MEDICAID DRUG REBATE PROGRAM

QUARTERLY REBATE FILE

Effective: July 1, 2021

Source: CMS
Target: State Agencies

Ordinal Positon	Field Name (.TXT) Header Row (.CSV)	Size	Position	Remarks
1	Record ID	4	1 - 4	Constant of "01@@"
2	Labeler Code	5	5 - 9	NDC 1
3	Product Code	4	10 - 13	NDC 2
4	Package Size	2	14 - 15	NDC 3
5	Period Covered	5	16 - 20	QYYYY
6	FDA Product Name	10	21 - 30	See Data Definitions
7	Drug Category	1	31 - 31	See Data Definitions
8	Therapeutic Equivalence Code	2	32 - 33	See Data Definitions
9	Unit Type	3	34 - 36	See Data Definitions
10	Units Per Package Size	11	37 - 47	9999999.999
11	Unit Rebate Amount	15	48 - 62	99999999.999999
12	URA Type	1	63 - 63	See Data Definitions
13	FDA Approval Date	8	64 - 71	MMDDYYYY
14	Market Date	8	72 - 79	MMDDYYYY
15	Termination Date	8	80 - 87	MMDDYYYY
16	Date Termination Date Certified	8	88 - 95	MMDDYYYY
17	Drug Type	1	96 - 96	See Data Definitions
18	Clotting Factor Indicator	1	97 - 97	Y or N
19	Exclusively Pediatric Indicator	1	98 - 98	Y or N
20	Covered Outpatient Drug Status	2	99 - 100	See Data Definitions
21	FDA Application Number/OTC Monograph Number	7	101 - 107	See Data Definitions
22	Reactivation Date	8	108 - 115	MMDDYYYY
23	Line Extension Drug Indicator	1	116 - 116	See Data Definitions
24	Record Type Indicator	1	117 - 117	See Data Definitions

Logical Record Length = 117

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Data Definitions

Effective: July 1, 2021

Record ID: Constant value of "01@@."

Labeler Code: First segment of the National Drug Code (NDC) that identifies the labeler.

Product Code: Second segment of the NDC.

Package Size: Third segment of the NDC.

Period Covered: The calendar quarter and year covered by the data submission.

Valid Values for Q:

1 = January 1 - March 31
2 = April 1 - June 30
3 = July 1 - September 30
4 = October 1 - December 31

Valid Values for YYYY: Four-digit calendar year.

FDA Product Name: The first 10 characters of the drug name as it appears on FDA SPL listing.

Drug Category: Indicates whether the drug has been reported as single source, innovator multiple source or non-innovator multiple source.

Valid Values:

S = Single source
I = Innovator multiple source
N = Non-innovator multiple source

Therapeutic Equivalence Code (TEC): FDA-assigned Therapeutic Equivalence Codes as found in the FDA's *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations*.

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

Unit Type: Basic measurement that represents the smallest unit by which the drug is normally dispensed.

Valid Values:

AHF = Injectable Anti-Hemophilic Factor
CAP = Capsule
EA = EACH (for drugs not identifiable by any other unit type)
GM = Gram
ML = Milliliter
SUP = Suppository
TAB = Tablet
TDP = Transdermal patch
MCI = Millicurie
UCI = Microcurie

Units Per Package Size: The total number of units in the smallest dispensable amount for the 11-digit NDC.

Unit Rebate Amount: The CMS-calculated amount (per reported unit type) to be claimed as a rebate by the state.

URA Type: The methodology that CMS used to calculate the URA. For any drug that is not a Line Extension, the URA Type will be the Standard methodology, and for Line Extension drugs, the URA Type will be the greater of the Standard or Alternative methodology. NOTE: If a zero URA appears on the quarterly file (i.e., along with a "1" rebate indicator), the URA Type field will be blank.

Valid Values:

S = Standard
A = Alternative

FDA Approval Date: NDA (including Authorized Generic), ANDA or BLA approval date. For covered outpatient drugs for which the FDA does not require approval, the FDA Approval Date will be 09/30/1990, or, if the drug was first marketed after 09/30/1990, the actual date the drug was first marketed.

Market Date: For S, I, and N drugs marketed under an FDA-approved application (e.g. ANDA, BLA, NDA, NDA Authorized Generic), the earliest date the drug was first marketed under the

application number by any labeler. For drugs marketed without an FDA-approved application (e.g. OTC monograph, unapproved drug), the earliest date the drug was first marketed by any labeler. Reported Market Dates that fall earlier than 9/30/1990 (i.e., the start of the Medicaid Drug Rebate Program) are automatically changed to 9/30/1990, since dates earlier than the start of the Medicaid Drug Rebate Program have no bearing on the program.

Termination Date: The date the drug was withdrawn from the market or the drug's last lot expiration date.

Date Termination Date Certified: The date on which the reported Termination Date was certified by the labeler in MDP.

Drug Type: Identifies the drug as prescription (Rx) or over-the-counter (OTC).

Valid Values:

1 = Rx
2 = OTC

Clotting Factor Indicator: In accordance with section 1927(c)(1)(B)(iii) of the Social Security Act, an indicator which identifies a Single Source or Innovator Multiple Source drug as a clotting factor for which a separate furnishing payment is made under section 1842(o)(5) of the Act.

Valid Values:

Y = Yes
N = No

Pediatric Indictor: In accordance with section 1927(c)(1)(B)(iii) of the Social Security Act, an indicator which identifies a Single Source or Innovator Multiple Source drug approved by the FDA exclusively
for pediatric indications for patients in the FDA-defined pediatric age group (i.e., birth to 16 years).

Valid Values:

Y = Yes
N = No

Covered Outpatient Drug 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.

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.

FDA Application Number/OTC Monograph Number: For drugs with a COD status of ANDA, BLA, NDA, or NDA Authorized Generic, this is the application number (assigned by the FDA for approval to market a drug or biological in the United States) under which the NDC is currently marketed.

For drugs with a COD status of OTC Monograph Tentative or Final, this is the FDA's regulatory citation for the OTC. For drugs with a COD Status of OTC Monograph Final, the first four characters are a constant of "PART"; the last three characters are the numeric values for the appropriate regulatory citation for the product (e.g., "225"). For drugs with a COD Status of OTC Monograph Tentative, the first four characters are a constant of "PART"; the last three characters are the numeric values for the appropriate regulatory citation for the product, or 3 zeroes if a Monograph Number is not available.

For drugs with a COD Status other than ANDA, BLA, NDA, NDA Authorized Generic, OTC Monograph Final, or OTC Monograph Tentative, the FDA Application No./OTC Monograph No. field is zero- filled.

Reactivation Date: The date on which a terminated product is re-introduced to the market.

Line Extension Drug Indicator: Identifies whether a product is a line extension drug as defined in Section 1927(c)(2)(C) of the Social Security Act, including whether the drug is excluded from the statutory definition of a line extension on the basis of being an abuse-deterrent formulation (ADF). If a labeler is seeking an ADF exclusion, a value of "R" will appear in this field. NOTE: If a Line Extension Drug Indicator has not been reported for an NDC, this field will be blank.

Valid Values:

Y = Yes
N = No (i.e., neither LE nor ADF)
R = Request for ADF Exclusion
E = Excluded (Due to ADF)

Record Type Indicator: Provides information regarding each individual line of data included on a quarterly rebate file.

Valid Values:

0 Indicator: Initial, valid URA for an NDC and a particular quarter/year

1 Indicator: Zero URA (due to missing quarterly pricing, 400/400 edit, systems Edits, etc.)

2 Indicator: Value of previously calculated URA

3 Indicator: Value of replacement URA (always appears along with a corresponding 2 Indicator record)

4 Indicator: Value of each initial Termination Date and value of each initial Reactivation Date in a Termination/Reactivation Date set. (Each NDC can have more than one set of Termination/Reactivation Dates.)

5 Indicator: Value of previously reported Termination Date and/or Reactivation Date period

6 Indicator: Value of replacement Termination Date and/or Reactivation Date period (always appears along with a corresponding 5 Indicator record)

7 Indicator: URA for this quarter/year is no longer valid due to a product change by the labeler (e.g., Term. Date change, Market Date change, etc.)

8 Indicator: URA for this quarter/year was previously invalid, but is now valid again due to another product data change by the labeler (e.g., Term. Date change, Market Date change, etc.)