Welcome

Thank you for joining our webinar for **Skin Substitute Manufacturers** and the ASP Data Collection System.

- This session will be recorded and posted.

- Participants can submit questions via the chat feature.

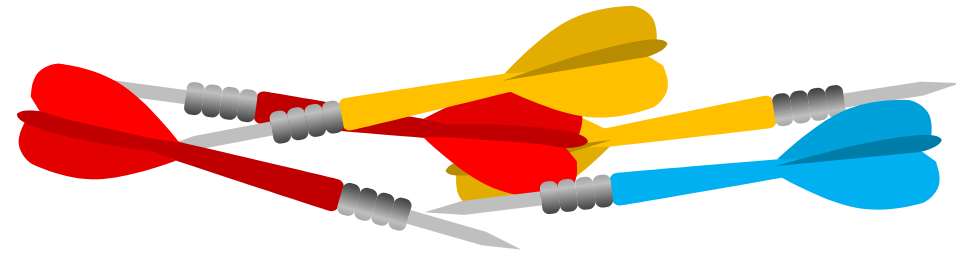- This is a one-hour session with time for questions at the end.

Agenda

Topic	Presenter	Time
Introductory Remarks	Mark Bremer, CMS	5 min
Process Overview	Katie Wilder, Contractor	5 min
How to Prepare	Katie Wilder, Contractor	10 min
Data Entry Examples	Michelle Berman, Contractor	10 min
What to Expect	Katie Wilder, Contractor	5 min
Q&A Session	Suzanne Bromley, Contractor	20 min
Closing Remarks	Mark Bremer, CMS	5 min

Goals

- Provide information for a stronger understanding of the quarterly reporting requirements for skin substitution products.

- Provide examples to support easier data entry and conversion.

- Open conversation to answer questions.
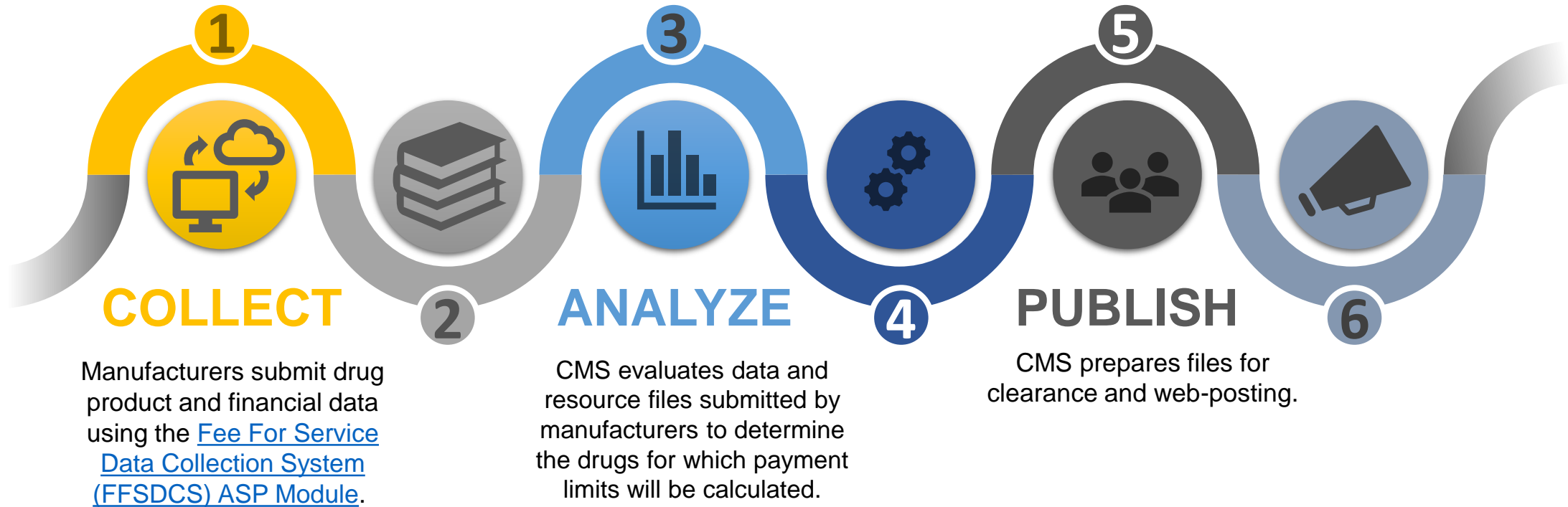
ASP Payment Limit Process

PREPARE
CMS maintains several resource files to reference when calculating ASP pricing.

CALCULATE
CMS sets ASP payment limits and calculates applicable substitutions.

ROLLOUT
ASP pricing files are posted to the ASP website and MACs implement for payments.*

1

2

3

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6

COLLECT
Manufacturers submit drug product and financial data using the Fee For Service Data Collection System (FFSDCS) ASP Module.

ANALYZE
CMS evaluates data and resource files submitted by manufacturers to determine the drugs for which payment limits will be calculated.

PUBLISH
CMS prepares files for clearance and web-posting.

If a HCPCS code is not posted in the files, it may be locally priced.

How to Prepare

01 Gather Product Data

02 Validate Website Information

03 Gather Financial Data

Gather Product Data

01

- Make changes to add or update existing product data

- Add new products
  - *Manufacturer Name**
  - *Alternate ID**
  - *Alternate ID Website URL**
  - *Brand and/or Generic Name**
  - *Number of Items per Alternate ID**
  - *Strength and Volume Data**
  - Package Type
  - FDA Registration Number
  - FDA Approval Date
  - FDA Approval Type
  - First Marketing Date
  - Date of First Sale for ALT ID

- Allow time for approval into the ASP Data Collection System

*Required to match information on the website

Alternate ID

- Skin substitutes are not assigned National Drug Codes or NDCs by the FDA.

- An Alternate ID is a unique identifier to distinguish between different drug or biological products within Medicare Part B.

- An Alternate ID can be any combination of letters or numbers unique to the product (i.e., Stock Keeping Number (SKN) or product number).

- Maximum of 23 characters and special characters (colon, dash, period) are allowed.

Validate Website Information

CMS CENTERS FOR MEDICARE & MEDICAID SERVICES

02

- Items that must match information provided on your publicly available website:
  - ✓ The manufacturer name is reflected in the Website URL.
  - ✓ The ALT ID is accurately displayed.
  - ✓ Product size information for strength and volume calculation/identification purposes.

- Any discrepancies between the data you are entering into the ASP Data Collection System and the product information listed on your website must be updated prior to entering the data.

- Information that is not verified will not be included in the ASP calculation process or the ASP pricing files.

Why Does Product Information Need to be Publicly Available?

- CMS is required to verify product data submitted by all drug manufacturers.

- For drugs with NDCs, that information is available through third-party resources, such as DailyMed, Medi-Span, and other compendia.

- For skin substitute products, there is not a collective source of information, so CMS relies on manufacturers to accurately provide this information.

Gather Financial Data

03

Field	Description
Manufacturer's Average Sales Price	A manufacturer average sales price for all NDC/Alt IDs assigned to the drug or biological product
Number of ASP Units	Units are equivalent to the product represented by the NDC, unless otherwise specified by CMS to account for situations where labeling indicates that the amount of drug product represented by an NDC/Alt ID varies.
Wholesale Acquisition Cost (WAC)	The manufacturer's list price for the drug or biological to wholesalers or direct purchasers as reported in wholesale price guides or other publications of drug or biological pricing data. For more on the definition of WAC, refer to 42 U.S.C. 1395w-3a.
Average Wholesale Price (AWP)	Average price paid for a drug from a manufacturer for a corresponding ASP unit

- Must have three decimal places (XXXXXXXXX.XXX)
- Can be positive, negative, or 0.000

ASP Data Collection System

- The data used in the following examples are designed for illustrative purposes only.

- This information does not represent the data from any existing company or actual products.

- Any likeness is purely coincidental.

Sample Website

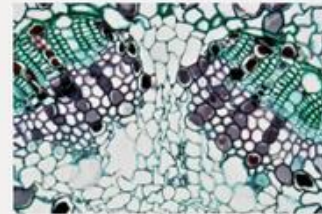www.indexbiomanufacturing.com

Sample Product Information

Our Products

Indexa

Product Material: Sheet
Generic Name: ambioxiasheetova
HCPCS Code: Q7890

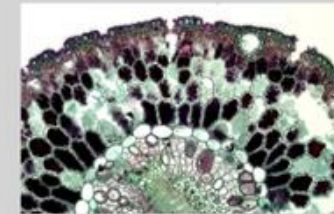| Product Code	Size	Number Per Package
1001-362990	2cm x 3cm	5
1001-362991	10mm (diameter)	1
1001-362992	3cm x 5cm	10

Indexapro

Product Material: Liquid
Generic Name: ambioxialiquidova
HCPCS Code: Q9153

Product Code	Size	Number Per Package
1101-386500	6ml vial	10

Indexacell

Product Material: Powder
Generic Name: ambioxiapowderova
HCPCS Code: Q1586

Product Code	Size	Number Per Package
1201-427730	50mg	5

Company Information

Let's Heal Together

Mailing Address

123 Anywhere St., Any City
State, Country 12345

Email Address

info@indexbiomanufacturingllc.com

Phone Number

(123) 456 7890

Request to Add a New Alt ID

Add New NDC1/ALT ID/Manufacturer/Generic Name   ✕

○ New NDC1   ⦿ New Alternate ID   ○ New Manufacturer Name   ○ New Generic Name

New Alternate ID (required) ⓘ

> 1001-362990

Alternate ID Website URL (required) ⓘ

> http://www.indexbiomanufacturing.com

⚠ Reporting of products in the ASP portal should be consistent with product information on publicly available sources, including FDA approved labels and manufacturers' public websites.

Because some products that are required to report ASP are not assigned 11-Digit National Drug Codes (NDCs), when reporting Alternate IDs into the ASP portal (i.e., Stock Keeping Number (SKN), catalog number or other Alternate ID's) please be sure that the identifier is consistent with the identifiers that are published on the manufacturer's public website. This will ensure more accurate and verifiable ASP reporting for products with an Alternate ID.

ⓘ Requests to add new items will be completed by ASP support staff. If you have questions or concerns, please contact the ASP Help Desk.

Send Request   **Cancel**

Request to Add a New Generic Name

Add New NDC1/ALT ID/Manufacturer/Generic Name   ✕

○ New NDC1   ○ New Alternate ID   ○ New Manufacturer Name   ⦿ New Generic Name

New Generic Name (required) ⓘ

ambioxiasheetova

ⓘ Requests to add new items will be completed by ASP support staff. If you have questions or concerns, please contact the ASP Help Desk.

Send Request   Cancel

Assigning an Alternate ID to a Manufacturer Name

← 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) ⓘ

1001-362990 ☒

Manufacturer Name (required)
Begin typing the manufacturer name to see names for selection

Index Biomanufacturing ☒

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

18

Success Message

← **Back to Welcome page**

Manage NDC1/ALT ID

Assign NDC1/ALT ID	**Request New NDC1/ALT ID/Manufacturer/Generic Name**

○ NDC1   ◉ Alternate ID

> ✓ The mapping for Index Biomanufacturing and 1001-362990 was completed successfully.

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

19

Add Product Data

Medicare Part B Average Sales Price

| Manage NDC1/ALT ID | Product Data ▾ | Financial Data ▾ | Compliance Summary | Generate One-Time Pass |

← 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

| Index Biomanufacturing ⊠ |

Manufacturer Name not in the system? Go to the Add NDC1/ALT ID page to add a new Manufacturer Name.

Alternate ID (required) ⓘ

| 1001-362990 ▾ |

Alternate ID Website URL (required) ⓘ

| https://indexbiomanufacturing.com |

☑ Drug has a brand name
Brand Name (required) ⓘ

| Indexa |

Generic Name (required) ⓘ
Begin typing the generic name to see names for selection

| ambioxiasheetova ⊠ |

Add Product Data: Sheet

Indexa

Product Material: Sheet
Generic Name: ambioxiasheetova
HCPCS Code: Q7890

Product Code	Size	Number Per Package
1001-362990	2cm x 3cm	5
1001-362991	10mm (diameter)	1

Generic Name (required) ⓘ

Begin typing the generic name to see names for selection

ambioxiasheetova	☒

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) ⓘ

EACH	⌄

Number of Items per Alternate ID (required) ⓘ

5

Package Type (required) ⓘ

Not applicable	⌄

Strength (required) ⓘ

6

Unit for Strength (required) ⓘ

SQ CM / EACH	⌄

Add Product Data: Disc

Indexa

Product Material: Sheet
Generic Name: ambioxiasheetova
HCPCS Code: Q7890

Product Code	Size	Number Per Package
1001-362990	2cm x 3cm	5
1001-362991	10mm (diameter)	1

Generic Name (required) ⓘ

Begin typing the generic name to see names for selection

| ambioxiasheetova | ☒ |

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) ⓘ

| EACH ⌄ |

Number of Items per Alternate ID (required) ⓘ

| 1 |

Package Type (required) ⓘ

| Not applicable ⌄ |

Strength (required) ⓘ

| .78 |

Unit for Strength (required) ⓘ

| SQ CM / EACH ⌄ |

Add Product Data: Liquid

Indexapro

Product Material:	Liquid
Generic Name:	ambioxialiquidova
HCPCS Code:	Q9153

Product Code	Size	Number Per Package
1101-386500	6ml vial	10

Generic Name (required) ⓘ

Begin typing the generic name to see names for selection

ambioxialiquidova	⊠

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

Volume per Item (required) ⓘ

6

Unit for Volume per Item (required) ⓘ

ML ⌄

Number of Items per Alternate ID (required) ⓘ

10

Package Type (required) ⓘ

Not applicable ⌄

Strength (required) ⓘ

6

Unit for Strength (required) ⓘ

ML ⌄

Add Product Data: Powder

Indexacell

Product Material: Powder
Generic Name: ambioxiapowderova
HCPCS Code: Q1586

Product Code	Size	Number Per Package
1201-427730	50mg	5

Generic Name (required) ℹ

Begin typing the generic name to see names for selection

```
ambioxiapowderova                                    ☒
```

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

Volume per Item (required) ℹ

```
1
```

Unit for Volume per Item (required) ℹ

```
EACH                                         ▼
```

Number of Items per Alternate ID (required) ℹ

```
5
```

Package Type (required) ℹ

```
Not applicable                               ▼
```

Strength (required) ℹ

```
50
```

Unit for Strength (required) ℹ

```
MG                                           ▼
```

Strength Calculation Tips

Product Size/Shape	Strength Calculation
Disc	Area of the disc
Crescent Shaped (not circular or square)	Area of product
Multi-dimensional (L x W x H)	Volume by Cubic CM

Financial Data Entry

Indexa

Product Material: Sheet
Generic Name: ambioxiasheetova
HCPCS Code: Q7890

Product Code	Size	Number Per Package
1001-362990	2cm x 3cm	5
1001-362991	10mm (diameter)	1
1001-362992	3cm x 5cm	10

HCPCS Code	Drug Name	Number of Items Per Alt ID (Patches/sheets/vials per Package)	Manufacturer's Average Sales Price (ASP Price per Package)	Number of ASP Units (Packages Sold)
Q7890	Indexa (2cm x 3cm)	5	1354.000	10
Q7890	Indexa (10mm)	1	711.020	75
Q7890	Indexa (3cm x 5cm)	10	1331.590	15

What to Expect After Submission

The deadline for completed, accurate submissions is the **30th of the month** following the close of the quarter.

CMS conducts validation checks to ensure accuracy and identify any errors in the ASP Data Collection System or within any publicly available information.

CMS will not change or edit submitted manufacturer ASP data. It is the responsibility of manufacturers to accurately report their data.

CMS may communicate with manufacturers to request clarification or additional information; CMS may ask manufacturers to provide documentation or evidence to support the accuracy of the reported data.

If data submitted do not match the data on the manufacturer's website, there could be significant delays in the calculation process, potentially causing omission from the ASP pricing files.

ASP Calculation Example

Data Entered by Manufacturers

CMS Calculations

HCPCS Code (Dosage = 1cm)	Drug Name	Number of Items Per Alt ID	Manufacturer's Average Sales Price	Number of ASP Units	Billing Units	Manufacturer's ASP x Number of ASP Units	Billing Units Sold (Number of ASP Units x Billing Units)
Q7890	Indexa (2cm x 3cm)	5	1354.000	10	30	13,540.000	300
Q7890	Indexa (10mm)	1	711.020	75	1	53,326.500	75
Q7890	Indexa (3cm x 5cm)	10	1331.590	15	150	19,973.850	2250
					Total:	86,840.350	2625

5 — Calculate the ASP (without Add-on) per Billing Unit

ASP = (Total ASP x Number of ASP Units) / Billing Units Sold

ASP = 86,640.350/2625

ASP = 33.082

6 — Calculate the ASP Payment Limit

ASP Payment Limit = ASP x 1.06

ASP Payment Limit = 33.082 x 1.06

ASP Payment Limit = 35.067

Why Is My Product Not Listed ?

If a product does not appear in the ASP pricing file, it may be that:

- Product data was submitted after the deadline
- Some portion of the submitted product information was unverifiable
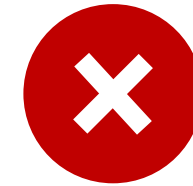- There were significant changes in price reporting within the ASP Data Collection System

Emailing the 303 Mailbox

sec303aspdata@cms.hhs.gov

CMS will:

- Respond as appropriate within a reasonable timeframe

- Confirm receipt of data submission

- Direct you to official guidance with examples

CMS will not:

- Offer specific instruction outside of published guidance

- Confirm or deny accuracy of data

- Tell you how to calculate your specific data

- Incorporate any late submissions

CMS will only respond to messages received via the 303 Mailbox.

Closing Remarks

- [Education and Outreach Page](#)

- **Technical Support**
  - 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