Keys to Submitting Skin Substitute Product Data

Background

The Consolidated Appropriations Act, 2021 (CAA) became law on December 27, 2020. With the passage of the CAA, manufacturers are required to report Average Sales Price (ASP) information to CMS for items, services, supplies, and products payable under Medicare Part B regardless of whether they have a Medicaid drug rebate agreement. In general, all manufacturers who are required to submit ASP information have the same reporting requirements. However, there are a few nuances to submitting skin substitute information, including using an Alternate ID and submitting specific product data. Here are some key steps for preparing to enter your quarterly data in the ASP Data Collection System.

Select an Alternate ID

Skin substitute products are tracked using Alternate IDs, not National Drug Codes (NDCs) by the Food and Drug Administration (FDA). An Alternate ID, also known as an ALT ID, is a manufacturer-selected unique identifier used to distinguish among different products within Medicare Part B. An ALT ID can be any number unique to the product (e.g., Stock Keeping Number (SKN), product catalog number, or other alternate IDs). The ASP Data Collection System allows for a maximum of 23 characters and special characters (colon, dash, period) in the ALT ID field.

TIP: Whatever ALT ID is used, ensure it is consistent with the unique product identifier posted on the manufacturer's publicly available website to allow for easy verification.

Gather Product Data

Once the sales quarter concludes and you gather your current product data, please note any changes to existing products, such as a new or changed product size. Also make note of any new products your company may have added since the last quarter. These updates and additions require approval in the ASP Data Collection System, so make sure this is the first action you take when entering the quarter's data. There are tooltips for each field within the ASP Data Collection System and field name descriptions in the Product Data Template to help you when entering a new product or updating an existing product.

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Verify Website Information

It is imperative that the product data you enter in the ASP Data Collection System are identical to what is displayed on the manufacturer's publicly available website. The URL for the website with the data for each Alternate ID should match the company name and should not be a third-party web source. This should be verified prior to submitting your quarterly data. Any discrepancies between the data you are entering into the ASP Data Collection System and the product information listed on your website must be resolved prior to entering the data. Information that is not verified will not be included in the ASP calculation process or the ASP pricing files. The following fields must match the product information listed on the manufacturer's publicly available website:

- Manufacturer Name
- Alternate ID
- Brand and/or Generic Name
- Number of Items per Alternate ID
- Strength and Volume Data

Gather Financial Data

Manufacturers report financial data in the ASP Data Collection System but do not need to post these data on their public website. There are tooltips for each field within the ASP Data Collection System and field name descriptions in the Financial Data Template to help you with data entry. Additionally, consider the following:

- **Calculation**
  - Financial data should be calculated and entered individually for each ALT ID sold by the manufacturer, and not grouped or blended in any way, such as at the Healthcare Common Procedure Coding System (HCPCS) level.
  - In calculating the manufacturer's average sales price, a manufacturer must deduct price concessions. Price concessions include the following types of transactions and items as listed in 42 CFR § 414.804: Volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, and chargebacks and rebates (other than rebates under the Medicaid program).
  - Bona fide services fees are not considered price concessions. Bona fide service fees, as defined in 42 CFR § 414.802, are fees paid by a manufacturer to an entity, that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

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Gather Financial Data (continued)

- **Data Entry**
  - Financial data must be entered with three decimal places.
  - The Wholesale Acquisition Cost (WAC) and Average Wholesale Price (AWP) should be positive numbers.
  - If there is no AWP, leave the field blank.
  - Zero and negative values for Manufacturer's ASP and Number of ASP Units are acceptable.

Enter Your Data

Once you have gathered all your data and verified your website information, it is time to enter your data in the ASP Data Collection System. The data collection period begins on the first day of the quarter following the close of the previous sales quarter and ends, as stated in statute, on the 30th of the month following the close of the previous quarter. Visit the ASP Reporting page on the Medicare Part B ASP website for more information on specific reporting dates. Once you submit your data, CMS will conduct validation checks to identify any errors in the ASP Data Collection System or in any of your publicly available information. It is the responsibility of manufacturers to accurately report their data. CMS will not change or edit submitted manufacturer data. CMS may reach out to request clarification or additional information and may ask you to provide documentation or evidence to support the accuracy of the reported data.

Please Note:
Section 1847A(d)(4)(A) of the Social Security Act (the Act) specifies the penalties associated with misrepresentations in the reporting of the manufacturer's average sales price as defined at 42 CFR § 414.902. CMS is authorized to validate the accuracy of data submitted to CMS for purposes of payment under Section 1927(3)(B) and (C) of the Act.