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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 will post a list of current drug classes which will be 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 FDA (DESI drugs);
   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 may reimburse for compounded nonrebatable API bulk powders and excipients on the Department's maintained drug formulary.

7. 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.

8. 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

☐ (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

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☑ (f) nonprescription drugs
*Aspirin, Laxatives, Antacids, Head lice treatment, H2 antagonist GI products, Bronchosaline, Proton Pump Inhibitors, Non-sedating Antihistamines, Diphenhydramine*

☐ (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

☑ (h) barbiturates

☑ (i) benzodiazepines.

☑ (j) smoking cessation for non-dual eligibles as Part D will cover

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.

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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 DUE CARE (Drug Utilization Review, Concurrent and Retrospective Evaluation) 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.

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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 on July, 2010 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 for 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.

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Reimbursement for drugs shall not exceed the lowest of:

1. The Estimated Acquisition Cost (EAC) of the drug plus a dispensing fee, or;
2. Federal Upper Limit (FUL) of the drug plus a dispensing fee, or;
3. The State Maximum Allowable Cost (SMAC) of the drug, in the case of multi-source (generic), plus a dispensing fee, or,
4. The provider's usual and customary charge of the drug to the general public.

Exception The FUL limitation shall not apply in a case where a physician certifies in his/her own handwriting the specific brand is medically necessary for a particular recipient. An example of an acceptable certification is the handwritten notation "Brand Necessary" or "Brand Required." A check off box on a form or rubber stamp is not acceptable.

Exception: For outpatient drugs provided to Medicaid recipients in state institutions, reimbursement will conform to the state contract for pharmacy services; or for institutions not participating in the state contract for pharmacy services, reimbursement will be the actual cost of the drug and dispensing fee. In either case, reimbursement will not exceed, in the aggregate, the EAC or FUL or the SMAC plus the dispensing fee.

The EAC is established by the state agency using the Federal definition of EAC as a guideline that is, "Estimated Acquisition Cost" means the state agency's best estimate of what price providers generally pay for a particular drug.

The EAC, which includes single source, brand necessary and drugs other than multi-source, is established using the following methodology:

> Drugs paid by their Average Wholesale Price (AWP) will be paid at AWP less 15 percent or Wholesale Acquisition Cost (WAC) plus 2 percent. If the state agency determines that acquisition cost is lower than AWP less 15 percent or WAC plus 2 percent then the state agency may set an allowable acquisition cost based on data provided by the drug pricing file contractor.

The SMAC for multiple-source drugs shall be equal to the state average acquisition cost per drug determined by direct pharmacy survey, wholesale survey and other relevant cost information.

A variable dispensing fee will be established by the state agency. The dispensing fee is based on the pharmacy's average cost of filling a prescription. The average cost of filling a prescription will be based on the direct and indirect costs that can be allocated to the cost of the prescription department and that of filling a prescription, as determined from the Montana dispensing fee questionnaire. A provider's failure to submit, upon request, the dispensing fee questionnaire property completed will result in the assignment of the minimum dispensing fee offered. A copy of the Montana dispensing fee questionnaire is available upon request from the department.

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Dispensing fees shall be established as follows

1. The dispensing fees assigned shall range between
   (i) a minimum of $2.00 and a maximum of $4.94 for brand name and nonpreferred generic drugs, and
   (ii) a minimum of $2.00 and a maximum of $6.40 for preferred brand name and generic drugs and generic drugs not identified on the preferred list.
2. Out-of-state providers will be assigned a $3.50 dispensing fee.
3. If the individual provider's usual and customary average dispensing fee for filling prescription is less than the foregoing method of determining the dispensing fee, then the lesser dispensing fee shall be applied in the computation of the payment to the pharmacy provider.

In-state pharmacy providers that are new to the Montana Medicaid program will be assigned the maximum dispensing fee in (1) until a dispensing fee questionnaire can be completed for six months of operation. At that time, a new dispensing fee will be assigned which will be the lower of the dispensing fee calculated for the pharmacy or the maximum allowed dispensing fee provided in (1). Failure to comply with the six months dispensing fee questionnaire requirement will result in assignment of dispensing fee of $2.00.

An additional dispensing fee of $0.75 will be paid for "unit dose" prescriptions. This "unit dose" dispensing fee will offset the additional cost of packaging supplies and materials which are directly related to filling "unit dose" prescriptions by the individual pharmacy and is in addition to the regular dispensing fee allowed. Only one unit dose dispensing fee will be allowed each month for each prescribed medication. A dispensing fee will not be paid for a unit dose prescription packaged by the drug manufacturer.

An additional compounding fee based on level of effort will be paid for compounded prescriptions. Montana Medicaid shall reimburse pharmacies for compounding drugs only if the client's drug therapy needs cannot be met by commercially available dosage strengths and/or forms of the therapy. Reimbursement for each drug component shall be determined in accordance with "lower of" pricing methodology. The compounding fee for each compounded drug shall be based on the level of effort required by the pharmacist. The levels of effort compounding fees payable are level 1: $12.50, level 2 $17.50, and level 3 $22 50.