



ADMINISTRATIVE RULES OF MONTANA

37.86.1101 OUTPATIENT DRUGS, DEFINITIONS

- (1) "Acquisition cost" means the actual price paid by a provider for a drug.
- (2) "Active pharmaceutical ingredient (API)" means a nonrebataable bulk drug substance, defined in 21 CFR 207.3(a)(4) (2011) as any substance that is represented for use in a drug and that, when used in manufacturing, processing, or packaging of a drug, becomes an active ingredient of the drug product.
- (3) "Allowed ingredient cost" means the "Average Acquisition Cost (AAC)" or "submitted ingredient cost," whichever is lower. If AAC is not available, drug reimbursement is determined at the lesser of "Wholesale Acquisition Cost (WAC)", "Federal Maximum Allowable Cost (FMAC)," or the "submitted ingredient cost."
- (4) "Average acquisition cost (AAC)" means the calculated average drug ingredient cost per drug determined by direct pharmacy survey, wholesale survey, and other relevant cost information.
- (5) "Average manufacturer price" means the price as defined at 42 CFR Part 447.504(a).
- (6) "Best price" means with respect to a single source drug or innovator multiple source drug of a manufacturer the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States. Best price includes the lowest price available to any entity for any such drug of a manufacturer that is sold under an approved new drug application.
- (7) "Federal maximum allowable cost" (FMAC) means the per unit amount the department reimburses a provider for a prescription drug included in the federal upper-limit program. FMAC is the federal upper limit the department will pay for multi-source drugs as published by the Centers for Medicare and Medicaid Services (CMS) at: <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/pharmacy-pricing.html>.
- (8) "Legend drugs" means drugs that federal law prohibits dispensing without a prescription.
- (9) "Maintenance medications" means oral tablet or capsule drugs that:
 - (a) have a low probability for dosage or therapy changes due to side effects;
 - (b) are subject to serum drug concentration monitoring or therapeutic response of a course of prolonged therapy;
 - (c) the most common use is to treat a chronic disease state;
 - (d) therapeutically are not considered curative or promoting of recovery; and
 - (e) are administered continuously rather than intermittently.

- (10) "Multi-source" means a drug product sold under its generic name for which the active ingredients are identical in chemical composition to one or more other drugs sold under trademark that can be purchased from different manufacturers or distributors.
- (11) "Outpatient drugs" means drugs that are obtained outside of a hospital.
- (12) "Preferred drug list (PDL)" means selected drugs that have a significant clinical benefit over other agents in the same therapeutic class and also represent good value to the department based on total cost.
- (13) "Submitted ingredient cost" means a pharmacy's actual ingredient cost. For drugs purchased under the 340B Drug Pricing Program, "submitted ingredient cost" means the actual 340B purchase price. For drugs purchased under the Federal Supply Schedule (FSS), "submitted ingredient cost" means the actual FSS purchase price.
- (14) "Usual and customary charge" means the price the provider charges a typical customer in the provider's typical course of business.
- (15) "Wholesale acquisition cost (WAC)" is the cost as defined in 42 USC 1395w-3a(c)(6)(B).

Authorizing statute(s): 53-2-201, 53-6-113, MCA

Implementing statute(s): 53-2-201, 53-6-101, 53-6-111, 53-6-113, MCA

History: NEW, 1998 MAR p. 495, Eff. 2/13/98; TRANS, from SRS, 2000 MAR p. 481; AMD, 2000 MAR p. 2313, Eff. 8/25/00; AMD, 2002 MAR p. 1788, Eff. 6/28/02; AMD, 2008 MAR p. 1157, Eff. 7/1/08; AMD, 2008 MAR p. 2669, Eff. 1/1/09; AMD, 2010 MAR p. 433, Eff. 3/1/10; AMD, 2010 MAR p. 2986, Eff. 1/1/11; AMD, 2011 MAR p. 2416, Eff. 11/11/11; AMD, 2016 MAR p. 1065, Eff. 7/1/16; AMD, 2017 MAR p. 2287, Eff. 1/1/18; AMD, 2018 MAR p. 2057, Eff. 10/20/18.