AFFORDABLE CARE ACT FEDERAL UPPER LIMIT METHODOLOGY AND DATA ELEMENTS GUIDE

Purpose

This document provides guidance concerning the methodology used to calculate the Affordable Care Act Federal upper limit (FUL), (also known as the average manufacturer price (AMP)-based FUL) under the revised process as codified in §42 CFR 447.514. This document also describes the Data Elements that will be included in the published FUL file.

Background

The Affordable Care Act revised the FUL provisions to require that the Secretary calculate the FULs as no less than 175 percent of the weighted average (determined on the basis of utilization) of the most recently reported monthly AMPs for pharmaceutically and therapeutically equivalent multiple source drug products that are available for purchase by retail community pharmacies on a nationwide basis. In accordance with these provisions, the Centers for Medicare & Medicaid Services (CMS) issued a proposed rule that FULs would be calculated as 175 percent of the weighted average of AMPs.

In accordance with the final rule with comment, (CMS-2345-FC), we established an exception to the FUL calculation, which allows for the use of a higher multiplier to calculate the FULs based on acquisition costs for certain multiple source drugs. Specifically, in the final rule with comment, we finalized an exception to calculating the FUL at an amount equal to 175 percent of the weighted average of the most recently reported monthly AMPs for pharmaceutically and therapeutically equivalent multiple source drugs in instances where that amount is less than the average retail community pharmacies' acquisition cost for such drugs as determined by the most current national survey of such costs. In situations where the FUL is less than the average retail community pharmacies' acquisition cost, we will establish the FUL using a higher multiplier so that the FUL amount would equal the most current average retail community pharmacies' acquisition cost as determined by the most current national survey of such costs. To implement this revision when we calculate the FULs each month, we intend to use the most current monthly National Average Drug Acquisition Cost (NADAC) pricing files. See the Methodology section of this Guide for further information on the calculation of the Affordable Care Act FUL.

These changes in methodology are codified in 42 CFR §447.514(b)(1) and (2).

Data Sources

CMS uses the following data sources to calculate the Affordable Care Act FUL:

- The Food and Drug Administration (FDA) online databases
- A National Drug Pricing Compendium
- Drug Data Reporting for Medicaid system reported and certified data
- NADAC survey data - please refer to Part II: Methodology for Calculating the NADAC on the Medicaid.gov website at http://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/survey-of-retail-prices.html

Methodology

In accordance with the requirements in CMS-2345-FC, CMS uses the following methodology to calculate the Affordable Care Act FUL:

- Include all innovator (I) and non-innovator (N) pharmaceutically and therapeutically equivalent (A-rated) multiple source drugs when calculating the weighted average of monthly AMPs in a FUL Product Group;
- Will not include single source (S) drugs when calculating the weighted average of monthly AMPs in a FUL Product Group;
- Will not include formulations of the drug that are not rated by the FDA as pharmaceutically and therapeutically equivalent to the reference listed drug, (A-rated) in the calculation of the weighted average of monthly AMPs, or apply the FUL to those formulations that are not A-rated, e.g., B-rated drugs;
- Will use the monthly AMP and AMP units reported and certified by manufacturers to calculate the weighted average of monthly AMPs in a FUL Product Group; and,
- Will not include the AMP of a terminated drug in the weighted average of monthly AMPs.

For those FUL Product Groups that have at least three (I) and/or (N) drug products at the national drug code (NDC)-9 level, that are A-rated, with three monthly AMPs with AMP units greater than zero reported and certified by manufacturers to calculate the weighted average of the most recently reported monthly AMPs, CMS uses the following process:

- The weighted average of monthly AMPs in a FUL Product Group will be multiplied by 175 percent.
- For a FUL Product Group, the weighted average of the most recently reported monthly AMPs multiplied by 175 percent will be compared to the generic (G) NADAC price published on the Medicaid.gov website based on the most current national monthly survey of such costs.
- The Affordable Care Act FUL will be calculated at an amount equal to 175 percent of the weighted average of the most recently reported monthly AMPs for pharmaceutically and therapeutically equivalent multiple source drugs, where that amount is equal to or greater than the most current average retail community

pharmacies' acquisition cost as determined by the most current national survey of such costs.

- Where 175 percent of the weighted average of the most recently reported monthly AMPs for pharmaceutically and therapeutically equivalent multiple source drugs is less than the most current average retail community pharmacies' acquisition cost as determined by the most current national survey of such costs, the Affordable Care Act FUL will be calculated to equal the most current average retail community pharmacies' acquisition cost as determined by the most current national survey of such costs.

CMS will not calculate a FUL for any FUL Product Group that cannot be compared to a (G) NADAC (based on the most current average retail community pharmacies' acquisition cost as determined by the most current national survey of such costs), due to one of the following:

1. Within certain FUL Product Groups, those NDC-9s that have more than one (G) NADAC price calculated at the NDC-11 (package size) level in the NADAC file will not have a FUL calculated, as we consider those drugs to not have a one-to-one corresponding NADAC to FUL for comparison. Generally, these products fall into one of the following categories:

    - The drug has a dosage form of liquid, cream, ointment, or gel, and the reported unit type is milliliter or gram. In the Medicaid Drug Rebate program, we refer to these products as "unbreakable," meaning that the pharmacist would generally have to dispense the product in its original packaging, such as a tube of ointment or a jar of cream.

    - The drug is available as a legend drug and as an over-the-counter drug,

    - The drug is available in more than one type of packaging, for example, a bottle and a blister pack.

2. Within a FUL Product Group, any NDC-11 that does not have at least one corresponding (G) NADAC NDC-11 for comparison will not have an Affordable Care Act FUL calculated, as there is no equivalent NADAC price to compare to the FUL Product Group.

Certain drugs, approved under an Abbreviated New Drug Application (ANDA), and classified as "N" drugs in the CMS covered outpatient drug product file are identified as Branded-ANDAs (B-ANDA) drugs on the NADAC pricing file. These proprietary named drugs, although approved under an ANDA, are generally marketed and priced as brand drugs. Therefore, CMS will not compare a FUL Product Group's weighted average of AMPs multiplied by 175 percent to the B-ANDA drugs listed on the NADAC file to calculate an Affordable Care Act FUL.

CMS will not include inhalation, infusion, instilled, implanted, or injectable (5i) drugs that are not generally dispensed through retail community pharmacies in the calculation of the FUL, or apply the FUL to 5i drugs that are not generally dispensed through retail community pharmacies at this time.

CMS will not calculate a FUL where all manufacturers' NDCs within the FUL Product Group are not reported with the same unit type for the drugs in the group.

In accordance with section 1927(b)(3)(D) of the Act, CMS will publish the weighted average of the most recently reported monthly AMPs for all FUL Product Groups that have an Affordable Care Act FUL calculated; however, CMS will not publish individual AMPs for multiple source drugs.

Affordable Care Act Federal Upper Limit (FUL) Data Elements Guide

File: ACA FUL Groups for Publication - Month/Year – (Note that this date reflects the month that the Affordable Care Act FUL file is published on the Medicaid.gov website, and is based on the previous monthly reported data. For example, the draft FULs published in January 2016 are based on the November 2015 monthly data which were due to CMS by or before December 30, 2015.)

This file includes the draft Affordable Care Act (ACA) FUL groups that have a FUL price calculated. The data elements/format on the "ACA FUL Groups for Publication" file will include the following:

- Product Group
- Ingredient
- Strength
- Dosage
- Route
- Weighted Average of the most recently reported monthlyAMPs
- ACA FUL
- Package Size
- NDC
- A-Rated (Yes or No)
- ACA FUL Calculation Basis – see Legend

Legend – ACA FUL Calculation Basis

ACA FUL equals the most current average retail community pharmacies' acquisition cost (NADAC) = *

ACA FUL equals 175 percent of the weighted average of the most recently reported monthly AMPs = X

Note: All NDC-11s for a FUL Product Group are included in this file; however, only the (I) and (N), A-rated, multiple source drugs are used to calculate the weighted average of the most recently reported monthly AMPs in a FUL Product Group.

In accordance with the requirements of § 447.512(c), the upper limit for payment for multiple source drugs for which a specific limit has been established under §447.514 does not apply if a physician certifies in his or her own handwriting (or by an electronic alternative means approved by the Secretary) that a specific brand is medically necessary for a particular beneficiary.