

The logo for SOFTRAMS features the word in a bold, dark blue sans-serif font. A red and white graphic element, resembling a stylized 'A' or a pen nib, is integrated into the letter 'A'. The background is decorated with abstract, flowing lines in shades of blue and purple on the left side, and a blue triangular pattern in the top right corner.

**SOFTRAMS**

# Drug and Biological Pass-through Application Screens

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**Sharadwanth Pusala**

# Welcome page

**HAPG**

Application Management System

[Home](#) [Tasks](#) [Applications](#) [Organizations](#) [Resource Library](#)



## Welcome to the Drug and Biological Pass-through Application

What you will need to know:



[Application Guidance](#)



[Application Process and Timeline](#)



[How the Online Application Works](#)

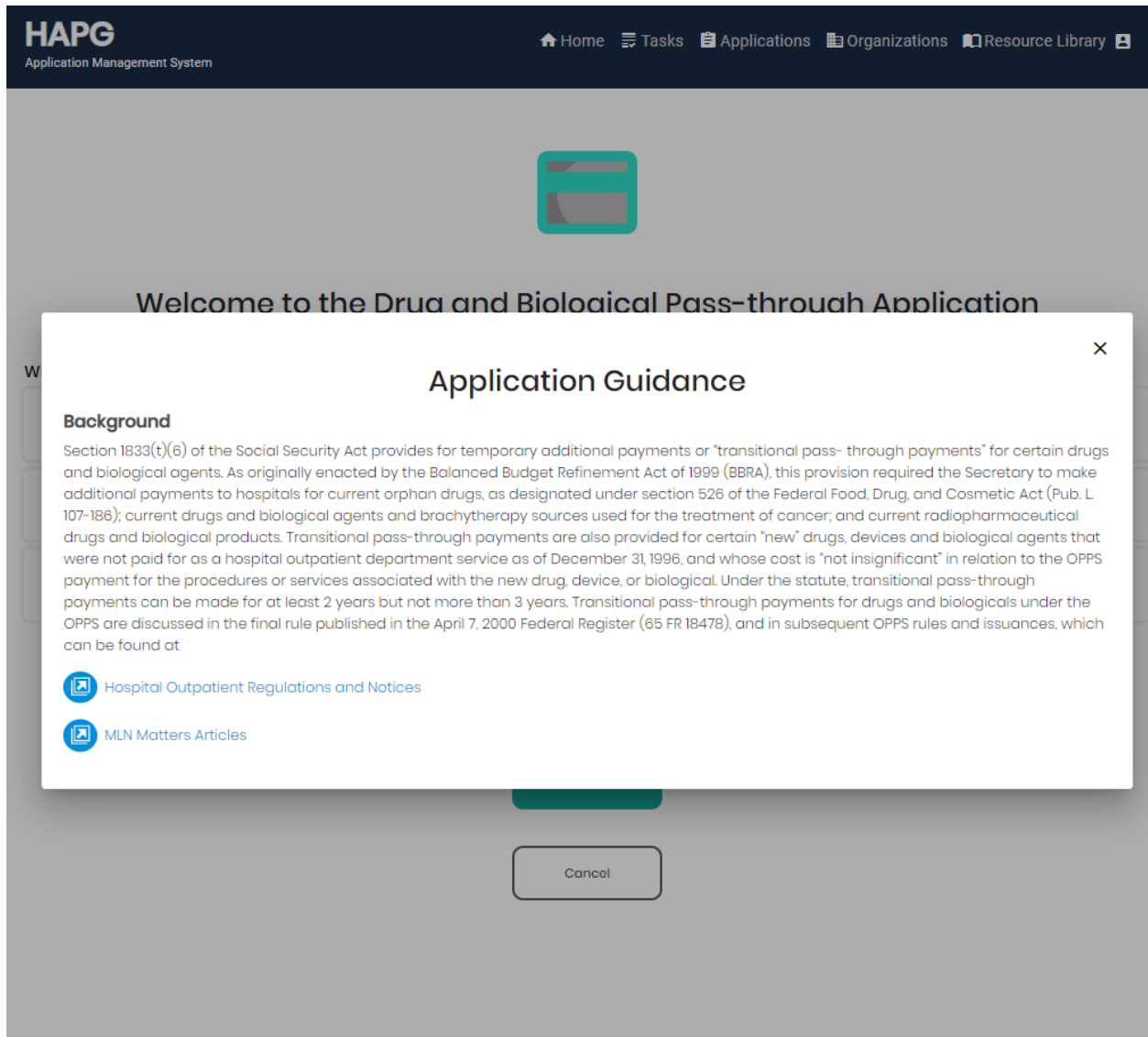
Ready to get Started?

Go

Cancel

---

# Application Guidance modal window – Screen 1



The screenshot displays the HAPG Application Management System interface. At the top, the logo 'HAPG' and the text 'Application Management System' are visible on the left. The navigation bar includes links for Home, Tasks, Applications, Organizations, and Resource Library. A teal icon representing a folder or document is centered on the page. Below it, the text 'Welcome to the Drua and Biooical Pass-through Application' is partially visible. A modal window titled 'Application Guidance' is open, featuring a close button (X) in the top right corner. The modal contains a 'Background' section with a detailed paragraph about Section 1833(t)(6) of the Social Security Act. Below the text are two links: 'Hospital Outpatient Regulations and Notices' and 'MLN Matters Articles', each with a document icon. A 'Cancel' button is located at the bottom center of the modal.

**HAPG**  
Application Management System



Home Tasks Applications Organizations Resource Library

Welcome to the Drua and Biooical Pass-through Application

## Application Guidance

**Background**

Section 1833(t)(6) of the Social Security Act provides for temporary additional payments or "transitional pass-through payments" for certain drugs and biological agents. As originally enacted by the Balanced Budget Refinement Act of 1999 (BBRA), this provision required the Secretary to make additional payments to hospitals for current orphan drugs, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act (Pub. L. 107-186); current drugs and biological agents and brachytherapy sources used for the treatment of cancer; and current radiopharmaceutical drugs and biological products. Transitional pass-through payments are also provided for certain "new" drugs, devices and biological agents that were not paid for as a hospital outpatient department service as of December 31, 1996, and whose cost is "not insignificant" in relation to the OPPS payment for the procedures or services associated with the new drug, device, or biological. Under the statute, transitional pass-through payments can be made for at least 2 years but not more than 3 years. Transitional pass-through payments for drugs and biologicals under the OPPS are discussed in the final rule published in the April 7, 2000 Federal Register (65 FR 18478), and in subsequent OPPS rules and issuances, which can be found at


-  [Hospital Outpatient Regulations and Notices](#)
-  [MLN Matters Articles](#)

Cancel

# Application Process and Timeline – Screen 1

**HAPG**  
Application Management System

Home Tasks Applications Organizations Resource Library



## Welcome to the Drug and Biological Pass-through Application

### Application Process and Timeline

**What is the application timeframe?**

We will accept transitional pass-through applications for drugs, biologicals, and radiopharmaceuticals on an ongoing basis. However, we must receive applications sufficiently in advance of the first calendar quarter in which transitional pass-through status is sought to allow time for analysis, decision making, and computer programming. The table below indicates the earliest date that pass-through status could be implemented once a completed application and all additional information are received.

Applications submitted by	Earliest effective date for pass-through status
March 1st	July 1st
Jun 1st	October 1st
September 1st	January 1st
December 1st	April 1st

Go

Cancel

# How the online application works

The screenshot displays the HAPG Application Management System interface. At the top, a dark blue header contains the HAPG logo and navigation links for Home, Tasks, Applications, Organizations, and Resource Library. The main content area is a light gray background with a central heading: "Welcome to the Device Pass-through Application". Below this heading, a modal window is open, titled "How the online application works". The modal contains the following text:

What you will need to know:

- Fields and Inputs**  
All fields are required unless marked as optional.
- Saving**  
The application saves automatically so you can continue where you left off.
- Submission**  
CMS may request additional information and/or documentation to support this application.

Below the modal, there are two buttons: a green "Go" button and a gray "Cancel" button. The footer of the page contains the text "HAPG Application management system" and "User Privacy Notice Accessibility Contact Us".

# Primary Contact – Screen 1

Ranbaxy pharmaceuticals | Drug and Biological Pass-through

## Who is the primary contact?

First name	Middle name (optional)	Last name
Phone number Ex. 1234567890		
Email address		
Mailing address line 1		
Mailing address line 2 (optional)		
City	State	ZIP code
Organization (optional)		
Relationship		

Next

# Primary Contact – Screen 2

Ranbaxy pharmaceuticals | Drug and Biological Pass-through

[Initial Info](#) [Drug Info](#) [FDA Info](#) [Cost Info](#) [Volume and Utilization](#) [Attachments](#) [Summary](#)

## Who is the primary contact?

First name	Middle name (optional)	Last name
Phone number Ex. 1234567890		
Email address		
Mailing address line 1		
Mailing address line 2 (optional)		
City	State	ZIP code
Organization (optional)		
Relationship Other		
Describe "other"		

Next

# Secondary Contact – Screen 1

## Who is the secondary contact?

First name	Middle name (optional)	Last name
Phone number Ex: 1234567890		
Email address		
Mailing address line 1		
Mailing address line 2 (optional)		
City	State	ZIP code
Organization (optional)		
Relationship		

Back

Next



# Secondary Contact – Screen 2

## Who is the secondary contact?

First name	Middle name (optional)	Last name
Phone number Ex: 1234567890		
Email address		
Mailing address line 1		
Mailing address line 2 (optional)		
City	State	ZIP code
Organization (optional)		
Relationship Other		
Describe "other"		

Back

Next

# Previous applications – Screen 1

**HAPG**

Application Management System

[Home](#) [Tasks](#) [Applications](#) [Organizations](#) [Resource Library](#)

Ranbaxy pharmaceuticals | Drug and Biological Pass-through

[Initial Info](#)

[Drug Info](#)

[FDA Info](#)

[Cost Info](#)

[Volume and Utilization](#)

[Attachments](#)

[Summary](#)

Have you completed other HAPG applications for this drug?



Yes



No

[Back](#)

# Previous applications – Screen 2

Ranbaxy pharmaceuticals | Drug and Biological Pass-through

## Please provide information about your previous applications

Enter an application details below and click to add them to the list

Application Type	Application status (optional)
Description	
Submission Date	<input type="checkbox"/>

**Add Application**

Previous application list

Back

**Next**

# Drug Info – Screen 1

## Provide information about the drug

Drug Trade Name

Generic Name

Drug Type



What is the drug's form?

- Solution
- Tablet
- Other

What is the date of commercial market availability or date of sale of first unit?

Date



What is the composition and clinical indication(s) of the drug?

Answer

0 / 2000

# Drug Info – Screen 2

Drug Type ▼

What is the drug's form?

- Solution
- Tablet
- Other

What is the date of commercial market availability or date of sale of first unit?

Date

What is the composition and clinical indication(s) of the drug?


Answer

0 / 2000

What is the manner of packaging (e.g., volume, dosages, concentrations per ml, per tablet, per mCi, etc.)?

Answer

0 / 2000

 Packaging, that is, the quantity of the drug, biological or radiopharmaceutical that is represented by an NDC or similar product identifier, must be able to be verified through a publically available source, e.g., the DailyMed web site.


Back

Next

# Drug Info – Screen 3

**HAPG**

Application Management System

[Home](#) [Tasks](#) [Applications](#) [Organizations](#) [Resource Library](#) 

Ranbaxy pharmaceuticals | Drug and Biological Pass-through

[Initial Info](#)

[Drug Info](#)

[FDA Info](#)

[Cost Info](#)

[Volume and Utilization](#)

[Attachments](#)

[Summary](#)

## Provide information about the drug

Drug Trade Name

---

Generic Name

---

Drug Type

Other



Describe "other"

---

What is the drug's form?

Solution

Tablet

Other

Describe "other"

---

What is the date of commercial market availability or date of sale of first unit?

Date



---

# Drug Info – Screen 4

Amazon MD | Drug and Biological Pass-through

Initial Info

Drug Info

FDA Info

Cost Info

Volume and Utilization

Attachments

Summary

## Provide administration and dosage information about the drug

Administration

Minimum dosage per patient

Maximum dosage per patient

The typical dosage per administration for a Medicare patient in the hospital outpatient department per one day. Specifically, based on a 70kg Medicare patient, what would be the typical dosage for this drug in the hospital outpatient setting for one day?

Answer

0 / 2000

# Drug Info – Screen 5

Administration ▼

Minimum dosage per patient \_\_\_\_\_

Maximum dosage per patient \_\_\_\_\_

The typical dosage per administration for a Medicare patient in the hospital outpatient department per one day. Specifically, based on a 70kg Medicare patient, what would be the typical dosage for this drug in the hospital outpatient setting for one day?

Answer

0 / 2000

How are dosages measured?

Answer

0 / 2000

 [Click to see dosage guidelines](#)



# Drug Info – Screen 6

## Provide administration and dosage information about the drug

Administration

Other

Describe "other"

Minimum dosage per patient

1

Maximum dosage per patient

1

The typical dosage per administration for a Medicare patient in the hospital outpatient department per one day. Specifically, based on a 70kg Medicare patient, what would be the typical dosage for this drug in the hospital outpatient setting for one day?

a

# Drug Info – Screen 7

Administration ▼

Minimum dosage per patient

Maximum dosage per patient

## Dosage Guidelines ×

### Guidance 1

For drugs and biologicals other than contrast agents or radiopharmaceuticals, specify how dosages are measured, e.g., in milligrams, micrograms,

### Guidance 2

For diagnostic and therapeutic radiopharmaceuticals and for contrast agents, specify the following information:

- A. Indicate whether the product is available in milligrams (mg), millicuries (mCi), or microcuries (uCi), including concentration before and after reconstitution.
- B. If the Average Wholesale Price (AWP) (or other price) is stated "per vial" or "per ampule," indicate how many doses can be administered from one vial or one ampule.
- C. If the AWP (or other price) is stated "per dose," "per vial," or "per ampule," but the item is administered in milligrams (mg), millicuries (mCi), or microcuries (uCi), indicate how many mg, mCi, or uCi are in one dose, one vial and/or one ampule.

0 / 2000



[Click to see dosage guidelines](#)

# Drug Info – Screen 8

**HAPG**

Application Management System

[Home](#) [Tasks](#) [Applications](#) [Organizations](#) [Resource Library](#)

Amazon MD | Drug and Biological Pass-through

[Initial Info](#)

[Drug Info](#)

[FDA Info](#)

[Cost Info](#)

[Volume and Utilization](#)

[Attachments](#)

[Summary](#)

Have you applied for a Healthcare Common Procedure Coding System (HCPCS) code?



Yes



No

[Back](#)

# Device Info – Screen 9

**HAPG**

Application Management System

[Home](#) [Tasks](#) [Applications](#) [Organizations](#) [Resource Library](#)

Amazon MD | Drug and Biological Pass-through

[Initial Info](#)

[Drug Info](#)

[FDA Info](#)

[Cost Info](#)

[Volume and Utilization](#)

[Attachments](#)

[Summary](#)

## What are the details of your HCPCS application

Submission date



What is the status (optional)

Approved

Pending

Back



Next

# Drug Info – Screen 10

## List all Healthcare Common Procedure Coding System (HCPCS) code(s) or CPT codes associated with the drug

Enter HCPCS or CPT codes below

 [View HCPCS Codes](#)

-  CPT or Level II HCPCS code that reflects the drug administration procedure code(s) or other procedure code associated with the product.
-  Level II HCPCS code that currently identifies the product/item, including an unlisted HCPCS code (e.g., A, C, J, or Q code). Note: Approval of a drug, biological or radiopharmaceutical for a transitional pass-through payment under the hospital OPSS is not contingent on prior assignment of a national HCPCS code. If no HCPCS code is currently available, please specify the requested code descriptor, including dosage units.

[Back](#)

[Next](#)

# FDA Info – Screen 1

Amazon MD | Drug and Biological Pass-through

Initial Info

Drug Info

FDA Info

Cost Info

Volume and Utilization

Attachments

Summary

## Upload your FDA approval letter

### List of Files for Drug Info

There are no files, please click the button below to add a referencing file.

Add/Edit File(s)

### What date was the FDA approval?

Approval date



Back

Next

# FDA Info – Attachments Screen 1

Amazon MD | Drug and Biological Pass-through

Initial Info Drug Info **FDA Info** Cost Info Volume and Utilization Attachments Summary

## Upload your FDA approval letter

Select an existing or attach a new file.

DevicePTP\_Summary\_Page\_8\_06092020.pdf

Drag and drop file(s) to upload or [Browse File\(s\)](#)

Supported formats include PDF, word, excel, powerpoint, JPEG, PNG, and plain text file(s)

Provide some details about the selected file

Page number(s)

212 page # section 1(a)

Upload your FDA approval letter

# Cost Info – Screen 1

## What is the current cost of the drug to hospitals?

\$  Current total cost

\$  Minimum dosage cost

\$  Maximum dosage cost

\$  Typical dosage cost



Current cost of the drug to hospitals should be the actual cost paid by hospitals net of all discounts, rebates, and incentives in cash or in kind.

[Back](#)

[Next](#)



# Cost Info – Screen 2

**HAPG**

Application Management System

[Home](#) [Tasks](#) [Applications](#) [Organizations](#) [Resource Library](#)

Amazon MD | Drug and Biological Pass-through

[Initial Info](#)

[Drug Info](#)

[FDA Info](#)

[Cost Info](#)

[Volume and Utilization](#)

[Attachments](#)

[Summary](#)

Please upload a copy of the **most recently** published Average Wholesale Price (AWP) and Wholesale Acquisition Cost (WAC)

What date was publication?

Date



What is the compendium where published? (please include either RED BOOKTM or Medi-Span Price Rx among the compendium in which the price is published)

Answer

### List of Files for Drug Info

There are no files, please click the button below to add a referencing file.

[Add/Edit File\(s\)](#)



The price submitted by the application deadline (which is subject to verification by CMS) will be used for initial determination of pass-through payment. No price updates after the application deadline will be accepted. If the applicant has not determined the price by the application deadline or if the applicant wants to update the price after the application deadline, then the applicant must withdraw the application and reapply for pass-through in a subsequent quarter.

# Cost Info – Screen 3

**HAPG**

Application Management System

[Home](#) [Tasks](#) [Applications](#) [Organizations](#) [Resource Library](#) [Help](#)

Amazon MD | Drug and Biological Pass-through

[Initial Info](#)

[Drug Info](#)

[FDA Info](#)

[Cost Info](#)

[Volume and Utilization](#)

[Attachments](#)

[Summary](#)

## If available, what is the average sales price (ASP) for each unit of the drug?

Enter unit cost details and click to add them to the list (optional)

<input type="text" value="Unit"/>	<input type="text" value="\$ Current cost"/>
-----------------------------------	--

[Add Item](#)

The following is a list of components

Looks like there is nothing here. Add an item above.

[Back](#)

[Next](#)

# Cost Info – Attachments Screen 1

Amazon MD | Drug and Biological Pass-through

Initial Info

Drug Info

FDA Info

Cost Info

Volume and Utilization

Attachments

Summary

Please upload a copy of the **most recently** published Average Wholesale Price (AWP) and Wholesale Acquisition Cost (WAC)

What date was publication?

Date

6/4/2020



What is the compendium where published? (please include either RED BOOKTM or Medi-Span Price Rx among the compendium in which the price is published)

Answer

Compendium RED BOOK TM

Select an existing or attach a new file.

DevicePTP\_Summary\_Page\_6\_06092020.pdf

Drag and drop file(s) to upload or

Browse File(s)

Supported formats include PDF, word, excel, powerpoint, JPEG, PNG, and plain text file(s)

Provide some details about the selected file

Page number(s)

Page 200. Section 1(a)

## Cost Info – Attachments Screen 2

What date was publication?

Date

6/4/2020



What is the compendium where published? (please include either RED BOOKTM or Medi-Span Price Rx among the compendium in which the price is published)

Answer

Compendium RED BOOK TM

Select an existing or attach a new file.

DevicePTP\_Summary\_Page\_6\_06092020.pdf

Drag and drop file(s) to upload or

Browse File(s)

Supported formats include PDF, word, excel, powerpoint, JPEG, PNG, and plain text file(s)

Provide some details about the selected file

Page number(s)

Page 200. Section 1(a)

Please upload a copy of the most recently published Average Wholesale Price (AWP) and Wholesale Acquisition Cost (WAC)

# Volume and Utilization – Screen 1

Amazon MD | Drug and Biological Pass-through

Initial Info

Drug Info

FDA Info

Cost Info

Volume and Utilization

Attachments

Summary

Identify all projected units/volume by site of service that reflects one full year of utilization based on the drug's package size.

Indicate the specific projected timeframe for the utilization

Date  to Date

Packaging size	
Hospital Outpatient	Ambulatory Surgical Center (ASC)
Amount	Amount
Hospital Inpatient	Physician Office
Amount	Amount
Other (optional)	
Amount	

Add to List

The following is a list of Packaging Amounts

Looks like there is nothing here. Add an item above.

# Attachments – Screen 1

Amazon MD | Drug and Biological Pass-through

[Initial Info](#) [Drug Info](#) [FDA Info](#) [Cost Info](#) [Volume and Utilization](#) [Attachments](#) [Summary](#)

## List all referencing files and documents

List of files and documents

+ DevicePTP\_Summary\_Page\_2\_06092020.pdf Delete

Add/Edit File(s)

 [Click to view important files and documents to include](#)

Back

Next

# Attachments – Screen 2

## List all referencing files and documents

Select an existing file or upload a new file

DevicePTP\_Summary\_Page\_2\_06092020.pdf

Drag and drop file(s) to upload or [Browse File\(s\)](#)

Supported formats include PDF, word, excel, powerpoint, JPEG, PNG, and plain text file(s)

Provide some details about the selected file

Page number(s)

100 section 1(a)

List all referencing files and documents

# Attachments – Screen 3

The screenshot displays the HAPG Application Management System interface. At the top, the HAPG logo and 'Application Management System' are on the left, and navigation links for Home, Tasks, Applications, Organizations, and Resource Library are on the right. Below the navigation bar, the breadcrumb 'Amazon MD | Drug and Biological Pass-through' is visible. A modal window titled 'Items to Include' is open, listing required attachments under three categories: Marketing Materials, FDA Documentation, and Cost Documentation.

**HAPG**  
Application Management System

Home Tasks Applications Organizations Resource Library

Amazon MD | Drug and Biological Pass-through

### Items to Include

**Marketing Materials**

- Booklets, pamphlets, and brochures
- Product catalogs
- Price lists and package inserts
- Case Studies

**FDA Documentation**

- FDA decision letter
- FDA New Drug application
- Biologics License application approval letter
- Premarket Approval (PMA) letter
- FDA label
- Package insert
- Carton label

**Cost Documentation**

- Itemized cost lists
- Manufacturing invoices
- Pricing guides



# Summary page – Screen 1

Amazon MD | Drug and Biological Pass-through

Initial Info

Drug Info

FDA Info

Cost Info

Volume and Utilization

Attachments

Summary

## Drug and Biological Pass-through Application Summary

Please Review and submit your application. A printable version is available on the next page

### Initial Info



#### Primary Contact

--	--

#### Secondary Contact

--	--

#### Applicant

--

#### Related Applications

Drug and Biological Pass-through – 06/01/2020

Inprogress

Device pass-through application submitted on 6/29/2020

Print

# Summary page – Screen 2

## Related Applications

Drug and Biological Pass-through – 06/01/2020

Inprogress

Device pass-through application submitted on 6/29/2020

Edit Section

## Drug Info

### Drug Trade Name:

Tylenol

### Generic Name:

Acetomorphin

### Drug Type:

Other

### Drug Type Other:

Other drug

### Drugs form:

Other

### Drugs form Other:

Suspension

### Availability or Sale Date:

06/25/2020

### Composition and Clinical Indication(s):

What is the composition and clinical indication(s) of the drug?

### Manner of Packaging:

What is the manner of packaging (e.g., volume, dosages, concentrations per ml, per tablet, per mCi, etc.)?

### Administration:

Other

### Administration Other:

# Summary page – Screen 3

**Administration:**

Other

**Administration Other:**

Other Administration Method

**Minimum Dosage:**

100 mg tylenol

**Maximum Dosage:**

200 mg tylenol

**Typical Dosage:**

The typical dosage per administration for a Medicare patient in the hospital outpatient department per one day. Specifically, based on a 70kg Medicare patient, what would be the typical dosage for this drug in the hospital outpatient setting for one day?

**Dosages Measured:**

How are dosages measured?

**Have you applied for a Healthcare Common Procedure Coding System (HCPCS) code?:**

Yes

**Submission date:**

06/05/2020

**Status:**

Approved

**CPT or HCPCS codes:**

CPT-100-PulmonaryDisorders

CPT-101PulmonaryDisorders

Edit Section

**FDA Info**



**Approval Date:**

06/04/2020

**Attachments**


# Summary page – Screen 4

**FDA Info** ▼

---

**Approval Date:**  
06/04/2020

**Attachments**

 DevicePTP\_Summary\_Page\_8\_06092020.pdf

**Page number(s):** 212 page # section 1(a)

Upload your FDA approval letter

[Edit Section](#)

**Cost Info** ▼

---

\$100.00
Current Total Cost
\$200.00
Minimum Dosage Cost
\$300.00
Maximum Dosage Cost
\$400.00
Typical Dosage Cost


**Publication Date:**

# Summary page – Screen 5

**Publication Date:**

06/04/2020

**Attachments**

 DevicePTP\_Summary\_Page\_6\_06092020.pdf

**Page number(s):** Page 200, Section 1(a)


Please upload a copy of the most recently published Average Wholesale Price (AWP) and Wholesale Acquisition Cost (WAC)

**Published Where Answer:**

Compendium RED BOOK TM

Unit	Cost
Unit-100	\$100.00
Unit-200	\$200.00
Unit-300	\$300.00

[Edit Section](#)

**Volume and Utilization** 

**Date Range:**

06/05/2020 - 06/05/2021

100

7%	Volume Info utilization Info amounts packaging	100
13%	Hospital Outpatient	200
20%	Ambulatory Surgical Center	300
27%	Hospital Inpatient	400
33%	Physician Office	500

# Summary page – Screen 6

## Volume and Utilization ▼

**Date Range:**

06/05/2020 - 06/05/2021

100

7%	VolumeInfo.utilizationInfo.amounts.packaging	100
13%	Hospital Outpatient	200
20%	Ambulatory Surgical Center	300
27%	Hospital Inpatient	400
33%	Physician Office	500
0%	Other	0

**Total** 1,500

Edit Section

## Attachments ▼

📎 DevicePTP\_Summary\_Page\_2\_06092020.pdf

**Page number(s):** 100 section 1(a)

List all referencing files and documents

### Attachments

📎 DevicePTP\_Summary\_Page\_2\_06092020.pdf

**Page number(s):** 100 section 1(a)

List all referencing files and documents

# Confirmation page – Screen 1

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You have successfully submitted your request!



Request Confirmation Code: **DRP2006** [REDACTED]

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Thank you for submitting the Drug and Biological Pass-through Payments Application Request! We will begin our review and a CMS analyst will be in contact. This confirmation page will be sent to you via email for your records.

So, what next?

While reviewing your request, a CMS analyst may reach out for additional information or supporting documentation.

■ [view a printer friendly version](#)

[Dashboard](#)

