

MEDICAID DRUG REBATE PROGRAM

MDP MONTHLY AMP FILE FORMAT

Effective: July 1, 2021

Target: States

Ordinal Position	Field Name (.TXT) Header Row (.CSV)	Size	Position	Remarks
1	Labeler Code	5	1 - 5	NDC 1
2	Product Code	4	6 - 9	NDC 2
3	Package Size	2	10 - 11	NDC 3
4	Month/Year	6	12 - 17	MMYYYY
5	Average Manufacturer Price	15	18 - 32	99999999.999999 or NR
6	AMP Units	14	33 - 46	999999999999.99
7	Covered Outpatient Drug Status	2	47 - 48	XX
8	Unit Type	3	49 - 51	XXX
9	Therapeutic Equivalence Code	2	52 - 53	XX
10	Units Per Package Size	11	54 - 64	9999999.999
11	FDA Product Name	63	65 - 127	FDA Product Name
12	Labeler Name	40	128 - 167	Company associated with NDC 1

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MDP MONTHLY AMP DATA DEFINITIONS

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Labeler Code: The first segment of the National Drug Code (NDC) that identifies the labeler. Numeric values; 5-digit field; right-justified; zero-padded.

Product Code: Second segment of the NDC. Alpha-numeric values; 4-digit field; right-justified; zero-padded.

Package Size: Third segment of the NDC. Alpha-numeric values; 2-digit field; right-justified; zero-padded.

Month/Year: The calendar month and year that the Average Manufacturer Price (AMP) represents.

Month Format: MM

Valid Values for MM:

01 = January
02 = February
03 = March
04 = April
05 = May
06 = June
07 = July
08 = August
09 = September
10 = October
11 = November
12 = December

Year Format: YYYY

Average Manufacturer Price (AMP): The AMP per unit per product code only for the month/year covered, based on sales. If a drug is distributed in multiple package sizes, there will be one “weighted” AMP for the product, which will be the same for all package sizes. Numeric values; 15-digit field: 8 whole numbers, the decimal point (‘.’) and 6 decimal places; right-justified; zero-padded for AMP values with fewer than 15 digits. If no AMP has been reported, this alphanumeric field will reflect a value of "NR."

AMP Units: The total sum of all units included in the calculation of the AMP per product code for the monthly reporting period covered. If a drug is distributed in multiple package sizes, there will be one AMP unit for the product, which is the same for all package sizes, as reported to CMS. Numeric values; 14-digit field: 11 whole numbers, the decimal point (‘.’) and 2 decimal places; right-justified; zero-padded.

Covered Outpatient Drug (COD) Status: A category that identifies how a product meets the statutory definition of a covered outpatient drug in accordance with sections 1927(k)(2) to 1927(k)(4) of the Social Security Act. Numeric values; 2-digit field.

Valid Values:

- 01 = Abbreviated New Drug Application (ANDA)
- 02 = Biological License Application (BLA)
- 03 = New Drug Application (NDA)
- 04 = NDA Authorized Generic
- 05 = DESI 5* – LTE/IRS drug for all indications
- 06 = DESI 6* – LTE/IRS drug withdrawn from market
- 07 = Prescription Pre-Natal Vitamin or Fluoride
- 08 = Prescription Dietary Supplement/Vitamin/Mineral (Other than Prescription Pre-Natal Vitamin or Fluoride)
- 09 = OTC Monograph Tentative
- 10 = OTC Monograph Final
- 11 = Unapproved Drug – Drug Shortage
- 12 = Unapproved Drug – Per 1927(k)(2)(A)(ii)
- 13 = Unapproved Drug – Per 1927(k)(2)(A)(iii)

*NDCs with a COD Status of DESI 5/6 are not eligible for coverage or rebates under the Medicaid Drug Rebate Program.

Unit Type: One of the 10 unit types by which a drug may be dispensed. 3-character field; left-justified; blank-filled for Unit Type values with fewer than 3 characters.

Valid Values:

- AHF = Injectable Anti-Hemophilic Factor
- CAP = Capsule
- SUP = Suppository
- GM = Gram
- ML = Milliliter
- TAB = Tablet
- TDP = Transdermal patch
- EA = Each
- mCi = Millicurie
- μCi = Microcurie

Therapeutic Equivalence Code (TEC): FDA-assigned Therapeutic Equivalence Codes as found in the FDA's *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations*. Alpha-numeric values; 2-digit field.

Valid Values:

AA = Products in Conventional Dosage Forms Not Presenting Bioequivalence Problems
AB = Products Meeting Necessary Bioequivalence Requirements assigned an FDA TEC of AB, or AB1 through AB9
AN = Solutions and Powders for Aerosolization
AO = Injectable Oil Solutions
AP = Injectable Aqueous Solutions and, in Certain Instances, Intravenous Non-Aqueous
AT = Topical Products
BC = Extended-Release Dosage Forms (Capsules, Injectables, and Tablets)
BD = Active Ingredients and Dosage Form With Documented Bioequivalence Problems
BE = Delayed-Release Oral Dosage Forms
BN = Products in Aerosol-Nebulizer Drug Delivery Systems
BP = Active Ingredients and Dosage Forms with Potential Bioequivalence Problems
BR = Suppositories or Enemas That Deliver Drugs for Systemic Absorption
BS = Products Having Drug Standard Deficiencies
BT = Topical Products with Bioequivalence Issues
BX = Drug Products for Which the Data Are Insufficient To Determine Therapeutic Equivalence
NR = Not Rated

Units Per Package Size (UPPS): The total number of units in the smallest dispensable amount for the 11-digit NDC. Numeric values; 11-digit field: 7 whole numbers, the decimal point (‘.’) and 3 decimal places; right-justified; zero-padded for UPPS values with fewer than 11 digits.

FDA Product Name: Drug name as it appears on FDA SPL listing. Alpha-numeric values; 63-character field; left-justified; blank-filled for FDA Product Names fewer than 63 characters.

Labeler Name: Name of labeler as it appears on the signed rebate agreement. Alpha-numeric values; first 40 letters of labeler name; left-justified; blank-filled.