

The logo for SOFTRAMS features the word in a bold, dark blue, sans-serif font. A red and white graphic element, resembling a stylized arrow or a pen nib, is integrated into the letter 'A'. The logo is set against a background of light blue wavy lines on the left and a blue triangular graphic on the right.

SOFTRAMS

Drug and Biological Pass-through Application Screens

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. On the right, a navigation bar includes links for 'Home', 'Tasks', 'Applications', 'Organizations', and 'Resource Library'. The main content area features a teal icon of a folder with a document. Below this, the text 'Welcome to the Drua and Biooical Pass-through Application' is partially visible. A modal window titled 'Application Guidance' is open, containing the following text:

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 As originally enacted by the Balanced Budget Refinement Act of 1999 (BBRA), this provision required the Secretary to make additional payments to hospitals for current orphan drugs,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](#)

At the bottom of the modal window, there is a 'Cancel' button.

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 logo 'HAPG Application Management System' on the left and navigation links for 'Home', 'Tasks', 'Applications', 'Organizations', and 'Resource Library' on the right. Below the header, a central area features a small icon of a device and the text 'Welcome to the Device Pass-through Application'. A modal window titled 'How the online application works' is open, providing instructions on application fields, saving, and submission. The modal includes a close button (X) in the top right corner. Below the modal, a green 'Go' button and a grey 'Cancel' button are visible. The footer of the page contains the text 'HAPG Application management system' and '© 2019 HAPG'.

HAPG
Application Management System

Home Tasks Applications Organizations Resource Library

Welcome to the Device Pass-through Application

What you will need to know:

How the online application works

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.

Go

Cancel

HAPG Application management system © 2019 HAPG

Primary Contact – Screen 1

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		

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](#)

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[Cost Info](#)

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[Summary](#)

Have you completed other HAPG applications for this drug?



Yes



No


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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	

Add Application

Previous application list

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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.


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Drug Info – Screen 3

HAPG

Application Management System

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Ranbaxy pharmaceuticals | Drug and Biological Pass-through

[Initial Info](#)

[Drug Info](#)

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[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](#)

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



Yes



No

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Device Info – Screen 9

HAPG

Application Management System

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Amazon MD | Drug and Biological Pass-through

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What are the details of your HCPCS application

Submission date



What is the status (optional)

Approved

Pending

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Drug Info – Screen 10

HAPG

Application Management System

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Amazon MD | Drug and Biological Pass-through

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[Summary](#)

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 OPPS 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.

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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



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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

HAPG

Application Management System

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Amazon MD | Drug and Biological Pass-through

[Initial Info](#)

[Drug Info](#)

[FDA Info](#)

[Cost Info](#)

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[Summary](#)

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.

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Cost Info – Screen 2

HAPG

Application Management System

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Amazon MD | Drug and Biological Pass-through

[Initial Info](#)

[Drug Info](#)

[FDA Info](#)

[Cost Info](#)

[Volume and Utilization](#)

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[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

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Amazon MD | Drug and Biological Pass-through

[Initial Info](#)

[Drug Info](#)

[FDA Info](#)

[Cost Info](#)

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[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](#)

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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)

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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 categories of attachments: 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

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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 ▼

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List all referencing files and documents

Attachments

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List all referencing files and documents

Confirmation page – Screen 1

You have successfully submitted your request!



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

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](#)

