



# Average Sales Price (ASP) Data Collection System Webinar

Submitter Training Session

March 2024

# Welcome



Thank you for joining our webinar to preview the modernized ASP Data Collection System for Submitters which will be live on April 1, 2024.

- This session will be recorded and posted.
- Participants can submit questions via the chat feature.
- This is a one-hour session with time for questions at the end.



## Speakers

- Katie Wilder, Contractor  
- Resources
- Michelle Berman,  
Contractor - System  
Overview



## Panelists

- Felicia Brown, CMS
- Kwan Saddler, CMS
- Siva Devarapalli, Contractor
- Suzanne Bromley, Contractor
- Brian Edwards, Contractor
- Jim Bullard, Contractor

# Modernization Priorities



User Experience



New Technology



Stakeholder  
Engagement and  
Support



Data Quality



# Resources

**New!**

## CMS Education and Outreach Website

- User Guides
- FAQs
- Fact Sheets
- *and more to come!*

**CMS.gov** Centers for Medicare & Medicaid Services

About CMS | Newsroom | Data & Research

Medicare | Medicaid/CHIP | Marketplace & Private Insurance | Priorities | Training & Education

Medicare > Payment > All Fee-For-Service-Providers > Medicare Part B Drug Average Sales Price > ASP Education & Outreach

### ASP Education & Outreach

#### All Fee-For-Service-Providers

- Home Health Agency (HHA) Center
- Hospice Center
- Shared Savings Program (SSP) / ACOs
- Hospital-Acquired Conditions (HAC)
- Physician bonuses in Health Professional Shortage Areas (HPSAs)
- Medicare Fee-for-Service 5010-D0

#### Medicare Part B Drug Average Sales Price

- ASP Reporting
- ASP Pricing Files
- ASP Billing Resources
- Vaccine Pricing
- ASP Regulations & Policy
- Discarded Drugs
- ASP Education & Outreach**
- Competitive acquisition

#### Newly Updated Average Sales Price (ASP) Data Collection System

On April 1, 2024, CMS will launch a newly updated Average Sales Price (ASP) Data Collection System designed on a modern platform to enhance the data collection and ASP payment limit calculation processes. These one hour sessions will provide a brief demo of the new system highlighting the new features and key changes and an opportunity for manufacturers to ask questions about the new system. We will have separate training sessions for Submitters and Certifiers and will offer two training dates for each audience. Sign up for the session that works best for you!

#### Submitter Training Sessions

- Tuesday, March 19, 2024, at 2:00 p.m. Eastern Standard Time (EST): [Zoom Registration Link](#)
- Thursday, March 21, 2024, at 2:00 p.m. EST: [Zoom Registration Link](#)

#### Certifier Training Sessions

- Tuesday, March 19, 2024, at 3:30 p.m. EST: [Zoom Registration Link](#)
- Thursday, March 21, 2024, at 3:30 p.m. EST: [Zoom Registration Link](#)

CMS collects Average Sales Price (ASP) data from manufacturers of Medicare Part B-covered drugs, biologicals, and related items, services, supplies, and products. Explore the resources below to learn more about the ASP data collection and payment limit calculation processes and other relevant topics.

Show Entries: 10 per page | Filter On: [ ]

Showing 1-3 of 3 entries

| Date                       | Title   | Description  | Format |
|----------------------------|---|--|--------|
| <a href="#">2024-01-31</a> | Keys to Submitting Skin Substitute Product Data           | Helpful information for manufacturers of Skin Substitute products when submitting ASP data to CMS  | PDF    |
| <a href="#">2024-01-31</a> | How to Prepare for the ASP Data Collection System Upgrade | A guide to help users prepare for the first time they log in to the new ASP Data Collection System | PDF    |
| <a href="#">2024-01-31</a> | What's New in the ASP Data Collection System              | A guide to explain the key highlights and changes in the new ASP Data Collection System            | PDF    |



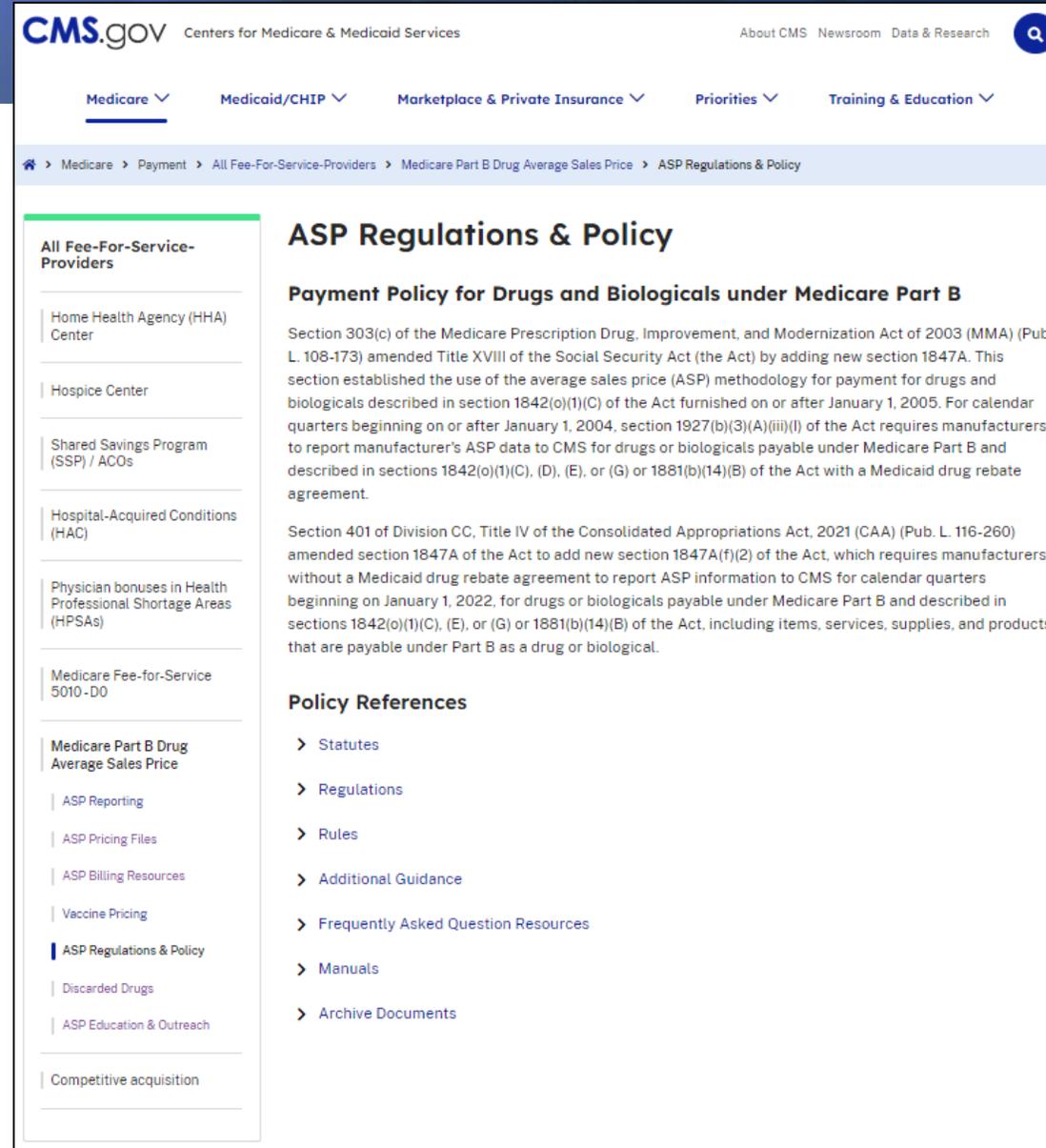
# Policy Page

## New Content!

## [ASP Regulations and Policy Page](#)

One resource for all ASP-Related:

- Statutes
- Regulations
- Rules
- Guidance



The screenshot shows the CMS.gov website interface. The header includes the CMS logo, navigation links for Medicare, Medicaid/CHIP, Marketplace & Private Insurance, Priorities, and Training & Education, and a search icon. The breadcrumb trail reads: Home > Medicare > Payment > All Fee-For-Service-Providers > Medicare Part B Drug Average Sales Price > ASP Regulations & Policy. The main content area is titled "ASP Regulations & Policy" and features a sub-section "Payment Policy for Drugs and Biologicals under Medicare Part B". This section contains two paragraphs of text detailing legislative changes to Medicare Part B drug payment rules. Below the text is a "Policy References" section with a list of links: Statutes, Regulations, Rules, Additional Guidance, Frequently Asked Question Resources, Manuals, and Archive Documents. A left-hand sidebar menu lists various categories, with "ASP Regulations & Policy" highlighted in blue.

# What's New?

- Key changes
- New features
- Additional context



## WHAT'S NEW IN THE ASP DATA COLLECTION SYSTEM

CMS will launch a newly updated Average Sales Price (ASP) Data Collection System designed on a modern platform to enhance the data collection and ASP payment limit calculation processes. The full list of all added features and functionalities, along with other training resources, will be released with the launch of the new system, but here are some of the key highlights and notable changes coming in April!



### MODERN PLATFORM

The new ASP Data Collection System is built on a modern platform which will allow CMS to easily add and expand system capabilities to pivot and respond to changing laws and regulations that affect Medicare Part B Drugs and payment limit calculations.



### IMPROVED USER EXPERIENCE

The new system has clear screens, intuitive navigation, hover-over definitions, links to resources and much more to improve the user experience!



### UPDATED DATA FIELDS

Data fields have been updated to eliminate data entry errors, standardize the data collected, and simplify the process for CMS to conduct data analysis and determine accurate calculations. Some updates include drop-down options instead of free-form text boxes when manually entering drug product data, and reorganized data fields such as two separate fields for strength and strength unit.



### NEW DATA TEMPLATES

The product and financial data templates for your Medicare Part B Drugs have been updated to match the data collection fields in the new system and continue to provide an option to easily upload your data.



### ONE LOCATION FOR FINANCIAL TASKS

In the new system, all Financial Data tasks, including restating financial data and adding data for prior quarters, are available in one location on the drop-down under the Financial Data menu.

# How to Prepare

- Visit our Resource Library
- Gather New or Changed Drug Product Information
- Prepare to Validate Existing Product Data
- Use the New Templates



## HOW TO PREPARE FOR THE ASP DATA COLLECTION SYSTEM UPGRADE

CMS will launch a newly updated Average Sales Price (ASP) Data Collection System designed on a modern platform to enhance the data collection and ASP payment limit calculation processes. The new system has clean screens, intuitive navigation, hover-over definitions, links to resources, and much more to improve the user experience. As we complete the final stages of preparation, there are some steps you can take to prepare your quarterly data for submission when the new system officially goes live in April!

### VISIT OUR WEBSITE AND REVIEW NEW RESOURCES

Along with the ASP Data Collection System upgrade, CMS has also been working to build a library of resources for manufacturers and other stakeholders to learn more about the ASP data collection and payment limit calculation processes and other relevant topics. CMS will continue to build and expand our Education and Outreach library in the coming months but has posted some initial resources to support manufacturers through the transition to the new system. View our library at: <https://www.cms.gov/medicare/payment/all-fee-service-providers/medicare-part-b-drug-average-sales-price/asp-education-outreach>.

### PLAN ADDITIONAL TIME FOR THE FIRST QUARTERLY DATA SUBMISSION

#### Validate Existing Product Data

With the new system and updated data fields, there may be drug product data that will need additional review when you log in to the new system for the first time. When the system is live, there will be an alert box on the home page with instructions on how to update all current product data. Please note, you may need to have previously submitted data available to reference when completing this task. You must complete this step before you can upload or enter new quarterly financial data into the new system for this first quarter only.

#### Gather New or Changed Drug Product Information

The new system includes an approval process for users to request new product information to be accepted into the system to minimize data entry errors. If you have new drug product information, such as a new National Drug Code (NDC) or Alternate ID, to enter since last quarter, or need to align an existing NDC to a new manufacturer, you will need to submit a request to have the data added to the new system. The approval process will be quick; however, there could be some initial delay due to an influx of requests with the launch of the new system.

#### Prepare your Data Using the New Templates

New templates have been created to match the newly configured ASP Data Collection System. Some data collection fields have been reorganized, such as having two separate fields for strength and strength unit. The product and financial templates have been updated to include these changes and are available now for you to prepare your data for an easy upload once the new system is live.

# User Guides



**Average Sales Price (ASP)  
Registration User Guide**

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Version 0.1  
Date: January 22, 2024



**Medicare Part B Average Sales Price  
(ASP) Module**

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**Certifier User Guide**

Version 0.1  
Date: January 22, 2024



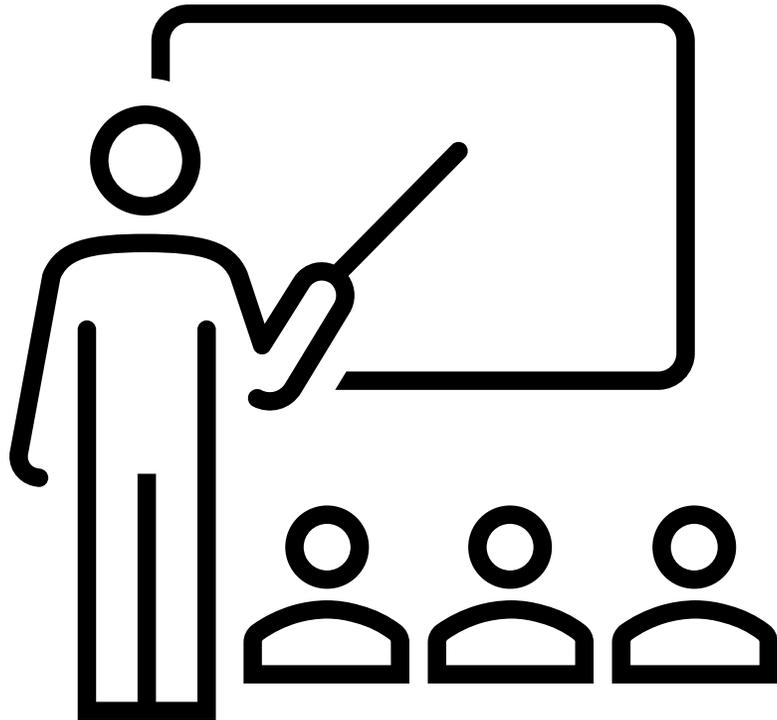
**Medicare Part B Average Sales Price  
(ASP) Module**

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**Submitter User Guide**

Version 0.1  
Date: January 22, 2024

# System Demonstration



The following slides present screenshots and an accompanying demo of the system.

# Welcome Page



## Medicare Part B Average Sales Price

Help Desk

User Guide (PDF)

My Profile

Manage NDC1/ALT ID

Product Data

Financial Data

Compliance Summary

Generate One-Time Password

Assumptions

FAQ

## Welcome, Michelle

Help

What's New 2

### Reporting Summary

Pricing Quarter: Q4 2023

Current Submission Period: 01/01/2024 - 01/30/2024

Days Remaining in the Current Submission Period: 0

### CMS Alerts

#### Validate Existing Product Data

03/01/2024

With the updated data fields, there may be drug product data that will need additional review when you log in for the first time. There is an alert box on this Welcome page with instructions on how to update all current product data. Please note, you may need to have previously submitted data available to reference when completing this task. You must complete this step before you can upload or enter new quarterly financial data into the system for this first quarter only.

### ASP Business Process Flow

Submitter

Certifier

1 Manage NDC1/ALT ID \*

- [Assign](#) NDC1/Alternate ID
- [Request](#) a new NDC1/Alternate ID/Manufacturer Name/Generic Name

# Manage NDC1/ALT ID

[← Back to Welcome page](#)

## Manage NDC1/ALT ID

**Assign NDC1/ALT ID**

Request New NDC1/ALT ID/Manufacturer/Generic Name

NDC1  Alternate ID

**Alternate ID** (required) ⓘ

**Manufacturer Name** (required)

Begin typing the manufacturer name to see names for selection

Don't see the Alternate ID or Manufacturer Name in the list? Click the [Request New NDC1/ALT ID/Manufacturer/Generic Name](#) tab to add a new Alternate ID or Manufacturer Name.

**Assign**

# Add Product Data/Update Product Data



[← Back to Welcome page](#)

## Product Data

### Add/Update Product Data

[Add Product Data](#)

[Update Product Data](#)

Add by NDC  Add by Alternate ID

**Manufacturer Name** (required)

Begin typing the manufacturer name to see names for selection

Test Manf Name impl

Manufacturer Name not in the system? Go to the [Add NDC1/ALT ID](#) page to add a new Manufacturer Name.

**NDC1** (required)

99999

**NDC2** (required)

9999

**NDC3** (required)

99

Drug has a brand name

**Generic Name** (required)

Begin typing the generic name to see names for selection

GENERICA

Generic Name not in the system? Go to the [Add NDC1/ALT ID](#) page to add a new generic name.

**Volume per Item** (required)

1

**Unit for Volume per Item** (required)

Capsule

**Number of Items per NDC** (required)

30

**Package Type** (required)

SINGLE SOURCE

**Strength** (required)

10

**Unit for Strength** (required)

%(GM/ACTIVATION)

**FDA Application (Primary)**

**FDA Application Number** (required)

000001

**FDA Application Supplement Number**

0001

[Add Additional FDA Application Numbers](#)

**FDA Approval Date** (required)

MM/DD/YYYY

12/31/2022

**FDA Approval Type** (required)

ANDA

**First Marketing Date** (required)

MM/DD/YYYY

01/01/2023

**Date of First Sale for this NDC** (required)

MM/DD/YYYY

02/01/2023

[Add Product Data](#)

# Upload Product Data



## Product Data

### Upload Product Data

Data being submitted for: Q4 2023

#### Upload New or Corrected Product Data

[Product Data Template \(Excel\)](#)

Supported File Format: Excel(.xlsx)

Excel File (required)

Maximum File Size is 10MB

[Select file](#)  
or drag file here

#### Uploaded Files

[Export to Excel](#)

| File Name                                    | Status  | Upload Date         | Reporting Period | Total Records | Total Accepted | Total Rejected | Actions                     |
|--|---------|---------------------|------------------|---------------|----------------|----------------|-----------------------------|
| <a href="#">TestProduct456.xlsx</a>          | Error   | 2024-03-12 14:55 PM | Q4 2023          | 1             | 0              | 1              | <a href="#">View Report</a> |
| <a href="#">ProductDataTemplate_124.xlsx</a> | Success | 2024-01-24 14:05 PM | Q4 2023          | 1             | 1              | 0              | <a href="#">View Report</a> |

# View Drugs

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## Product Data

### View Drugs

Active Drugs

Expired Drugs

Export to Excel

| Drug Identifier      | Manufacturer Name    | Generic Name         | Brand Name           | Volume per Item      | Unit for Volume per Item | Number of Items per NDC | Package Type         | Strength             | Unit                 |
|----------------------|----------------------|----------------------|----------------------|----------------------|--------------------------|-------------------------|----------------------|----------------------|----------------------|
| <input type="text"/>     | <input type="text"/>    | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| 99999-9999-99        | Test Manf Name impl  | GENERICA             |                      | 1                    | Capsule                  | 30                      | SINGSRC              | 10                   | % (C                 |
| xyz                  | Test Manf Name impl  | GENERICA             |                      | 1                    | Capsule                  | 30                      | SINGSRC              | 10                   | %                    |

10 items per page

1 - 2 of 2 items

# Add/Update Financial Data



Manage NDC1/ALT ID Product Data Financial Data Compliance Summary Generate One-Time Password Assumptions FAQ

[← Back to Welcome page](#)

## Financial Data

### Add/Update Financial Data

Data being submitted for: Q4 2023

Uncertified

Certified

\* denotes a required field.

[Export to Excel](#)

[Save All](#)

#### Drug Identifiers with missing or incorrect Financial Data

| Drug Identifier  | Manufacturer Name                     | Generic Name                                      | Manufacturer's ASP* | Number of ASP Units* | Wholesale Acquisition Cost* | Average Wholesale Price | Status                 | Action |                            |                                   |                                  |  |                                  |   |   |                                      |                                |  |                                       |   |
|--|---------------------------------------|---|---------------------|----------------------|-----------------------------|-------------------------|------------------------|--------|----------------------------|-----------------------------------|----------------------------------|--|----------------------------------|---|---|--------------------------------------|--------------------------------|--|---------------------------------------|---|
| <input type="checkbox"/> 00000-0000-00   | Test Manf Name impl                   | GENERICA  | \$ 0.000            | 0.000                | \$ 0.000                    | \$ 0.000                | Awaiting Certification |        |                            |                                   |                                  |  |                                  |   |   |                                      |                                |  |                                       |   |
| <div style="border: 1px solid gray; padding: 5px;"> <p><b>Product Info</b></p> <table border="0"> <tr> <td><b>Brand Name:</b> No Data</td> <td><b>Strength of Product:</b> 20 MG</td> <td><b>Volume per Item:</b> 1 Ampule</td> </tr> <tr> <td><b>Number of Items per NDC/Alt ID:</b> 1</td> <td><b>Package Type:</b> SINGLE DOSE</td> <td><b>First Marketing Date:</b> 08/05/2023</td> </tr> <tr> <td><b>Expiration Date of Final Lot Sold:</b> No Data</td> <td><b>FDA Approval Date:</b> 08/01/2023</td> <td><b>FDA Approval Type:</b> ANDA</td> </tr> <tr> <td><b>Date of First Sale for this Product:</b> 08/10/2023</td> <td><b>FDA Application Number:</b> T98765</td> <td><b>FDA Application Supplement Number:</b> No Data</td> </tr> </table> </div> |                                       |   |                     |                      |                             |                         |                        |        | <b>Brand Name:</b> No Data | <b>Strength of Product:</b> 20 MG | <b>Volume per Item:</b> 1 Ampule | <b>Number of Items per NDC/Alt ID:</b> 1 | <b>Package Type:</b> SINGLE DOSE | <b>First Marketing Date:</b> 08/05/2023 | <b>Expiration Date of Final Lot Sold:</b> No Data | <b>FDA Approval Date:</b> 08/01/2023 | <b>FDA Approval Type:</b> ANDA | <b>Date of First Sale for this Product:</b> 08/10/2023 | <b>FDA Application Number:</b> T98765 | <b>FDA Application Supplement Number:</b> No Data |
| <b>Brand Name:</b> No Data   | <b>Strength of Product:</b> 20 MG     | <b>Volume per Item:</b> 1 Ampule                  |                     |                      |                             |                         |                        |        |                            |                                   |                                  |  |                                  |   |   |                                      |                                |  |                                       |   |
| <b>Number of Items per NDC/Alt ID:</b> 1   | <b>Package Type:</b> SINGLE DOSE      | <b>First Marketing Date:</b> 08/05/2023           |                     |                      |                             |                         |                        |        |                            |                                   |                                  |  |                                  |   |   |                                      |                                |  |                                       |   |
| <b>Expiration Date of Final Lot Sold:</b> No Data  | <b>FDA Approval Date:</b> 08/01/2023  | <b>FDA Approval Type:</b> ANDA                    |                     |                      |                             |                         |                        |        |                            |                                   |                                  |  |                                  |   |   |                                      |                                |  |                                       |   |
| <b>Date of First Sale for this Product:</b> 08/10/2023   | <b>FDA Application Number:</b> T98765 | <b>FDA Application Supplement Number:</b> No Data |                     |                      |                             |                         |                        |        |                            |                                   |                                  |  |                                  |   |   |                                      |                                |  |                                       |   |
| <input type="checkbox"/> 00000-0001-00   | Test Manf Name impl                   | GENERICA  | \$ 0.000            | 0.000                | \$ 0.000                    | \$ 0.000                | Awaiting Certification |        |                            |                                   |                                  |  |                                  |   |   |                                      |                                |  |                                       |   |

# Upload Financial Data

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## Financial Data

### Upload Financial Data

#### Upload New or Corrected Financial Data

Data being submitted for: Q3 2023

[Financial Data Template \(Excel\)](#)

Supported File Format: undefined (.xlsx)

Excel File (required)

Maximum File Size is 10MB

[Select file](#)

or drag file here

#### Uploaded Files

[Export to Excel](#)

| File Name            | Status | Upload Date | Reporting Period | Total Records | Total Accepted | Total Rejected | Actions |
|----------------------|--------|-------------|------------------|---------------|----------------|----------------|---------|
|                      |        |             |                  |               |                |                |         |
| No records available |        |             |                  |               |                |                |         |

◀ ◁ ▷ ▶10 items per page0 - 0 of 0 items

# Restatement

## Financial Data

### Restate Financial Data or Add for Prior Quarters

Restatement Period (required)

Drug Identifier (required)

Q4 2023

00000-0000-00 : Test Manf Name impl

\* denotes a required field.

Export to Excel

Save

#### Restatement Financial Data

| Drug Identifier | Manufacturer Name   | Generic Name | Manufacturer's ASP*<br><i>i</i> | Number of ASP Units*<br><i>i</i> | Wholesale Acquisition Cost*<br><i>i</i> | Average Wholesale Price<br><i>i</i> | Status                 | Action |
|-----------------|---------------------|--------------|---------------------------------|----------------------------------|---|-------------------------------------|------------------------|--------|
| 00000-0000-00   | Test Manf Name impl | GENERICA     | \$ 0.000                        | 0.000                            | \$ 0.000                                | \$ 0.000                            | Awaiting Certification |        |

#### Product Info

Brand Name: No Data

Number of Items per NDC/Alt ID: 1

Expiration Date of Final Lot Sold: No Data

Date of First Sale for this Product: 08/10/2023

Strength of Product: 20 MG

Package Type: SINGLE DOSE

FDA Approval Date: 08/01/2023

FDA Application Number: T98765

Volume per Item: 1 Ampule

First Marketing Date: 08/05/2023

FDA Approval Type: ANDA

FDA Application Supplement Number: No Data

# Compliance Summary



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## Compliance Summary

Reporting Period (required)

< Q4 2023 >

**i** Labelers are out of compliance with data reporting requirements. **20%** of drugs are certified out of **72** total drugs. (**8** certified, **64** restatement certified)

Missing **0**

Pending **2**

Certified **2**

New **0**

Off Cycle **0**

Expired **0**

All Pending Certification  Pending Certification  Pending Restatement Certification

[Export to Excel](#)

**2 Drug Identifiers waiting for certification/restatement certification**

| Drug Identifier | Manufacturer Name   | Reporting Period | Manufacturer's ASP | Number of ASP Units | Wholesale Acquisition Cost | Average Wholesale Price | Action                                |
|-----------------|---------------------|------------------|--------------------|---------------------|----------------------------|-------------------------|---------------------------------------|
| xyz             | Test Manf Name impl | Q4 2023          | 123.450            | 123.450             | 123.450                    | 123.450                 | <a href="#">Go to Certification →</a> |
| 99999-9999-99   | Test Manf Name impl | Q4 2023          | 1234567890.000     | 1234567890.000      | 1234567890.000             | 1234567890.000          | <a href="#">Go to Certification →</a> |

# Generate OTP

## Medicare Part B Average Sales Price

[Manage NDC1/ALT ID](#) [Product Data](#) [Financial Data](#) [Compliance Summary](#)

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### Generate One-Time Password (OTP)

All ASP submissions by an authorized submitter to CMS must be certified by an authorized certifier. Please click below to generate a one-time password (OTP) and share this with your data certifier. Upon accessing the system to certify your manufacturer's data, they will be asked for this password to verify their identity.

**Manufacturer Name** (required)

Test Manf Name impl

ecYa1RceQ7O9vUvDco2FOA== [Copy OTP](#)

**⚠** The one-time password for **Test Manf Name impl** is active and expires on 01/18/2024.

[Create New OTP](#)

# Assumptions

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## Assumptions

✔ File upload has completed successfully.

Reporting Period (required)

<  >

[Create Assumption or Upload Assumption File](#)

[Export to Excel](#)

### Saved Files

| File Name   | File Description                                     | Manufacturer Name   | Date Saved          | Saved By                               | Actions                |
|---|--|---------------------|---------------------|--|------------------------|
| <a href="#">user_entry_assumptions_test_manf_name_i<br/>mpl_2024_01_09_16_54_29.txt</a> | akdjfei djewiwj jdioiwej<br>jfislkwejeic jakdj kweic | Test Manf Name impl | 2024-01-09 16:54 PM | ASP Certifier, Jennifer<br>(certifier) | <a href="#">Delete</a> |

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## FAQ

This information will be updated to address the most frequently asked questions regarding the ASP Data Collection System.

For questions regarding policy, process, calculation, and the publication of ASP pricing files, please refer to the FAQ document posted on the [CMS ASP Education and Outreach](#) page.

⌵ Expand All

⌶ Collapse All

**What is the difference between an NDC1 and an Alternate ID?**



**What is a unit of a drug?**



For the purposes of ASP data submissions, the term "unit" (defined at section 1847A(b)(2)(B) and codified at 42 CFR 414.802) means the product represented by the 11-digit NDC, unless otherwise specified by CMS to account for situations where labeling indicates that the amount of drug product represented by a NDC varies. Note that the definition of "unit" is different than the term "billing unit" (defined in section 1847A(b)(6)(B) of the Act), which means the identifiable quantity associated with the billing and payment code.

**I submitted my data, now what do I do?**



### Help Desk Contact Information

**Phone:** +1 (844) 876-0765

**Email:** [asphelpdesk@dcca.com](mailto:asphelpdesk@dcca.com)

**Hours:** Monday - Friday, 9am - 6pm EST



# Closing Remarks

- [Education and Outreach Page](#)
- **Technical Support**
  - [ASPHelpDesk@dcca.com](mailto:ASPHelpDesk@dcca.com)
  - 1-844-876-0765
  - 9:00 a.m. through 6:00 p.m., Eastern Standard Time (EST), Monday through Friday
- **Feedback and Other Questions**
  - [sec303aspdata@cms.hhs.gov](mailto:sec303aspdata@cms.hhs.gov)

