



Methodology for Calculating the National Average Drug Acquisition Cost (NADAC) for Medicaid Covered Outpatient Drugs

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Background

Section 1927(f) of the Social Security Act provides, in part, that CMS may contract with a vendor to conduct monthly surveys with respect to prices for covered outpatient drugs dispensed by retail community pharmacies. In addition, section 1927(i) also provides in part that CMS complete an annual report to Congress that includes ingredient costs paid for single source, multiple source, and non-prescription covered outpatient drugs.

Monthly surveys focus on the drug invoice prices that retail community pharmacies pay to acquire drugs. Specifically, the vendor surveys these acquisition costs of covered outpatient drugs purchased by independent and chain retail community pharmacies.

In the past, many state Medicaid agencies utilized published drug pricing benchmarks as a primary mechanism to determine payment for drug ingredient costs. The Average Wholesale Price (AWP) was a primary drug pricing benchmark utilized for covered outpatient drug ingredient cost reimbursement by state Medicaid agencies. However, this benchmark has been the subject of much scrutiny and litigation over concerns that many AWP's were artificially inflated. The effect of artificially inflated AWP's resulted in the overpayment of the ingredient costs for drugs by state Medicaid agencies. Through numerous investigations, the Office of Inspector General found that AWP-based reimbursement was "fundamentally flawed" and caused Medicaid to pay too much for certain drugs.¹ Following the AWP litigation, a major publisher of pharmacy data discontinued its publication of AWP in September 2011. This heightened the need for an alternative data source for states to use when setting drug ingredient costs. Other published drug pricing benchmarks, such as Wholesale Acquisition Cost (WAC), Average Sales Price (ASP), and Direct Price (DP) are available for consideration, but each has limitations.

In late 2009, a working group within the National Association of State Medicaid Directors (NASMD) convened to discuss various alternatives to AWP. The working group authored a white paper in June 2010 entitled "Post AWP Pricing and Reimbursement" that evaluated and developed options for the replacement of AWP in Medicaid reimbursement methodologies. Among the recommendations presented in the white paper was the establishment of a single national pricing benchmark based on average drug acquisition costs. Such a benchmark would provide state Medicaid agencies with a better estimate of prices paid by pharmacies for drugs because it would be based upon actual drug purchases. This approach to drug ingredient price

¹ Replacing Average Wholesale Price: Medicaid Drug Payment Policy. Office of Inspector General. July 2011. <http://www.oig.hhs.gov/oei/reports/oei-03-11-00060.pdf>

determination provides greater accuracy and transparency in how drug prices are established and is generally more resistant to manipulation. The NASMD requested that CMS coordinate, develop, and support this benchmark.

CMS contracted with Myers and Stauffer LC, a national certified public accounting firm, to conduct surveys of retail community pharmacy prices, including drug ingredient costs, and to develop the National Average Drug Acquisition Cost (NADAC) pricing benchmark. The NADAC survey process focuses on retail community pharmacy drug ingredient costs. The survey collects acquisition costs for covered outpatient drugs purchased by retail community pharmacies, which include invoice purchase prices from independent and chain retail community pharmacies.

The NADAC pricing benchmark was initially published in draft form beginning in October of 2012. The first official NADAC production file was published in November 2013 and has been continually published on a weekly basis. CMS published the Covered Outpatient Drug Final Rule (CMS-2345-FC) on February 1, 2016.

The final rule replaced estimated acquisition cost (EAC) with actual acquisition cost (AAC) for retail community pharmacy drug ingredient cost payment. AAC was defined as the agency's determination of the pharmacy providers' actual prices paid to acquire drug products marketed or sold by specific manufacturers. The NADAC or an AAC program administered by the state satisfies the requirements of the rule for AAC. In addition, "dispensing fee" was changed to "professional dispensing fee" which reflects the pharmacist's professional services and costs necessary to transfer a covered outpatient drug to a Medicaid beneficiary.

The effective date of the final rule was April 1, 2016. States were required to submit a pharmacy reimbursement state plan amendment (SPA) no later than June 30, 2017, with an effective date of no later than April 1, 2017.

Purpose

The purpose of this document is to describe and illustrate the methodology utilized to calculate the NADAC for Medicaid covered outpatient drugs.

The NADAC is designed to create a national benchmark that is reflective of the prices paid by retail community pharmacies to acquire prescription and over-the-counter covered outpatient drugs. States may want to consider the use of the NADAC. However, we note that a state must submit a SPA in accordance with the state plan requirements if it decides to use NADACs as a basis for payment.

We recognize that pharmacy providers should be reimbursed adequately for their professional services. As states revise their reimbursement for the ingredient cost of a drug, they should also consider whether their current dispensing fee continues to provide adequate reimbursement for the cost of dispensing a prescription to a Medicaid beneficiary, as well as the need to submit a SPA to modify their dispensing fee.

NADAC Reporting Level

The NADAC for prescription and over-the-counter covered outpatient drugs is reported at the 11-digit National Drug Code (NDC) level. The NADAC is calculated at the drug grouping, drug category, and pharmacy type level.

Drug grouping is primarily based on active ingredient(s), strength, dosage form, and route of administration. In most cases, NDCs for drugs that are pharmaceutically equivalent are assigned to the same drug group.

In some cases, additional parameters are included in defining a drug group. For example, package size is included as an additional delineation when there is a demonstrated variation in acquisition prices between package sizes for drugs in which the most cost effective package size cannot be purchased and easily repackaged for dispensing (e.g., topical creams and ointments). Please refer to the “NADAC Calculation” section for more details.

Drug category represents the classification of each NDC as one of the following: Single source ('S'), Innovator multiple source ('I'), or Non-innovator multiple source ('N'). In general, NDCs designated as 'S' and 'I' are considered brand drugs and NDCs designated as 'N' are considered generic drugs for purposes of calculating the NADAC. Drug category designations are listed in the “Classification for Rate Setting” field in the NADAC reference file. The Drug Category is obtained from the most recent CMS covered outpatient drug product file.

Drug category overrides indicate when the CMS covered outpatient drug product file drug category, 'S', 'I', and 'N', has not been applied. The override indicator is to alert states that this 'S/I/N' categorization was not followed during the NADAC calculation for the applicable NDCs. In light of this, the process to override the drug category is necessary to align with reimbursement designations used by states for these drugs. States will not be required to match the NADAC designations or to reconcile previous reimbursement to match overrides.

When utilizing the NADAC for reimbursement, state Medicaid programs have the flexibility to apply their own brand or generic designations when determining reimbursement for these drugs. States must submit a SPA in accordance with state plan requirements if they decide to use NADACs as a basis for payment.

For example, authorized generic drugs are listed in the CMS covered outpatient drug product file as 'I' drugs as they were approved under a New Drug Application (NDA). For NADAC calculations, authorized generic drugs are identified as generic drugs since

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they are generally designated as generic by most state Medicaid programs for the purposes of reimbursement.

Another example is proprietary named drugs, approved under an Abbreviated New Drug Application (ANDA), and labeled 'N' in the CMS covered outpatient drug product file. For NADAC calculations, proprietary named drugs, approved under an ANDA are identified as brand drugs since they are generally marketed and priced as brand drugs. In this example, the NDC is identified with a 'B-ANDA' designation in the "Classification for Rate Setting" field of the NADAC reference file and, if available, both the brand and corresponding generic pricing are shown.

Pharmacy type is the classification of a pharmacy into categories. There is currently one type of pharmacy: retail community pharmacy as defined in section 1927(k) of the Social Security Act. For purposes of the NADAC, only chain and independent retail community pharmacies have been surveyed.

Application of NADACs to Individual NDCs

The below example illustrates the application of NADACs to NDCs using the drug grouping, drug category, and pharmacy type indicator. Only NDCs with the same drug grouping, drug category, and pharmacy type indicator will share the same NADAC.

Example 1: Application of NADACs to Individual NDCs

Drug Grouping	NDC	Drug Category	Pharmacy Type Indicator	NADAC
Lipitor 10mg tablet	xxxxx-xxxx-xx	S/I	C/I	2.00000
atorvastatin 10mg tablet	xxxxx-xxxx-xx	N	C/I	1.00000
Lipitor 20mg tablet	xxxxx-xxxx-xx	S/I	C/I	4.00000
atorvastatin 20mg tablet	xxxxx-xxxx-xx	N	C/I	3.00000

Note: This example does not illustrate the contents of the NADAC file, show actual NADACs, or list all NDCs for these drug groupings.

Drug Grouping: All NDCs for Lipitor and atorvastatin 10mg tablets are classified into one drug group since they contain the same combination of active ingredient, strength, dosage form, and route of administration. However, when a NADAC is calculated for the

applicable NDCs in the drug group, these NDCs are further delineated by drug category and pharmacy type. Likewise, the NDCs for Lipitor and atorvastatin 20mg tablets would be classified together into a drug group separate from the 10mg version, due to the different strengths (10mg versus 20mg).

Please note that a drug group is comprised of pharmaceutically equivalent products at the active ingredient, strength, dosage form and route of administration level. Oral dosage forms of tablets and capsules will not be separated by package size. A NADAC may be calculated for package sizes within a drug group when the drug form is 'ml' or 'gram'.

Drug Category: The drug category differentiates the 'S/I' NDCs and the 'N' NDCs. Among NDCs with the same drug grouping, NDCs with a drug category of 'S/I' will receive the brand NADAC and NDCs with a drug category of 'N' will receive the generic NADAC. This is illustrated in the example for Lipitor 10mg tablets and atorvastatin 10mg tablets having the same drug grouping but different drug categories and therefore different NADACs.

Pharmacy Type Indicator: The pharmacy type indicator of 'C/I' signifies that the NADAC was based on drug acquisition costs from chain and independent pharmacies.

Data Sources

Numerous data sources are relied upon in order to facilitate the collection, calculation, analysis and reporting of the NADAC. Those data sources include:

- Drug acquisition cost data collected through voluntary monthly surveys of retail community pharmacy entities (independent and chain pharmacies).
- A national pharmacy file used to identify individual pharmacies.
- Drug identification and published pricing information obtained from national drug compendia files.
- The most recently available covered outpatient drug product file from CMS' Medicaid website, [Medicaid.gov](https://www.medicaid.gov), to use in NADAC criteria evaluation. In addition, interim updates, when available, are received from CMS for newly available covered outpatient drugs.
- The most recently available CMS list of labelers that are in the Medicaid Drug Rebate file (MDR) from CMS' Medicaid website, [Medicaid.gov](https://www.medicaid.gov), to use in NADAC criteria evaluation. In addition, interim updates, when available, are received from CMS for new rebating labelers.

Data Collection – Monthly Survey Process

On a monthly basis, Myers and Stauffer LC will collect acquisition cost data from a random sample of pharmacies selected from all 50 states and the District of Columbia. Pharmacy entities surveyed include independent and chain retail community pharmacies in the United States.

A national pharmacy compendia file containing information on retail pharmacies throughout the country is used to determine the pool of pharmacies eligible for each survey.

Independent and Chain Pharmacies - A random sample of independent and chain retail community pharmacies is generated each month. The sample is drawn from the total population of such pharmacies. The composition of the survey sample closely aligns with the composition of the pharmacy population with regards to general pharmacy characteristics (i.e., independent, chain, rural, and urban). Pharmacies that have been selected for a survey will be withheld from future survey selection for a three-month period. Samples are still considered random since the remaining pharmacies will have an equal probability of being sampled in any given month.

Specialty Pharmacies – Closed door pharmacies, including specialty pharmacies, who provide covered outpatient drugs primarily through the mail, are excluded from the surveys at this time. There is no statutory, regulatory, or universal industry accepted definition or listing of “specialty pharmacies” used within state Medicaid programs. However, pharmacies can choose to self-designate that they are primarily a “specialty pharmacy” in their reporting to the National Council for Prescription Drug Programs (NCPDP) database, or through the Utilization Review Accreditation Commission (URAC) quality accreditation process. For purposes of the NADAC survey distribution, self-designated “specialty pharmacies” are identified for potential survey exclusion through a review of the NCPDP database and URAC accreditation list.

Some covered outpatient drugs that are dispensed by closed door “specialty pharmacies” may also be dispensed by retail community pharmacies that are included in the NADAC survey. Although self-designated “specialty pharmacies” are generally excluded from the surveys at this time, NADAC rates will be established for covered outpatient drugs that may be considered “specialty drugs”, to the extent that acquisition costs for those drugs are available from retail community pharmacies.

Specialty Drugs – “Specialty drugs” typically refer to high-cost prescription drugs used to treat complex, chronic conditions. These drugs often require special handling and administration, along with continuous monitoring by a health care professional. Currently, there is no statutory, regulatory, or universal industry accepted definition of the term “specialty drugs,” nor a uniform list of “specialty drugs” utilized within state Medicaid programs. While “specialty drugs” may frequently be dispensed by closed door “specialty pharmacies” that are not included in the NADAC survey, these drugs may have a NADAC rate if acquisition costs are available from retail community pharmacies that are included in the NADAC survey.

Survey Process – Prior to the first of each month, survey letters are mailed to the physical location address of each selected pharmacy. The survey letter requests the voluntary submission of drug acquisition cost data from the pharmacy’s previous month of drug purchases. Pharmacies are asked to submit the requested information within two (2) weeks. Upon request from a pharmacy, survey letters can also be sent by electronic mail to the pharmacy or, in the case of chain providers, a corporate contact. Reminders are sent 10 to 14 days following the initial letter.

Survey Request – Pharmacies are requested to voluntarily submit invoices on all covered outpatient drug purchases made from all wholesalers or manufacturers during the specified time period. Information requested through the survey consists of a minimum of the following:

- NDC
- Unit Price Paid
- Invoice Date
- Quantity Purchased

The data items listed above are the only information collected from submitted documents that are used in calculating the NADAC. Other information from the survey submissions is not used for calculating the NADAC.

The information collected through the survey is information that is already contained in documentation maintained by a pharmacy; therefore, it is readily available and requires minimal effort to locate, identify and submit. The time needed to respond to the survey request should take no more than 30 minutes of non-pharmacist staff time. Moreover, many pharmacy inventory systems have functionality that allows them to easily and quickly produce and send a report that includes the requested survey information. Another option available to pharmacies is to contact their wholesalers and request that

they produce and send the requested survey information on the pharmacy's behalf. Survey data is accepted in hard copy and electronic formats.

Pharmacy invoices that reflect drugs purchased through the 340B program are requested to be excluded from survey submissions. If invoices with 340B pricing are submitted and able to be identified, they are excluded from the NADAC calculation. When pricing varies from a range of expected values, further research is done to determine if the pricing reflects 340B pricing including contacting the provider to confirm the type of acquisition prices being submitted. For purposes of this survey, discounts or rebates that are not reflected on the invoice at the drug line item level are not factored into the NADAC calculation.

In addition to information on drug purchases, pharmacies are requested to send back the cover sheet that accompanied the survey letter. This cover sheet indicates the pharmacy's intent that its submitted information remain confidential. If the cover sheet or other documentation requesting confidentiality is not included in the pharmacy's submission, Myers and Stauffer LC will contact the pharmacy to confirm its intent regarding the confidentiality of the submitted data. Regardless, please note that CMS is the owner of submitted data and Myers and Stauffer LC is contractually prohibited from releasing this data to any other parties. Refer to [Appendix 3](#) of this document for a sample of the survey letter and cover sheet.

Processing of Survey Data

Acquisition cost data submitted for the survey is accepted in many formats. Pharmacies or their wholesalers can submit their acquisition costs in electronic format via electronic mail delivery, send hard copy duplicates via postal mail, or transmit submissions via facsimile.

As survey responses are received, several tasks are performed to process the submissions. Submissions are entered in a receipt log to ensure that survey responses are tracked and counted. Whether a pharmacy has marked its submission as confidential is tracked. In cases where the pharmacy has not indicated that data provided is confidential, Myers and Stauffer LC will contact the pharmacy to clarify whether this omission was intentional. If the pharmacy chooses to indicate that its submission is confidential, a note is made in the receipt log.

Survey data is reviewed to ensure that costs entered into the database reflect the submitted data and that the NDCs are valid and active. Myers and Stauffer LC may contact pharmacies that submitted survey data to clarify questions about the submissions. Drug prices that are found to be equal to or greater than AWP, or otherwise aberrant, are evaluated in accordance with the process described in the “Quality Assurance” section of this document and entered into the database only if they meet the criteria for inclusion in that section. Refer to the “Background” section of this document for further discussion on limitations with the AWP.

If required data (e.g., NDC information) is not submitted or does not pass one of the quality assurance checks (such as NDCs that do not match the NDC listed in the CMS Medicaid Drug Rebate file or acquisition cost outliers), the vendor deems the submission is to be excluded from consideration in the calculation of the NADAC. Universal Product Code (UPC) and Health Related Item (HRI) codes, to the extent that they can be, are converted to their corresponding 11-digit NDCs for purposes of the NADAC calculation.

Survey data received in electronic format is directly imported while data received in hard copy are manually entered into the database. Once the database is complete, quality assurance procedures are performed to ensure that data is accurately and completely entered. Such procedures include comparisons between the actual submitted documents and related database entries, and reconciliation between the number of data lines submitted electronically versus those entered into the database.

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All submitted electronic and hard copy survey responses are stored in a secure and confidential manner. Hard copy files are stored in a locked environment until sent to CMS or destroyed upon CMS direction, in accordance with federal records retention requirements. All information submitted is the property of CMS, and Myers and Stauffer LC is prohibited from utilizing this data for any purpose other than as directed by CMS.

National Average Drug Acquisition Cost (NADAC) Calculation

Prior to NADAC calculations, the data are grouped based on active ingredient(s), strength, dosage form, and route of administration. The data is also classified according to its drug category as either Single source ('S'), Innovator multiple source ('I'), or Non-innovator multiple source ('N').

In order to be included in the NADAC calculations, the data must satisfy the following criteria:

- Data must be from pharmacies surveyed in the month under review.
- Invoice dates must be from the month under review.
- Acquisition cost data must be for valid, active NDCs listed in published pricing compendia. NDCs with an obsolete date are excluded from NADAC calculations. The obsolete date is reported by the manufacturer and indicates the NDC is to be discontinued, no longer marketed, no longer produced, no longer distributed, or otherwise made unavailable to the marketplace. This date is obtained from a national drug compendia file.
- NDCs with a defined CMS Termination Date are excluded from NADAC calculations unless the NDC also has a defined CMS Reactivation Date that is prior to the day on which calculation of the NADAC occurs.
- Products must be on the latest CMS covered outpatient drug product file or a newly added drug determined by CMS to be a covered outpatient drug as defined by section 1927 of the Social Security Act. Products must not have a Covered Outpatient Drug Status (COD) code that indicates the drug has been declared less than effective by the CMS Drug Product Efficacy Study and Implementation (DESI). Such drugs, identified as having a CMS COD Status of 05 or 06, are excluded. CMS COD Status codes are obtained from the CMS covered outpatient drug product file.
- Only one cost observation (a price that appears on an invoice), for each pharmacy, for each NDC, is included in the NADAC calculation. If a pharmacy submits more than one cost observation for the same NDC during the month, the cost observation with the latest date of purchase is used. Use of acquisition cost for the latest date of purchase allows for drug price changes that occur during the month to be reflected in the costs that are used to calculate the NADAC. If a pharmacy submits more than one cost observation for the same NDC with the same purchase date, the lowest cost is used. The basis for the inclusion of the

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lower rate is that if a pharmacy makes multiple purchases of the same NDC on the same purchase date, then the pharmacy is able to acquire the drug at the lowest cost possible.

A minimum number of cost observations necessary to calculate a NADAC has not been established. The number of cost observations necessary to obtain estimates with reasonable precision depends on the overall variation of acquisition costs, with no less than five cost observations used for NADAC calculations where costs are closely aligned. A thorough review of each NADAC calculation is performed to ensure reliable rate calculations, appropriate removal of outlier costs, and other measures defined in the “Quality Assurance” section of this document.

The NADAC rate, defined by drug grouping, drug category, and pharmacy type is calculated as the average of the per unit cost observations. The NADAC is a simple average of the drug acquisition costs submitted by retail community pharmacies. NADACs are calculated as a single national average; regional price variations are not incorporated at this time as the relative impact on the NADAC calculation is minimal. Also, NADACs are not weighted based upon independent or chain pharmacy types as the relative impact of the differences in their respective acquisition costs are minimal.

The dispersion of drug prices is measured by the standard deviation. Cost observations greater than +/- two (2) standard deviations from the mean are removed as outliers. This approach eliminates values that are substantially inconsistent with the majority of observations, while retaining a large majority of cost observations used to calculate a mean. Other outlier removal processes have been examined by consulting statisticians. At this time, this approach is the most effective process for removing outliers.

Once outlier observations are removed, the average of the remaining per unit costs is calculated. A drug-by-drug review of the remaining cost observations is conducted by a review team comprised of pharmacists and analysts.

Separate NADACs are calculated for ‘S/I’ drugs and ‘N’ drugs. The NADAC for ‘S’ and ‘I’ products is referred to brand drug NADACs. The NADAC for ‘N’ products is referred to as generic drug NADACs. Generally, there is one brand drug NADAC for ‘S’ and ‘I’ NDCs within a drug grouping. Likewise, one generic drug NADAC will apply to all ‘N’ NDCs within a drug grouping. This aligns with brand and generic reimbursement policies and requirements generally utilized by state Medicaid programs. For example, in accordance with their approved state plan, Medicaid programs may generally use a different reimbursement rate for brand drugs when a multiple source brand is preferred

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on the preferred drug list (PDL) or if the prescription is written brand medically necessary.

Application of Drug Category Overrides

Since the primary purpose of the drug category field in the CMS covered outpatient drug product file is to support the Medicaid Drug Rebate Program (MDRP) for the calculation and determination of rebates due from manufacturers to state Medicaid programs, it is necessary to make some adjustments to the application of these values to assist in their use as a basis for payment. Cost data for Single source ('S') and Innovator multiple source ('I') products are separated from Non-innovator multiple source ('N') products for NADAC calculations. The 'S', 'I', and 'N' designations are determined using the most current CMS covered outpatient drug product file. Processes to override the drug category to generally align with reimbursement designations used by states are described in further detail in the "NADAC Reporting Level" section of this document.

The following is an example of the use of the drug category and drug category overrides for NADAC purposes.

Example 2: Use of Drug Category Overrides for Application of NADACs to Individual NDCs

Drug Name (Labeler)	NDC	Drug Category	NADAC Per Unit	Note
Lipitor 10mg tablet (Manufacturer A)	xxxxx-xxxx-xx	S/I	2.00000	-
atorvastatin 10mg tablet (Manufacturer B)	xxxxx-xxxx-xx	N	1.00000	-
atorvastatin 10mg tablet (Manufacturer C)	xxxxx-xxxx-xx	N	1.00000	-
atorvastatin 10mg tablet (Manufacturer D)	xxxxx-xxxx-xx	S/I	1.00000	Overridden to a generic drug NADAC due to authorized generic status

Note: This example does not illustrate the contents of the NADAC file, show actual NADACs, or list all NDCs for this drug grouping.

This example illustrates the use of drug category overrides for the application of NADACs to NDCs.

In this example, Lipitor 10mg tablet is a brand drug and the NADAC that applies to this NDC within this drug grouping has a drug category of 'S/I'. Atorvastatin made by Manufacturers B and C are generic drugs, and the NADAC that applies to these NDCs within this drug grouping have a drug category of 'N'.

The NDC for atorvastatin made by Manufacturer D has a drug category of 'S/I' on the covered outpatient drug file. However, it is an authorized generic drug so state Medicaid programs may consider this drug to be a generic drug and in such situations, the drug category is overridden.

Application of Differential NADACs Based on Package Size

There are some situations where exceptions to NADAC drug grouping are applied to ensure appropriate drug grouping. While most NADAC drug groupings will consist of all package sizes available, a separate NADAC may be calculated for package sizes within a drug grouping when the drug form is 'ml' or 'gram' and when there is a demonstrated variation in acquisition costs between package sizes for drugs in which the most cost effective package size cannot be purchased and easily repackaged for dispensing (e.g., topical creams and ointments). Drug forms with kits will also be evaluated for pricing per package size. These situations require the use of differential NADAC drug groupings that vary by package size. These NADACs are calculated for unique drug grouping / drug category / pharmacy type / package size combinations.

Application of Differential NADACs Based on Drug Class

Another situation of exceptions to the typical NADAC drug grouping process is calculating separate NADACs based upon a drug's class. Drug class is based on whether a prescription is required for dispensing a drug product. If a prescription is required, the NDC is referred to as 'legend.' If a prescription is not required, the NDC is referred to as 'over-the-counter,' or 'OTC'. The OTC field on the NADAC file will indicate whether the NDC is considered legend or OTC.

Different NADAC groups are assigned in cases where NDCs within a NADAC drug grouping share identical active ingredients, strength, dosage form, and route of administration but differ by drug class. These NADACs are calculated for unique drug grouping / drug category / pharmacy type / drug class combinations. In other words, NADACs for legend drugs are calculated only from costs for legend drug NDCs. Also, over-the-counter (OTC) drugs are calculated only from costs for OTC NDCs. As with all Medicaid covered outpatient drugs, a prescription is required.

Application of Differential NADACs Based on Therapeutic Equivalency

Therapeutic equivalency is the equivalency rating assigned by the Food and Drug Administration (FDA) as reported in the Orange Book. The majority of NADAC drug groupings will consist of NDCs that share the same therapeutic equivalency. For a small number of NADAC drug groupings where NDCs share identical active ingredients, strength, dosage form, and route of administration but differ by therapeutic equivalency, there may be a need to subdivide the group and calculate separate NADACs per therapeutic equivalency code. These NADACs are calculated for unique drug grouping / drug category / pharmacy type / therapeutic equivalency combinations. In other words, NADACs for drugs with a specific therapeutic equivalency code are calculated only from costs for NDCs with that specific therapeutic equivalency code.

Application of Differential NADACs Based on Multiple Brand Manufacturers within the Same NADAC Grouping

Brand drug NADAC will generally be based upon the products from a single manufacturer that is identified as the innovator of the drug grouping. There are situations where products from more than one manufacturer within a drug grouping are classified brand drugs by state Medicaid programs and separate NADACs are typically calculated per manufacturer product within the same drug grouping.

Application of Differential NADACs to Biosimilars

NDCs approved as biosimilar products are considered brand ('B') and will be designated as ('B-BIO'). Each approved biosimilar for the reference listed biologic will have its own individual NADAC rate. Biosimilars containing the same ingredient, dosage form, and strength will not have their invoice costs combined for purposes of the NADAC calculation.

Statistical Validity

Validity means that the sample mean is an accurate estimate of the true mean and the sample mean is estimated precisely. Simple random sampling helps to ensure accuracy as the sample reflects the characteristics of the population. Precision depends upon the characteristics of the sample. In particular, as the observations in the population become more concentrated around a single value, the sample mean becomes more precise.

Brand drug NADACs exhibit a high level of precision, demonstrated by low margins of error. For brand drugs, 99.3% of NADACs have a margin of error of less than 5% of the

mean unit cost at a confidence interval of 95%. In other words, 99.3% of the NADACs for brand drugs are within 5% of the true average drug cost 95 out of 100 times. The average margin of error as a percent of the mean unit cost is very low at 0.5%, at a confidence level of 95%.

As with brand drug NADACs, calculations for generic drug NADACs result in high levels of precision with low margins of error. For generic drugs, 100% of NADACs have a margin of error of less than 10% of the mean unit cost at a confidence interval of 95%. In other words, 100% of the NADACs for generic drugs are within 10% of the true average drug cost 95 out of 100 times. The average margin of error as a percent of the mean unit cost is very low at 2.4%, at a confidence level of 95%.

NADAC Updates

NADAC file updates occur on a weekly and monthly schedule.

Non-innovator multiple source drugs (Generic drugs)

After an initial NADAC has been determined using the results of the monthly pharmacy acquisition cost surveys, it is reviewed for updates on both a weekly and monthly schedule.

On a weekly basis, the NADACs for generic drugs are reviewed and adjusted, as necessary, based on research initiated by pharmacy inquiries into the NADAC Help Desk. If research, such as evaluating marketplace availability and contacting other pharmacies, substantiates that a change in price for a generic drug has occurred, a revised NADAC is calculated and included in the next weekly NADAC reference file update. Refer to the “Help Desk Support Functions” section of this document for further details.

Provider inquiries regarding the NADAC will be investigated and evaluated based upon invoice data collected from the pharmacy initiating the review, additional pharmacies contacted by the help desk, and other market factors, such as compendia price changes. NADACs will be adjusted when drug pricing changes have been substantiated and those adjustments will be reflected in the NADAC rate updates published on a weekly basis.

In addition, new drugs as identified by CMS that meet the NADAC criteria are added.

On a monthly basis, existing NADACs for generic drugs are replaced with updated NADACs using the results of the ongoing monthly pharmacy acquisition cost surveys. New drugs as identified by CMS that meet the NADAC criteria are also added during the monthly update.

Some existing NADACs may not be updated due to limited subsequent survey data. In these cases, the existing NADAC for the generic drug will remain on the NADAC file until the sooner of 1) the first month for which a NADAC can be calculated, or 2) twelve months. If an updated NADAC cannot be calculated with survey data or updated based on Help Desk review after twelve consecutive months, the NADAC is removed from the NADAC reference file. Once a NADAC can be calculated for a previously removed drug grouping, the NADAC will again appear on the reference file.

Single source or Innovator multiple source drugs (Brand drugs)

Published pricing compendia pricing changes associated with brand drugs are considered prior to the publication of updated NADACs that are based on monthly surveys. Drug costs used for determining the brand drugs' NADAC are adjusted to reflect the relative change in published drug prices, as described below. This ensures that brand drug NADACs are reflective of current drug prices at the time of publication. After a NADAC has been determined using the results of the monthly pharmacy acquisition cost surveys, it is further reviewed for updates on a weekly schedule.

On a weekly basis, the NADACs for brand drugs are reviewed and adjusted as necessary based on changes in published prices. Changes in published prices are measured as the relative percentage difference between the new published price and the previous published price. Therefore, if the published price for a drug increases by 5%, then the NADAC for that drug is also increased by 5%. The pricing change is validated with survey data obtained from the next monthly survey. The relationship between changes in published brand drug prices and changes in actual brand drug prices obtained from surveys are tracked and monitored to ensure that a consistent correlation continues to exist.

Additionally, Myers and Stauffer LC operates a Help Desk to respond to inquiries related to drug price changes that are not reflected on the current NADAC reference file. NADACs are reviewed and adjusted based on research initiated in response to pharmacy inquiries made to the NADAC Help Desk. If research, such as evaluating marketplace availability and contacting other pharmacies, substantiates that a change in price for a generic drug has occurred, a revised NADAC is calculated and included in the next weekly NADAC reference file update. Refer to the "Help Desk Support Functions" section of this document for further details.

On a monthly basis, existing NADACs for brand drugs are evaluated and then updated based on new survey data. For consistency and smoothing purposes, the results of each subsequent monthly pharmacy acquisition cost survey for brand products are compared to the existing brand NADAC to evaluate whether a change is warranted. Historic month-over-month published pricing changes were evaluated to determine trends in pricing. A 2% pricing change variance threshold for brand drug NADACs was established after extensive analysis of published pricing changes. Published pricing changes were very rarely less than 2%. Therefore, changes of less than 2% from the previous month's brand NADAC will not generally warrant a change in the published NADAC. Since manufacturer published price changes are already being accounted for through the regular weekly processes, small pricing variations observed from month-to-

month are likely reflective of fluctuations due to the composition of responding pharmacies and not related to marketplace changes in the price of the drug. Utilizing this threshold in the evaluation of brand drug NADACs will avoid implementing NADAC adjustments that are not based on changes in marketplace prices.

Conversely, if the 2% variance threshold is exceeded, the current brand drug NADAC is replaced with the new brand drug NADAC based on the latest monthly survey findings. If the threshold is not exceeded, the current brand drug NADAC will remain on the NADAC file with the current effective date. Refer to the “Effective Date Assignment” section for details on effective dates.

NADACs for generic drugs do not have thresholds established since prices tend to be more volatile. Due to this volatility in pricing, a smoothing process would only serve to dampen the effects of true changes in market prices. Utilizing changes in published pricing for generic drug NADACs is also not practical since the relationship between reported prices and actual prices do not demonstrate a level of consistency for generic drugs as it does for brand drugs. In other words, published pricing changes, such as WAC or AWP, for generic drugs have not been shown to represent actual pricing changes. Therefore, the calculated monthly NADACs for generic drugs are utilized without any smoothing processes.

Some existing NADACs may not be updated due to limited subsequent monthly survey data. In these cases, the existing NADAC for brand drugs will remain on the NADAC file until the sooner of 1) the first month for which a NADAC can be calculated, or 2) twelve months. If an updated NADAC cannot be calculated with survey data, or updated due to a change in published drug pricing or Help Desk review based on a pharmacy inquiry after twelve consecutive months, the NADAC is removed from the NADAC reference file. Once a NADAC can be calculated for a previously removed drug grouping, the NADAC will again appear on the reference file.

Addition of NADACs for new drugs not listed on current quarterly CMS covered outpatient drug product file

The CMS covered outpatient drug product file available on [Medicaid.gov](https://www.medicicaid.gov) is updated on a quarterly basis. There may be instances when drugs that are new to the pharmacy marketplace are not listed until the next quarterly covered outpatient drug product file is published. The lag between the availability of the new drug product in the marketplace and its inclusion on the covered outpatient drug product file could potentially delay the addition of new drugs to the NADAC file. To address these instances, Myers and Stauffer LC receives updates from CMS with regard to new drug products. The drug

Methodology for Calculating the National Average Drug Acquisition Cost (NADAC)

category for the new drug is assigned through the drug category review process discussed in the “NADAC Calculation” section. When acquisition cost data is available for these new drugs, a NADAC is calculated and added to the NADAC reference file.

Deliverables

The NADAC reference file is publically available on CMS' Medicaid website, [Medicaid.gov](https://www.Medicaid.gov). The most current reference file is posted, and contains all NADACs and associated information.

NADAC Reference File Format and Layout

The NADAC reference file is published as an Excel file. The file is sorted by NDC Description in alphabetical order and contains the following fields:

- NDC Description – Identifies the drug name, strength, and dosage form of the drug product.
- NDC – The National Drug Code (NDC) is a numerical code maintained by the FDA that includes the labeler code, product code, and package code. The NDC is an 11-digit code.
- NADAC Per Unit – The National Average Drug Acquisition Cost per unit.
- Effective Date – The effective date of the NADAC Per Unit cost.
- Pricing Unit – Indicates the pricing unit for the associated NDC ('ML', 'GM' or 'EA').
- Pharmacy Type Indicator – The source of pharmacy survey data used to calculate the NADAC. 'C/I' indicates data was collected from surveys of Chain/Independent pharmacies. Other pharmacy type indicators are not used at this time.
- OTC – Indicates whether or not the NDC is for an over-the-counter (OTC) product ('Y' or 'N').
- Explanation Code – Codes that pertain to how the NADAC was calculated. These codes are identified in an accompanying NADAC Data Field Definitions document that is posted on [Medicaid.gov](https://www.Medicaid.gov). Refer to [Appendix 2](#) for further information.
- Classification for Rate Setting – Indicates whether the NDC was considered brand ('B') or generic ('G') for the NADAC rate calculation process. NDCs that were considered brand and are approved by the FDA under an Abbreviated New Drug Application (ANDA) are designated with ('B-ANDA'). NDCs approved as

biosimilar products are considered brand ('B') and will be designated as ('B-BIO').

- Please see more information on ('B-ANDA') in the "NADAC Reporting Level" section of this document.
- Corresponding Generic Drug NADAC Per Unit *and* Corresponding Generic Drug NADAC Effective Date are presented in further detail later in this section.

[Appendix 1](#) contains an example of the NADAC reference file.

NADAC Reference File Publication

The NADAC reference file is posted weekly on [Medicaid.gov](https://www.Medicaid.gov). The file contains all of the NDCs that have an assigned NADAC. Each NADAC reference file update contains a full listing of covered outpatient drug products' NDCs with assigned NADACs; therefore, this is a full reference file replacement each week. The header of the NADAC reference file indicates whether the NADAC updates reflect the results of the monthly acquisition cost survey or account for the weekly NADAC update processes described in the "NADAC Updates" section. The header will display:

<Monthly/Weekly> NADAC Reference File as of <date>

Additional details regarding the reason for specific NADAC pricing changes are available in the NADAC Week-to-Week Comparison File, presented in further detail later in this section.

Once a NADAC is calculated for a drug grouping, the NADAC is only applied to covered outpatient drug NDCs within that group. NADACs are applied to the entire grouping regardless of whether or not costs were collected for a specific NDC within the drug group, however they will not be published for NDCs that are not CMS covered outpatient drugs.

NDCs with a CMS Termination Date that is before the posting date are excluded from the reference file, unless it also has a CMS Reactivation Date that is before the posting date. In these cases, the NDCs will not be excluded from the reference file. The updated NADAC reference file will replace the existing reference file available through the [Medicaid.gov](https://www.Medicaid.gov) website. Changes to the NADAC reference file are identified through the Explanation Code field.

Methodology for Calculating the National Average Drug Acquisition Cost (NADAC)

In addition to the NADAC reference file, an accompanying NADAC Data Field Definitions document is published to assist in the interpretation of the NADAC reference file. Information in this document includes the field names, field descriptions, and explanation codes.

Effective Date Assignment

The Effective Date associated with a NADAC will depend on whether the NADAC was updated.

- For NADACs that do not change from the previous reference file, the NADAC and Effective Date will carry forward to the new reference file.
- For NADACs that are added or changed from the previous reference file, a new Effective Date is assigned to the NADAC. This Effective Date is the date on which the NADAC becomes effective.

NADACs are posted two months after the surveyed pharmacy invoices are collected and utilized to calculate prices, as illustrated below.

Description	Month 1	Month 2
Date of Drug Purchases for Acquisition Costs	November 1 – November 30	December 1 – December 31
Month of Survey Collection, Processing and NADAC Calculations	December	January
Month of NADAC Reference File Publication	January	February

Please refer to the “NADAC Updates” section for more detail regarding how drug acquisition costs are updated prior to NADAC reference file publication.

Brand and Generic Drug NADACs for Multiple Source Brand Drug NDCs

In cases where a multiple source brand drug NDC and its corresponding generic drug counterpart both have assigned NADACs, the NADAC reference file will list the NADAC for the corresponding generic drug on the same record line as the multiple source brand NDC. The corresponding generic drug NADAC will also include situations where the only generic drug available is the authorized generic. The effective date associated with the corresponding generic drug NADACs will also be shown on the same record line.

The NADAC reference file contains two columns where the corresponding generic drug NADAC information is contained. These columns are:

- Corresponding Generic Drug NADAC Per Unit – The NADAC for the corresponding generic drug.
- Corresponding Generic Drug NADAC Effective Date – The effective date of when the corresponding generic drug NADAC is assigned to a multiple source brand drug NDC. This date may not correspond to the NADAC effective date for the generic drug due to the method by which the corresponding generic drug NADAC effective date is assigned.

The corresponding generic drug NADAC effective date is the latter of the following dates: a) date of the NADAC reference file upon which the corresponding generic drug NADAC first appears, b) the current corresponding generic drug NADAC effective date plus one day – one day is added to the previous date so that there are no overlapping rate segments, or c) the NADAC Effective Date for the generic drug group. This date assignment process is necessary to update the corresponding generic drug NADACs.

The corresponding generic drug NADAC columns will not be populated when 1) the NDC is not a multiple source brand drug, or 2) there is no NADAC for the corresponding generic drug.

NADAC Week-to-Week Comparison File

A separate file is published on the CMS Medicaid website, [Medicaid.gov](https://www.Medicaid.gov), which compares the most current NADAC reference file with the immediately preceding NADAC reference file. This comparison file is updated and published on a weekly basis.

Methodology for Calculating the National Average Drug Acquisition Cost (NADAC)

The comparison will only consist of NDCs whose NADACs have changed since the previous NADAC reference file. The file will not be inclusive of all NDCs in the NADAC reference file. New NDCs or terminated NDCs are not included in this file. NDCs whose NADACs have not changed since the previous NADAC reference file will not be included in this file.

The file is sorted by NDC Description and will contain the following fields:

- NDC Description – Identifies the drug name, strength and dosage form of the drug product.
- NDC – The National Drug Code (NDC) is the numerical code maintained by the FDA that includes the labeler code, product code, and package code. The NDC is an 11-digit code.
- Old NADAC Per Unit – The National Average Drug Acquisition Cost per unit from the previous NADAC Reference File.
- New NADAC Per Unit – The National Average Drug Acquisition Cost per unit from the current NADAC Reference File.
- Classification for Rate Setting – Indicates whether the NDC was considered brand ('B') or generic ('G') for the NADAC rate calculation process. If the NDC was considered brand ('B') and approved under an Abbreviated New Drug Application (ANDA), the indicator is shown as ('B-ANDA'). NDCs approved as biosimilar products are considered brand ('B') and will be designated as ('B-BIO').
- Percent Change – The difference between the New NADAC Per Unit and the Old NADAC Per Unit, divided by the Old NADAC Per Unit.
- Primary Reason – Describes the primary reason for the NADAC Per Unit change, see explanation below for each reason:
 - Survey Rate: The NADAC Per Unit has been updated using information from the most recently completed pharmacy survey.
 - WAC Adjustment: The NADAC Per Unit has been updated to reflect changes in published pricing.

- Help Desk Adjustment: The NADAC Per Unit has been updated as a result of an inquiry to the help desk.
- Brand Generic Change: The NADAC Per Unit has been updated as a result of a change in the Classification for Rate Setting.
- Rate Group Change: The NADAC Per Unit has been updated due to placement into a new NADAC drug grouping because of a change in NDC attributes.

In addition to the NADAC Week-to-Week Comparison File, an accompanying NADAC Week-to-Week Comparison File Field Definitions document is published to assist in the interpretation of the file. Information in this document includes field names, field descriptions, and primary reasons.

[Appendix 5](#) contains an example of the NADAC Week-to-Week Comparison File. [Appendix 6](#) contains the NADAC Week-to-Week Comparison File Data Field Definitions.

Quality Assurance

Myers and Stauffer LC fully incorporates quality assurance procedures to ensure that acquisition cost submissions are reasonable (as discussed below), are associated with valid, active NDCs, and calculations are performed in accordance with the methodology outlined in this document.

Prior to initiation of NADAC calculations, data is reviewed to ensure that costs entered into the database reflect the submitted data and that the NDCs are valid and active. Quality assurance checks are performed to ensure that acquisition costs are being reported and not being substituted with commercial pricing benchmarks such as WAC or AWP. For an entire submission from one pharmacy, the percentage of costs reported that are equal to or greater than AWP is calculated. If costs equal to or above AWP meet an established threshold in the aggregate, further investigation is initiated to ensure that actual cost data is submitted.

As part of this investigation process, individual pharmacies are contacted if there are questions with the pharmacy's acquisition cost submissions. As described earlier in the "NADAC Calculation" section, price outliers are removed through two processes. The first process removes all cost observations that are not within two (2) standard deviations from the mean acquisition cost for the drug grouping. This approach eliminates values that are substantially inconsistent with the majority of observations, while retaining a large majority of values used to calculate a mean.

The second process is a manual review of the NADAC calculations. A drug-by-drug review is conducted by a review team comprised of pharmacists and analysts to ensure that reliable NADAC calculations have been performed. These reviews consist of measures to determine the reliability of the NADACs. The array of invoice costs collected are carefully analyzed to determine if factors such as price increases or drug shortages during the invoice collection period may have adversely impacted the NADAC calculation. Obvious outliers, data entry/data import errors and package size discrepancies are identified and addressed. NADAC files are reviewed weekly and monthly to ensure consistency of drug groups, drug categories, and NDC counts. Additionally, large increases and decreases in NADACs prompt further research to confirm drug price changes.

These quality assurance measures prevent outlier acquisition costs from inappropriately impacting the NADAC calculation, distinguish potential inconsistencies in data, proactively identify changes that require further investigation, and ensure reliable NADAC calculations. Myers and Stauffer LC also performs ongoing quality review of

calculations and procedures for the acquisition cost survey and NADAC reference file publication in order to continue to refine these processes. Examples of quality assurance analyses used for this type of review include monitoring price change trends compared to published price references and comparison of acquisition costs across various pharmacy characteristics, such as chain or independent pharmacies.

Help Desk Support Functions

Myers and Stauffer LC provides a NADAC Help Desk, which is staffed with certified pharmacy technicians, trained analysts, and pharmacists. This Help Desk will assist pharmacies and state Medicaid agencies with the following types of issues:

- Survey Support - Pharmacies are able to contact Myers and Stauffer LC with questions related to the survey, survey process, options for responding to the survey, what information to submit, or other related questions.
- Pharmacy Rate Inquiries and Drug Price Changes – Pharmacies are able to submit rate inquiries and provide notification of recent drug price changes that are not reflected in posted NADACs to the Help Desk. If not submitted with the inquiry, the Help Desk staff will request additional information to assist in the research of these changes, such as invoices or screen shots of drug ordering systems reflecting current acquisition costs.
- General NADAC Related Questions

The Help Desk will receive and research each and every inquiry received. Pharmacy inquiries regarding the NADAC will be investigated and evaluated based upon invoice data collected from the pharmacy initiating the review, additional pharmacies contacted by the Help Desk, and other market factors, such as compendia pricing changes and drug shortages.

Since the NADAC is an average, it is expected that some pharmacies will purchase covered outpatient drugs on invoice below the NADAC and some pharmacies will purchase covered outpatient drugs on invoice above the NADAC.

NADACs will be adjusted when drug pricing changes have been substantiated and those adjustments will be reflected in the NADAC rate updates published on a weekly basis. If a pharmacy invoice cost is within the range of invoice costs utilized to establish the current NADAC rate and there is no change in the most recent invoice data available, then the current NADAC will remain unchanged.

Pharmacies can check the next weekly NADAC file, the NADAC Week to Week Comparison File or contact the Help Desk to check the status of their inquiry. The NADAC rate files and NADAC Week to Week Comparison Files are available at:

<https://www.medicaid.gov/medicaid/prescription-drugs/pharmacy-pricing/index.html>

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The Help Desk is not able to address pharmacy inquiries into specific state or claim reimbursement related questions or concerns. A standard NADAC pricing inquiry form is available for pharmacies at:

<https://www.medicaid.gov/medicaid/prescription-drugs/survey-of-retail-prices/index.html>

The NADAC Help Desk can be contacted through the following means:

Toll-free phone: (855) 457-5264

Electronic mail: info@mslcrps.com

Facsimile: (844) 860-0236

Glossary

Term	Definition
Active Ingredient(s)	The active ingredient(s) represents the text description of the generic name of the drug product for the NDC.
Classification for Rate Setting	Indicates whether the NDC was a brand ('B') or generic ('G') for the NADAC rate calculation process. NDCs that were reported brand and are approved by FDA under an Abbreviated New Drug Application (ANDA) are designated by ('B-ANDA') NDCs approved as biosimilar products are considered brand ('B') and will be designated as ('B-BIO').
CMS Covered Outpatient Drug (COD) Status	A category that identifies whether or not a product meets the statutory definition of a covered outpatient drug in accordance with sections 1927(k)(2) to 1972(k)(4) of the Social Security Act. A COD value of '05' and '06' indicate that the drug is not eligible for coverage or rebates under the Medicaid Drug Rebate Program because they have been determined to be less than effective by the Drug Product Efficacy Study and Implementation (DESI).
CMS Reactivation Date	Date on which a terminated product is re-introduced to the market.
CMS Termination Date	Date the drug was withdrawn from the market or the drug's last lot expiration date.
CMS Drug Category	'S/I' drug or 'N' drug, as determined through the 'Single-source', 'Innovator Multiple Source', and 'Non-innovator Multiple Source' drug category designations listed on the most current CMS outpatient covered drug product file.

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Term	Definition
Corresponding Generic Drug NADAC Per Unit	The NADAC for the corresponding generic drug that is assigned to a multiple source brand drug NDC.
Corresponding Generic Drug NADAC Effective Date	The date when the corresponding generic drug NADAC is assigned to a multiple source brand drug NDC.
Drug Grouping	The drug grouping is based on active ingredient, strength, dosage form, and route of administration for a formulation. In some cases, the drug grouping is further differentiated by package size. This additional delineation occurs when there is a demonstrated variation of acquisition cost among package sizes for drugs in which the most cost effective package size cannot be purchased and easily repackaged for dispensing.
Effective Date	The effective date of the NADAC Per Unit cost.
Explanation Code	Codes that pertain to how the NADAC was calculated. These codes are identified in an accompanying NADAC Data Field Definitions document that is posted on Medicaid.gov . Refer to Appendix 2 for further information.
NADAC	The National Average Drug Acquisition Cost (NADAC). Represents a national pricing benchmark that is reflective of actual invoice costs that pharmacies pay to acquire prescription and over-the-counter drugs. It is based upon invoice cost data collected from retail community pharmacies and reflects actual drug purchases.

Methodology for Calculating the National Average Drug Acquisition Cost (NADAC)

Term	Definition
<i>NDC</i>	The National Drug Code (NDC) is a numerical code maintained by the FDA that includes the labeler code, product code, and package code. The NDC is an 11-digit code.
<i>NDC Description</i>	Identifies the drug name, strength, and dosage form of the drug product.
<i>Obsolete Date</i>	The estimated date reported by the manufacturer, that indicates the NDC is to be discontinued, no longer marketed, no longer produced, no longer distributed, or otherwise made unavailable to the marketplace. This date is obtained from drug pricing compendia.
<i>Outlier</i>	Drug cost observations that exhibit a deviation from other known cost observations for similar drugs. The two standard deviation approach combined with a manual review is the most effective process for removing outliers.
<i>Pharmacy Type</i>	<p>A category of pharmacies. Entities such as chain and independent pharmacies (C/I), as determined through self-reported pharmacy identification, or other supplemental resources. This information is obtained from a national pharmacy compendia file.</p> <p>A chain pharmacy is defined as a pharmacy that belongs to a group of four or more pharmacies that are all under the same ownership and all have the same name. An independent pharmacy is defined as a pharmacy that is not owned or operated by a chain. Franchise pharmacies are classified as independent pharmacies.</p>

Methodology for Calculating the National Average Drug Acquisition Cost (NADAC)

<i>Term</i>	Definition
<i>Pricing Unit</i>	Indicates the pricing unit for the associated NDC (e.g., 'ML', 'GM', or 'EA').
<i>Specialty Pharmacy</i>	Closed door pharmacies, who provide covered outpatient drugs primarily through the mail, that dispense specialty drugs, as identified by the classification of their pharmacies as primarily specialty pharmacies in the National Council for Prescription Drug Programs (NCPDP) database. In addition, URAC specialty pharmacy certification is used as a supplement to identify closed door specialty pharmacies.

Appendix

- 1) Sample NADAC Reference File
- 2) NADAC Data Field Definitions
- 3) Survey Letter and Cover Sheet
- 4) Paperwork Reduction Act Statement
- 5) Sample NADAC Week-to-Week Comparison File
- 6) NADAC Week-to-Week Comparison File Data Field Definitions

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APPENDIX 1: Sample NADAC Reference File, with a deliverable date of 2/15/2013

NDC Description	NDC	NADAC Per Unit	Effective Date	Pricing Unit	Pharmacy Type Indicator	OTC	Explanation Code ¹	Classification for Rate Setting	Corresponding Generic Drug NADAC Per Unit	Corresponding Generic Drug NADAC Per Unit
Drug A 5mg Tab	XXXXX-XXXX-XX	0.12345	1/1/2013	Tablet	C/I	N	1,6	G	-	-
Drug B 5mg Tab	XXXXX-XXXX-XX	6.54321	2/1/2013	Tablet	C/I	N	1	B	0.12345	2/15/2013
Drug C 15mg Tab	XXXXX-XXXX-XX	12.34567	2/1/2013	Tablet	C/I	N	1	B-ANDA	0.98765	2/1/2013

¹NADAC Attribute - 1 identifies that the posted NADAC reflects the average cost from submitted invoice costs only. NADAC Attribute - 6 identifies that the drug category on the CMS covered outpatient drug product file was not applied (overridden).

In the example above, Drug B is a multisource brand drug and Drug A is its corresponding generic drug. Please refer to the discussion on *Brand and Generic Drug NADACs for Multiple Source Brand Drug NDCs* within the *Deliverables* section of this document for further explanation of the corresponding generic drug NADAC columns.

Drug C is an example of a drug that is classified as a brand drug for purposes of Medicaid payment and is approved by FDA under an Abbreviated New Drug Application (ANDA).

APPENDIX 2: NADAC Data Field Definitions

NATIONAL AVERAGE DRUG ACQUISITION COST (NADAC) DATA FIELD DEFINITIONS

National Drug Code (NDC) Description:

Identifies the drug name, strength, and dosage form of the drug product.

NDC:

The National Drug Code (NDC) is a numerical code maintained by the FDA that includes the labeler code, product code, and package code. The NDC is an 11-digit code.

NADAC Per Unit:

The National Average Drug Acquisition Cost per unit.

Effective Date:

The effective date of the NADAC Per Unit cost.

Pricing Unit:

Indicates the pricing unit for the associated NDC ('ML', 'GM' or 'EA').

Pharmacy Type Indicator:

The source of pharmacy survey data used to calculate the NADAC. 'C/I' indicates data was collected from surveys of Chain/Independent pharmacies. Other pharmacy type indicators are not used at this time.

OTC:

Indicates whether or not the NDC is for an over-the-counter (OTC) product ('Y' or 'N').

Explanation Code:

Codes that pertain to how the NADAC was calculated; see explanation code descriptions below.

- Code 1: The NADAC was calculated using information from the most recently completed pharmacy survey.
- Code 2: The average acquisition cost of the most recent survey was within $\pm 2\%$ of the current NADAC; therefore, the NADAC was carried forward from the previous file.
- Code 3: The NADAC based on survey data has been adjusted to reflect changes in published pricing, or as a result of an inquiry to the help desk.
- Code 4: The NADAC was carried forward from the previous file.
- Code 5: The NADAC was calculated based on package size.

Methodology for Calculating the National Average Drug Acquisition Cost (NADAC)

- Code 6: The CMS Covered Outpatient Drug Product File drug category type of 'S/I/N' (Single Source/Innovator/Non-Innovator) has not been applied. Most 'S/I' drugs with the same strength, dosage form and route of administration were grouped together for the purpose of the NADAC calculation and 'N' drugs were also grouped together. In some cases, however, in calculating a NADAC, the CMS 'S/I/N' designation was not applied when the State Medicaid brand or generic payment practices for these drugs generally differed from the Covered Outpatient Drug Product File designation.

For example, authorized generic drugs are appropriately listed in the CMS covered outpatient drug file as 'I' drugs for the purpose of rebates as they were approved under a New Drug Application (NDA). However, they are grouped as 'N' for the NADAC calculation since they are generally designated as generic by most State Medicaid programs for the purposes of reimbursement. Another example of this occurrence is when proprietary named drugs, approved under an Abbreviated New Drug Application (ANDA) are appropriately in the CMS Covered Outpatient Drug file as 'N' for the purpose of rebates. However, they are grouped as 'S/I' for the NADAC calculation since they are generally reimbursed as brand drugs by State Medicaid programs.

- Codes 7 through 10: Reserved for future use.

Classification for Rate Setting:

Indicates whether the NDC was considered brand ('B') or generic ('G') for the NADAC rate calculation process. If the NDC was considered brand ('B') and approved under an Abbreviated New Drug Application (ANDA), the indicator is shown as ('B-ANDA'). NDCs approved as biosimilar products are considered brand ('B') and will be designated as ('B-BIO').

Corresponding Generic Drug NADAC Per Unit:

The NADAC for the corresponding generic drug.

Corresponding Generic Drug Effective Date:

The effective date of when the Corresponding Generic Drug NADAC Per Unit is assigned to a multiple source brand drug NDC. This date may not correspond to the NADAC effective date for the generic drug due to the method by which the corresponding generic drug NADAC effective date is assigned.

The corresponding generic drug NADAC effective date is the latter of the following dates: a) date of the NADAC reference file upon which the corresponding generic drug NADAC first appears, b) the current corresponding generic drug NADAC effective date plus one day – one day is added to the previous date so that there are no overlapping rate segments, or c) the NADAC Effective Date for the generic drug group. This data assignment process is necessary to eliminate the potential for applying corresponding generic drug NADACs to past claims.

Methodology for Calculating the National Average Drug Acquisition Cost (NADAC)

APPENDIX 3: Survey Letter



Center for Medicaid and CHIP Services

August 1, 2016

Dear Pharmacy Owner / Manager:

As you are aware, changes in the availability of drug pricing benchmarks necessitate that many State Medicaid programs evaluate alternative pricing methods for use in reimbursing pharmacies for drugs that they dispense. Because of these changes, we have the unique opportunity to work together to recognize the contributions pharmacists make to the health of Medicaid recipients through the realignment of drug ingredient reimbursement for estimating pharmacy's acquisition costs, and the provision of reasonable Medicaid dispensing fees that consider professional services performed by pharmacists.

The Centers for Medicare and Medicaid Services (CMS) is working with State Medicaid programs, with input from national pharmacy associations and many other stakeholders, regarding the design and development of a National Average Drug Acquisition Cost (NADAC) reference file. We expect that the NADAC reference file will represent a new pricing benchmark based on the national average costs that pharmacies pay to acquire Medicaid covered outpatient drugs. This pricing benchmark will be based on drug acquisition costs collected directly from pharmacies through a nationwide survey process. This survey will be conducted on a monthly basis to ensure that the NADAC reference file remains current and up-to-date.

CMS envisions that the NADAC reference file will provide State Medicaid agencies with an additional pricing reference which they can use to evaluate their current drug reimbursement methodologies. If a Medicaid program chooses to utilize the NADAC reference file for drug ingredient reimbursement, we expect that States will simultaneously evaluate their Medicaid dispensing fee.

One of the primary goals of this program is to create and maintain an up-to-date NADAC reference list for Medicaid covered outpatient drugs reflecting the average price paid for drugs by entities (e.g., independent pharmacies and chain pharmacies in the United States). The drug acquisition cost survey process has been designed to minimize the administrative burdens on pharmacies that participate and to streamline the process of obtaining drug cost data from pharmacies.

CMS has contracted with Myers and Stauffer LC, a national certified public accounting firm that provides professional accounting, consulting, data management and analysis services to government-sponsored healthcare programs. Myers and Stauffer has extensive experience working with State Medicaid pharmacy programs and collecting acquisition costs directly from pharmacies. Under this CMS contract, Myers and Stauffer has developed a methodology for collecting drug acquisition costs and calculating the NADAC reference file prices for covered outpatient drugs.

A meeting with stakeholders was held on August 4, 2011 at the CMS offices in Baltimore, during which the proposed methodology for the NADAC was presented. Since that meeting, further stakeholder input has been received and considered in the final design and development of the drug acquisition cost survey and NADAC reference file initiative. Additional information and routine updates will be available from the <http://www.Medicaid.gov> website.

Over →
OMB Control #0938-1041

Methodology for Calculating the National Average Drug Acquisition Cost (NADAC)

Pharmacy Owner/Manager

August 1, 2016

Page 2

Your pharmacy has been randomly selected to participate in this month's survey. We are requesting that you provide a copy of the selected purchase invoices for drugs purchased by your pharmacy. The attached survey instructions prepared by Myers and Stauffer outline the survey process for submitting one (1) month's worth of drug invoices by fax, mail, or electronic submission. Pharmacies are randomly selected to participate in the survey each month, and the probability that your pharmacy will be selected more than once during the year is 5% or less. Based on the contractor's experience, it is estimated to take less than 30 minutes of non-pharmacist time to assemble and submit the requested information.

It is important to note that all drug purchase price information submitted for this project will remain under the control of CMS, will only be used for the purposes described above, and will remain secure to the extent provided by law, consistent with Exemption 4 of the Freedom of Information Act (FOIA). Accordingly, neither CMS nor Myers and Stauffer will release invoice information and pharmacy identification that is submitted voluntarily and is identified by you as proprietary, except as is required by law.

By participating in the survey, you will have the opportunity to ensure that the market conditions facing your pharmacy are represented in the calculation and evaluation of the NADAC. One of the goals of the NADAC program is to account for the prices that pharmacies pay to acquire drugs.

To accomplish this goal, information from your pharmacy is necessary. Your participation in this endeavor is strongly encouraged and greatly appreciated.

This Retail Price Survey represents an opportunity for Medicaid pharmacies to participate in an initiative to determine a reference price representing the acquisition cost of drugs. Please note that current Federal regulations require State Medicaid programs to consider the professional services performed when setting their dispensing fee rates.

Please contact the Help Desk operated by Myers and Stauffer LC at (855) 457-5264 should you have any questions regarding this survey.

Sincerely,



Michael Nardone
Director, Disabled and Elderly Health Programs Group
Center for Medicaid and CHIP Services
Centers for Medicare & Medicaid Services

OMB Control #0938-1041



Center for Medicaid and CHIP Services

National Average Drug Acquisition Cost (NADAC)
Survey Request for Information

August 1, 2016

Your pharmacy has been randomly selected for a sampling of invoices. **We are requesting your pharmacy provide the following information within 14 days:**

- 1) **Copies** of all wholesaler, distributor, or manufacturer invoices, reflecting all brand, generic and OTC drug purchases transacted with all your wholesale supplier(s) and/or drug manufacturer(s) between
July 1, 2016 through July 31, 2016
- 2) Enclosed Cover Sheet (on gold-colored paper), if identifying submitted information as proprietary and confidential

These records are to be limited to drug ingredient costs only. All costs that are not drug ingredient costs, such as those for shipping, storage, warehousing, or other administrative costs or other internal mark-ups, will not be considered when calculating the NADAC. For purposes of this survey, drug ingredient costs should represent the invoice price paid by your pharmacy to an unrelated third party supplier of outpatient drugs, such as your wholesaler or drug manufacturer. Drug ingredient costs charged to your pharmacy by related parties that also include administrative costs or other mark-ups will not be included in the NADAC calculations. Please do not submit any patient-identifiable information.

Information should be submitted in printed or electronic format and should include the following information:

- 1) National Drug Code (NDC)
- 2) Purchase price of drug (drug ingredient cost only – see instructions above)
- 3) Quantity purchased
- 4) Purchase date for each product
- 5) “Item number”-to-NDC crosswalk, if item numbers or other proprietary nomenclature is used on your invoices.

As a time-saving alternative to you or your pharmacy staff submitting invoice records, you may contact your drug supplier(s) to request and authorize them to forward an electronic or hard copy of your purchasing history (as described above) for the requested period directly to Myers and Stauffer LC.
Please do not include any invoices that include Public Health Services 340B drug pricing.

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Methodology for Calculating the National Average Drug Acquisition Cost (NADAC)

August 1, 2016
Page 2

Information should be mailed, faxed, or sent electronically to the following address within 14 days:

Myers and Stauffer LC

Attention: CMS Pharmacy Survey
9265 Counselors Row, Suite 100
Indianapolis, IN 46240-6419

OR

844-860-0236 FAX

OR

survey@mslcrps.com (Please indicate “CMS Pharmacy Survey – confidential and proprietary” in the subject line.)

***** PLEASE USE THE ENCLOSED COVER SHEET (ON GOLD-COLORED PAPER) WHEN SUBMITTING YOUR PHARMACY’S INFORMATION TO IDENTIFY THIS INFORMATION AS PROPRIETARY. FAILURE TO DO SO MAY MEAN IT WILL NOT BE CONSIDERED PROPRIETARY.**

Please be aware that information submitted will not be returned, therefore, please submit copies or electronic files of these records. Your participation in this endeavor is strongly encouraged and greatly appreciated. Please contact the Help Desk operated by Myers and Stauffer LC at (855) 457-5264 should you have any questions.

PRA Disclosure Statement

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is **0938-1041**. The time required to complete this information collection is estimated to average 30 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

OMB Control #0938-1041



Center for Medicaid and CHIP Services

COVER SHEET

National Average Drug Acquisition Cost (NADAC) Survey Request for Information

TO: Myers and Stauffer LC
ATTENTION: CMS Pharmacy Survey

9265 Counselors Row, Suite 100

Indianapolis, IN 46240-6419

OR

844-860-0236 FAX

OR

survey@mslcrps.com

(Please indicate “CMS Pharmacy Survey – confidential and proprietary” in the subject line.)

The data contained in this submission is proprietary and confidential financial information that has been submitted voluntarily.

OMB Control #0938-1041



Protections for Drug Acquisition Cost Data Submitted by Pharmacies

In response to the National Average Drug Acquisition Cost (NADAC) Survey, chain and independent pharmacies have inquired about the disclosure, uses, and confidentiality of data submitted by pharmacies to Myers and Stauffer LC through its contract with CMS. The following information describes the government-provided protections offered to all pharmacies that voluntarily submit drug acquisition cost data.

1. Will the names of pharmacies responding to the survey be disclosed?

No. Information that identifies a particular pharmacy or pharmacy organization will not be disclosed or published by Myers and Stauffer LC. Such identifying information is known only to Myers and Stauffer LC (and to CMS upon its request). Disclosure by Myers and Stauffer LC to third parties is strictly prohibited by the contract between CMS and Myers and Stauffer LC.

2. Will drug acquisition cost data submitted by pharmacies participating in the survey be exempt from disclosure under the federal Freedom of Information Act (FOIA)?

Yes. Drug acquisition cost data submitted by pharmacies in response to the NADAC survey is exempt from disclosure under Exemption 4 of FOIA if the following conditions are met. The submitted information must be (1) provided voluntarily, and (2) is designated by the submitting pharmacy as “confidential,” i.e., the kind of information that would customarily not be released to the public by the pharmacy.

3. Will Myers and Stauffer LC use the submitted data for purposes other than to design, develop, implement and maintain NADAC rates as required under its contract with CMS?

No. Myers and Stauffer LC is contractually prohibited from using any drug acquisition cost data for any purpose other than to design, develop, implement and maintain NADAC rates as required under its contract with CMS.

4. Does Myers and Stauffer LC own the data collected from pharmacies?

No. Myers and Stauffer LC has assigned and conveyed to the Government all copyright, ownership and other intellectual property interests in and to all data/information obtained by Myers and Stauffer LC under its contract with CMS.

Again, Myers and Stauffer LC is prohibited from using or disclosing drug acquisition cost data submitted by pharmacies in response to the NADAC survey, except to

design, develop, implement and maintain NADAC rates as required under its contract with CMS.

5. Who controls the data submitted by pharmacies?

The U.S. Government (CMS) has exclusive control of all drug acquisition cost data submitted by pharmacies in response to the National Average Drug Acquisition Cost (NADAC) Survey.

6. For what purposes will CMS use the data collected from pharmacies?

CMS will use these data for construction of the published NADAC, which is used by CMS and state Medicaid agencies in the administration of their programs.

APPENDIX 4: Paperwork Reduction Act Statement

PRA Disclosure Statement

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is **0938-1041**. The time required to complete this information collection is estimated to average 30 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

Methodology for Calculating the National Average Drug Acquisition Cost (NADAC)

APPENDIX 5: Sample NADAC Week-to-Week Comparison File

NDC Description	NDC	Old NADAC Per Unit	New NADAC Per Unit	Classification for Rate Setting	Percent Change	Primary Reason	Start Date	End Date	Effective Date
Drug A 5mg Tab	xxxxx -xxxx- xx	0.12345	0.10234	G	-17.10%	Survey Rate	MM/DD/YYYY	MM/DD/YYYY	MM/DD/YYYY
Drug B 5mg Tab	xxxxx -xxxx- xx	6.54321	6.78901	B	3.76%	WAC Adjustment	MM/DD/YYYY	MM/DD/YYYY	MM/DD/YYYY

In the example above, Drug A and Drug B have NADACs in a previous and current NADAC Reference File.

The NADAC for Drug A decreased by 17.10% from the previous NADAC due to results of the monthly pharmacy acquisition cost survey.

The NADAC for Drug B increased by 3.76% from the previous NADAC based upon changes to the Wholesale Acquisition Cost (WAC).

APPENDIX 6: NADAC Week-to-Week Comparison File Data Field Definitions

NATIONAL AVERAGE DRUG ACQUISITION COST (NADAC) WEEK TO WEEK FILE COMPARISON DATA FIELD DEFINITIONS

National Drug Code (NDC) Description:

Identifies the drug name, strength and dosage form of the drug product.

NDC:

The National Drug Code (NDC) is the numerical code maintained by the FDA that includes the labeler code, product code, and package size code. The NDC is an 11-digit code.

Old NADAC Per Unit:

The National Average Drug Acquisition Cost per pricing unit from the previous NADAC Reference File.

New NADAC Per Unit:

The National Average Drug Acquisition Cost per pricing unit from the current NADAC Reference File.

Classification for Rate Setting:

Indicates whether the NDC was considered brand ('B') or generic ('G') for the NADAC rate calculation process. If the NDC was considered brand ('B') and approved under an Abbreviated New Drug Application (ANDA), the indicator is shown as ('B-ANDA'). NDCs approved as biosimilar products are considered brand ('B') and will be designated as ('B-BIO').

Percent Change:

The difference between the New NADAC Per Unit and the Old NADAC Per Unit, divided by the Old NADAC Per Unit.

Primary Reason:

Describes the primary reason for the NADAC Per Unit change, see explanation below for each reason:

- Survey Rate: The NADAC Per Unit has been updated using information from the most recently completed pharmacy survey.
- WAC Adjustment: The NADAC Per Unit has been updated to reflect changes in published pricing.
- Help Desk Adjustment: The NADAC Per Unit has been updated as a result of an inquiry to the help desk.
- Brand Generic Change: The NADAC Per Unit has been updated as a result of a change in the Classification for Rate Setting.
- Rate Group Change: The NADAC Per Unit has been updated due to placement into a new NADAC drug grouping because of a change in the NDC attributes.

Methodology for Calculating the National Average Drug Acquisition Cost (NADAC)

Start Date:

The start date indicates the initial NADAC file utilized in the comparison.

End Date:

The end date indicates the latest NADAC file utilized in the comparison.

Effective Date:

The effective date indicates the new effective date for the new NADAC rate.