PAYMENT METHODOLOGY FOR COVERED OUTPATIENT DRUGS

Medi-Cal's payment methodology for covered outpatient drugs complies with the Centers for Medicare and Medicaid (CMS) Covered Outpatient Drug Final Rule in accordance with 42 C.F.R. Part 447.

1. Payment for legend and non-legend covered outpatient drugs dispensed by a retail community pharmacy shall be the lower of the drug's ingredient cost plus a professional dispensing fee, or the pharmacy's usual and customary charge to the public.

2. Payment for specialty drugs not dispensed by a retail community pharmacy but dispensed primarily through the mail shall be the lower of the drug's ingredient cost plus a professional dispensing fee, or the pharmacy's usual and customary charge to the public.

3. Payment for legend and non-legend covered outpatient drugs not dispensed by a retail community pharmacy (i.e. institutional or long-term care facility pharmacies) shall be the lower of the drug's ingredient cost plus a professional dispensing fee, or the pharmacy's usual and customary charge to the public.

4. For purposes of this supplement, the "drug's ingredient cost" means the lowest of:

    a. The National Average Drug Acquisition Cost (NADAC) of the drug, or when no NADAC is available, the Wholesale Acquisition Cost (WAC) + 0%, or
    b. The Federal Upper Limit (FUL), or
    c. The Maximum Allowable Ingredient Cost (MAIC).

    The FUL is the maximum allowable ingredient cost reimbursement established by the federal government for selected multiple source drugs. The aggregate cost of product payment for drugs with FULs will not exceed the aggregate established by the federal government.

5. The "professional dispensing fee" shall be based on a pharmacy's total (Medicaid and non-Medicaid) annual claim volume of the previous year, as follows:

    a. Less than 90,000 claims = $13.20, or
    b. 90,000 or more claims = $10.05

6. The department may establish a list of MAICs for generically equivalent drugs.

7. Medi-Cal providers that are covered entities (as defined in Section 256b of Title 42 of the United States Code) and purchase drugs through the 340B Drug Pricing Program are required to use only 340B purchased drugs when dispensing drugs to Medi-Cal beneficiaries. If a covered entity is unable to purchase a specific 340B drug, the covered entity may dispense a drug purchased at regular drug wholesale rates to a Medi-Cal beneficiary.

   a. For drugs purchased pursuant to the 340B program, a covered entity is required to bill and will be reimbursed an amount not to exceed the entity's actual acquisition cost for the drug, as charged by the manufacturer at a price consistent with Section 256b of Title 42 of the United States Code, plus the professional dispensing fee described in Paragraph 5.

   b. If a covered entity dispenses a drug purchased at regular drug wholesale rates because it is unable to purchase it pursuant to the 340B program, the covered entity is required to maintain documentation of their inability to obtain the 340B drug and payment will be made as described in Paragraph 1 of this supplement.

   c. A contract pharmacy, under contract with a 340B covered entity described in Section 1927(a)(5)(B) of the Social Security Act may only use 340B drugs to dispense Medicaid prescriptions if the covered entity, the contract pharmacy, and the State Medicaid agency have established an arrangement to prevent duplicate discounts as outlined in the HRSA Final Notice regarding Contract Pharmacy Services published at 75 Fed. Reg. 10272 (Mar. 5, 2010) and the details of that arrangement have been shared with HRSA.

      i. If the covered entity provides medications through contracted pharmacies, payment will be made as described in either Paragraph 7a or 7b of this supplement.

ii. Covered entities that utilize contract pharmacy arrangements are expected to ensure compliance with all the requirements in the HRSA Final Notice.

8. Pharmacy providers purchasing drugs through the Federal Supply Schedule (FSS) or drug pricing program under 38 U.S.C. 1826 will be reimbursed no more than the actual acquisition cost for the drug, plus a professional dispensing fee as described in Paragraph 5 of this supplement.

9. Pharmacy providers purchasing drugs at Nominal Price (outside of 340B or FSS) will be reimbursed no more than the actual acquisition cost for the drug, plus a professional dispensing fee as described in Paragraph 5 of this supplement.

10. Payment for legend and non-legend covered outpatient drugs dispensed by Indian Health Service, tribal, and urban Indian pharmacies shall be the drug's ingredient cost as defined in Paragraph 4, 7, 8 or 9 of this supplement, as applicable, plus a professional dispensing fee as described in Paragraph 5.

11. All investigational drugs require prior authorization, and shall be reimbursed as described in paragraph 1 of this supplement.

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METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES -PRESCRIBED DRUGS

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PAYMENT METHODOLOGY FOR CLOTTING FACTOR

1. Clotting factor is defined as coagulation factors and their recombinant analogs.

2. Payment for clotting factor purchased through and dispensed by a federally recognized hemophilia treatment center (HTC) or its contracted pharmacy will be the lower of:

   a. The HTC's actual acquisition cost for the drug as defined in Welfare and Institutions Code section 14105.46, plus a professional dispensing fee of $0.14 per unit, or

   b. The Average Sales Price as reported to the federal Centers for Medicare and Medicaid Services by the manufacturer pursuant to Section 1847A of the federal Social Security Act (42 U.S.C. §1395w-3a), plus 20%.

3. Payment for clotting factor purchased outside of a federally recognized HTC and dispensed by specialty pharmacies, Centers of Excellence, or any other provider will be the lower of:

   a. The provider's actual acquisition cost for the drug equal to invoice price minus any discounts (excluding a prompt pay discount of less than, or equal to 2%), rebates, or chargebacks, plus a professional dispensing fee of $0.04 per unit, or

   b. The Average Sales Price as reported to the federal Centers for Medicare and Medicaid Services by the manufacturer pursuant to Section 1847A of the federal Social Security Act (42 U.S.C. §1395w-3a) plus 20%.

This payment methodology is applicable to both pharmacy and non-pharmacy clotting factor claims.

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
STATE: CALIFORNIA

METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES – PRESCRIBED DRUGS

PAYMENT METHODOLOGY FOR PHYSICIAN ADMINISTERED DRUGS

The reimbursement rate for physician administered drugs shall be equal to the Medicare Part B reimbursement rate for drugs and biologicals, when available for a particular product and published by CMS in the Medicare Fee Schedule (MFS), as described in Section 1847A of the Social Security Act.

When a Medicare Part B reimbursement rate is not available or published by CMS for a physician administered drug, the reimbursement rate will be determined as follows:

- If based on a National Drug Code (NDC), the NDC rate of reimbursement shall be equal to the drug's ingredient cost, as described in Paragraph 4 of this supplement, or
- If based on a Healthcare Common Procedure Coding system (HCPCS) code, the HCPCS code rate of reimbursement shall be equal to the volume-weighted average of the drug's ingredient cost for generically equivalent drugs as described in Paragraph 4 of this supplement.

For physician administered drugs purchased pursuant to the 340B program, a covered entity is required to bill and will be reimbursed an amount not to exceed the entity's actual acquisition cost for the drug, as charged by the manufacturer at a price consistent with Section 256b of Title 42 of the United States Code.

DRUG REBATE PROGRAM

The State Agency is in compliance with Section 1927 of the Social Security Act. The State Agency reimburses providers of drugs of manufacturers participating in the drug rebate program and is in compliance with reporting requirements for utilization and restrictions to coverage. Pharmaceutical manufacturers can audit utilization data to the extent allowed under the Health Insurance Portability and Accountability Act (HIPAA) in order to ensure that the Department is protecting information in accordance with HIPAA. The unit rebate amount is confidential and is not disclosed to anyone not entitled to the information for purposes of rebate contracting, invoicing and verification.

SUPPLEMENTAL REBATE PROGRAM

The State Agency negotiates supplemental rebates in addition to the federal rebates provided for in Title XIX. Rebate agreements between the state and a pharmaceutical manufacturer are separately identified from the federal rebates.

Supplemental rebates received by the State Agency in excess of those required under the national drug rebate agreement are shared with the Federal government on the same percentage basis as applied under the national rebate agreement. CMS has authorized the State of California to enter into the Medi-Cal Supplemental Drug Rebate Average Manufacturer Price (AMP) Agreement. This supplemental drug rebate agreement was submitted to CMS on December 1, 2014 and has been authorized by CMS. CMS has also authorized the State of California to enter into the Medi-Cal Net Cost Supplemental Drug Rebate Agreements. This supplemental drug rebate agreement was submitted to CMS on February 13, 2019 and has been authorized by CMS. All drugs covered by the program, notwithstanding a prior authorization agreement, will comply with the provisions of the national drug rebate agreement.