization is under the provisions of Section 1927(d)(5) of the Social Security Act. For drugs requiring prior authorization, an automated voice response system is used to meet the requirements for providing a response within 24 hours. Up to a 72-hour supply of medication requiring prior authorization may be dispensed in an emergency.

Preferred Drug List:

Certain designated therapeutic classes will be reviewed periodically to consider which products are clinically appropriate and most cost-effective. Those products within the therapeutic class that are not determined to be clinically superior and/or are not cost-effective will require prior authorization. The Department may maintain a Preferred Drug List containing the names of pharmaceutical drugs for which prior authorization will not be required under the medical assistance program. All other pharmaceutical drugs not on the Preferred Drug List, and determined by the Department to be in the same drug class and used for the treatment of the same medical condition as drug(s) placed on the Preferred Drug List, will require prior authorization.

The Department will appoint a Formulary Committee or utilize the drug utilization review committee in accordance with Federal law.

MONTANA

Supplemental Drug Rebate Programs:

The State is in compliance with section 1927(d)(4) of the Social Security Act. The State has the following policies for the Supplemental Rebate Program for the Medicaid population:

- CMS has authorized the State of Montana to enter into the Michigan Multi-State Pooling Agreement (MMSPA), also referred to as the National Medicaid Pooling Initiative (NMPI) for drugs provided to Medicaid beneficiaries. The NMPI Supplemental Rebate Agreement (SRA) and the Amendment to the SRA submitted to CMS on August 10, 2004 have been authorized for pharmaceutical manufacturers' existing agreements through their current expiration dates. The updated NMPI SRA submitted to CMS in October 2013 has been authorized for renewal and new agreements with pharmaceutical manufacturers for drugs provided to Medicaid beneficiaries.
- CMS has authorized Montana's collection of supplemental rebates through the NMPI.
- The prior authorization process complies with the requirements of Section 1927 of the Social Security Act and provides a turn-around response by either telephone or other telecommunications device within 24 hours of receipt of a prior authorization request. In emergency situations, providers may dispense a 72-hour supply of medication (except for those drugs that are excluded or restricted from coverage).
- Supplemental rebates received by the State in excess of those required under the National Drug Rebate Program will be shared with the Federal government on the same percentage basis as applied under the National Drug Rebate Agreement.
- All drugs covered by the National Drug Rebate Agreements remain available to Medicaid beneficiaries, although some may require prior authorization.
- All drugs covered by the program, irrespective of a supplemental rebate agreement, will comply with the provisions of the National Drug Rebate Agreement.
- The unit rebate amount is confidential and will not be disclosed except in accordance with §1927 (b)(3)(D) of the Act.