

Health Plan Management System Outlier Justification Submission Module User Manual

Version 02.00

Contract Year 2009



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1 Introduction

The Outlier Justification Submission (OJS) module provides a coordinated approach for Part D Sponsors and Formulary Consultants to submit HPMS Outlier Justifications based on requests from CMS. All Outlier Justification Submissions are evaluated by the Centers for Medicare and Medicaid Services (CMS). This module serves as a replacement for CMS' previous process of providing notification of potential formulary issues and receiving Part D sponsor justifications for these issues via email. The same justification information previously submitted to CMS using MS Excel documents will now be directly entered into HPMS. The justifications provided to CMS through the HPMS Outlier Justification Submission module should address whether the Part D Sponsors will resolve potential formulary issues via a resubmission of the formulary file or by providing a clinical justification for review by CMS.

The Outlier Justification Submission module is organized into the following three functional areas:

- Outlier Justification Submission(s) – Allows you to provide Outlier Justifications for formulary issues identified by CMS during the review of your formulary. You will be required to select a formulary (one at a time) and respond Yes/No as to whether a Resubmission will be utilized to resolve the identified issue. If a Yes is entered then you will be required to provide a Resubmission Comment. If a No is entered then a detailed Clinical Justification must be provided. Note: You will be able to export the Outlier Justification page to MS Excel.
- Apply Submitted Justification(s) to Other Formulary ID(s) – Allows you to submit Justifications to other formularies based on previously submitted justifications. You will be required to select a formulary you have previously provided a justification for. Then you will be given a list of Justifications that are available to be applied to another formulary. Select the formulary you want the Justifications applied to and then click Submit.
- Reports – Allows you to access the Outlier Justification History Report to view the history for a formulary. Once a Formulary ID is selected, the Outlier History Report will open in MS Excel.

Note: There will be a Documentation link that will direct you to the OJS User Manual and will be available for download.

2 Outlier Justification Submission Module

To access the **Outlier Justification Submission module**, select the “Plan Formularies” link from the left navigation bar. From the “Plan Formularies” link, select the “Formulary Maintenance” option.

Exhibit 1 Formulary Maintenance Welcome Page

HPMS: Home Page - Microsoft Internet Explorer provided by CGI Federal

File Edit View Favorites Tools Help

HPMS Health Plan Management System Home

Plan Bids

Plan Formularies

Log Off HPMS

This is a U.S. Government computer system subject to Federal law.

Hello Mark King !

Formulary Submission

Formulary Review

Formulary Reports

Negative Formulary Change Requests

NCR Review

Formulary Maintenance

2004 and 2005 MPPF. drug card [bulletin #15](#). MA organization monitoring review guide cover [memo](#) and attachments [1](#) and [2](#).

- 10/05/2004 Release of [letter](#) re: 2005 Model Evidences of Coverage.
- 10/04/2004 - 10/05/2004 Second MCO preview of 10/19 MPPF update.
- 9/29/2004 Release of updated [drug card reporting requirements](#).
- 9/27/2004 Release of [Medicare Health Outcomes Survey \(HOS\)](#) Cohort 4 Performance Measurement Reports and Cohort 6 Baseline Reports in HPMS.
- 9/20/2004 - 9/22/2004 MCO preview of CY 2005 handbook data and 10/19 MPPF update.
- 9/20/2004 Release of drug card [bulletin #14](#) (Attachments [1](#) and [2](#)).
- 9/20/2004 [Update](#) to Chapter 13 of the Medicare Managed Care Manual.
- 9/17/2004 3rd Quarter Medicare Managed Care Manual [Training Call](#).
- 9/13/2004 Release of Version 3.0 of [HPMS Monitoring Worksheet Tool](#).
- 9/13/2004 Deadline for CY 2005 ACRP uploads.
- 9/10/2004 Release of [memo](#) re: the 2005 Medicare Part B premium and rates and the PBP/SB.
- 9/8/2004 Release of [memo](#) re: the Part B premium and the ACR.
- 9/8/2004 Release of [cover memo](#) and attachments [1](#), [2](#), [3](#), [4](#), and [5](#) re: pancreatic islet cell transplants.
- 9/7/2004 - 9/10/2004 Annual Managed Care Enrollment and Payment Conference in Baltimore, Maryland.
- 9/7/2004 [Update](#) to Chapter 17 of the Medicare Managed Care Manual.
- 9/7/2004 Release of drug card [bulletin #11](#) (attachment [1](#)).
- 9/7/2004 Release of drug card [bulletin #12](#).
- 9/7/2004 Release of drug card [bulletin #13](#) (Attachments [1](#), [2](#), [3](#), [4](#)).

Click here for the [archived in the News](#) items.

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Exhibit 2 Formulary Maintenance Module Selection Page

HPMS

CY 2009

Top of Page

Back

Health Plan Management System

Home

Formulary Maintenance

- To access Formulary Maintenance for Contract Year 2009, select the "CY 2009" link.

You must click on the “CY 2009” link from the left navigation bar. Once the **Contract Year** is selected, you will be able to access the **Formulary Maintenance Start Page**.

Exhibit 3 *Formulary Maintenance Start Page*

HPMS

Health Plan Management System

Home

Formulary Maintenance Start Page

Outlier Justification Submission – Submit a Resubmission Comment or Justification for requested outliers.

Apply Submitted Justification(s) to Other Formulary ID(s) – Select submitted Justifications and submit them for additional formularies.

Reports – The following report is available:
Outlier Justification History Report – View justification requests and submissions.

Documentation – The following documentation is available:
User Guide.

Help – Access the Outlier Justification Submission Help.

Outlier Justification Submission

Apply Submitted Justification(s) to Other Formulary ID(s)

Reports

Documentation

Help

Top of Page

Back

The following links will be available from the left navigation bar:

- Outlier Justification Submission -- Allows you to complete Outlier Justification Submissions for one Formulary ID at a time.
- Apply Submitted Justification(s) to Other Formulary ID(s) – Allows you to complete Outlier Justification Submissions based on previously submitted justifications.
- Reports -- Allows you to access the Outlier Justification Submission History Report.
- Documentation -- Allows you to access the Outlier Justification Submission User Manual.
- Help -- Allows you to access the Outlier Justification Submission on-line Help files.

3 Submit Outlier Justifications

When you click on the “Outlier Justification Submission” link from the left navigation bar, the **Outlier Justification Formulary Selection** page will display. This page allows you to select a formulary for submission of Outlier Justifications.

Exhibit 4 *Outlier Justification Formulary Selection Page*

The screenshot displays the 'Outlier Justification Formulary Selection' page within the Health Plan Management System (HPMS). The page features a dark blue left navigation bar with links for 'Outlier Justification Submission', 'Apply Submitted Justification(s) to Other Formulary ID (s)', 'Reports', 'Documentation', and 'Help'. The main content area has a red header with the HPMS logo and a 'Home' link. Below the header, the page title 'Outlier Justification Formulary Selection' is followed by the instruction 'Select a Formulary'. A numbered list indicates the steps: '1. Select one Formulary ID.' and '2. Click Next.' A 'Formulary ID:' label is positioned next to a dropdown menu currently showing '(-Select a Formulary ID-)'. A 'Next' button is located directly beneath the dropdown menu. At the bottom of the left navigation bar, there are links for 'Top of Page' and 'Back'.

The following fields will be displayed on the Outlier Justification Formulary Selection page.

Field	Definition
Formulary ID	Drop Down. Displays formularies for which you can submit Outlier Justifications. Only one Formulary ID may be selected.

Please complete the following steps to view search results:

Step 1. Select a “Formulary ID” from the drop down. Only one Formulary ID can be selected from this page.


Step 2. Click the “Next” button to view the Outliers requiring Justification for the selected formulary. The Outlier Justification Details Page will display.

3.1 Outlier Justification Details

The Outlier Justification Details page allows you to provide details as to how you will address potential formulary issues identified by CMS. For each potential issue, you must select “Yes” or “No” from the “Resubmission? (Yes/No)” drop down and enter a Resubmission Comment or Justification. Selecting a “Yes” indicates that you will modify your formulary resubmission to appropriately address the listed potential issue. You must also enter a brief Resubmission Comment that describes how you modified your formulary file to address the potential issue. Selecting “No” indicates that you do not intend to modify your formulary submission and thus you must provide a detailed clinical justification that supports the submitted formulary structure and content.

Note: You must address all potential issues that are available for justification submission by the listed deadline.

Exhibit 5 Outlier Justification Details Page



Health Plan Management System

Home

Outlier Justification Details

1. Select a Resubmission Yes/No Option.
2. Enter a Resubmission Comment/Justification.
3. Click Submit.

Formulary ID - Version

00008022 - v2

Issue	Deadline Date	Detail 1	Detail 2	Detail 3	Resubmission? (Yes/No)	Resubmission Comment/Justification
USP Comparison Review	05/15/2008	ANTINEOPLASTICS	MONOCLONAL ANTIBODIES	0	<div></div>	<div></div>
USP Comparison Review	05/15/2008	CARDIOVASCULAR AGENTS	ALPHA- ADRENERGIC BLOCKING AGENTS	1	<div></div>	<div></div>

Submit

Reset

Export to Excel

Select Another Formulary

[Go To: HPMS Home](#) | [Formulary Maintenance Home](#) | [Outlier Justification Submission](#) | [Apply Submitted Justification\(s\) to Other Formulary ID\(s\)](#) | [Reports](#) | [Documentation](#)

The following fields will be displayed on the Outlier Justification Detail Page.

Field	Definition
Formulary ID – Version	Display Only. Displays the Formulary ID and Version selected.
Issue	Display Only. Displays the Issue which generated with the Outlier.
Deadline Date	Display Only. Displays the date by which the Outlier Justification must be submitted.
Detail 1	Display Only. The first Detail Level associated with the Issue.
Detail 2	Display Only. The second Detail Level associated with the Issue.
Detail 3	Display Only. The third Detail Level associated with the Issue.
Resubmission? (Yes/No)	Drop Down. Yes or No selection must be made to indicate whether a new version of the formulary will be submitted to address the Outlier.
Resubmission Comment/Justification	Text Field. Allows you to enter a Resubmission Comment or Clinical Justification. Field completion is mandatory and the maximum character length is 2000. You may copy and paste text into the text field.
Submit Button	Finalizes the submission. Allows Outlier Justifications to be submitted for CMS evaluation.
Reset Button	Removes any Resubmission? (Yes/No) selection(s) and removes any Comment/Justification entries prior to submission.
Select Another Formulary Button	Returns the user to the Outlier Justification Formulary Selection Page. Note: If this option is selected prior to submitting active Outlier Justifications, the active Outlier Justifications will not be saved.

Please complete the following steps to successfully submit Outlier Justifications:

1. Select “Yes” or “No” from the Resubmission (Yes/No) drop down.
2. Enter a Resubmission Comment or Justification.

Note: You may copy and paste into the text field. The maximum character length is 2000 (numbers and/or letters). The following characters may not be used in the Resubmission Comment/Justification text field (< > ; &).

4 Apply Submitted Justification(s) to Other Formulary ID(s)

You must select one Formulary ID.

You must select an issue and click on “Next” button.

Exhibit 6 **Apply Submitted Justification(s) to other Formulary ID(s) – Search Page**

The screenshot shows the HPMS (Health Plan Management System) interface. The top header is red with 'HPMS' on the left and 'Health Plan Management System' with a 'Home' link on the right. A left sidebar contains navigation links: 'Outlier Justification Submission', 'Apply Submitted Justification(s) to Other Formulary ID(s)', 'Reports', 'Documentation', and 'Help'. The main content area is titled 'Apply Submitted Justification(s) to Other Formulary ID(s) – Search Page' and contains the following instructions: 1. Select the Formulary ID for which you have already submitted a Justification to be applied to additional Formulary ID(s); 2. Select the Issue(s); 3. Click Next. Below these instructions, there is a 'Select a Formulary:' label followed by a dropdown menu showing 'Select a Formulary ID'. To its right is a 'Select the Issue(s):' label followed by a dropdown menu showing 'Select All Issues' and a list of issues: 'Discrimination Review', 'USP Comparison Review', 'Two Drugs Requirement', 'Common Medicare Drugs Review', 'Common Medicare Drugs Tier Review', 'USP Formulary Key Drug Types Review', and 'Treatment Guidelines Review'. At the bottom left of the main content area is a 'Next' button. The sidebar at the bottom has links for 'Top of Page' and 'Back'.

Exhibit 7 Apply Submitted Justification(s) to Other Formulary ID(s) – Search Results Page

Health Plan Management System
[Home](#)

Apply Submitted Justification(s) to Other Formulary ID(s)

1. Select the Formulary ID(s) you wish to apply the Justification(s) to
2. Select the Justification(s) to be applied
3. Click Submit
4. Click the Export Errors to Excel button if an error log was generated

Apply Justification to Formulary ID:

Select Justifications or Resubmission Comments from Formulary ID 00008028 to be applied to other formularies.

Select All	Submission Date	Issue	Detail 1	Detail 2	Detail 3	Resubmission? (Yes/No)	Resubmission Comment/Justification
<input type="checkbox"/>	05/08/2008	Discrimination Review	HORMONAL AGENTS, STIMULANT/ REPLACEMENT/ MODIFYING (SEX HORMONES/ MODIFIERS)	SELECTIVE ESTROGEN RECEPTOR MODIFYING AGENTS		Yes	
<input type="checkbox"/>	05/05/2008	Two Drugs Requirement	ANTINEOPLASTICS	RETINOIDS		Yes	sg testing - new version 3
<input type="checkbox"/>	05/07/2008	Key Drug Type Review	MULTITARGETED KINASE INHIBITORS, HER2 RECEPTOR TYROSINE KINASE INHIBITORS			Yes	Rachel Testing ----*****!@#%^^^ ()
<input type="checkbox"/>	05/08/2008	Six Classes Review	PHENYTOIN SUSP ORAL			Yes	Rachel Testing ----*****!@#%^^^ ()

Go To: [HPMS Home](#) | [Formulary Maintenance Home](#) | [Outlier Justification Submission](#) | [Apply Submitted Justification\(s\) to Other Formulary ID\(s\)](#) | [Reports](#) | [Documentation](#)

The following table contains a description of each field on the page:

Field	Definition
Apply Justification to Formulary ID	List box where you can select one or many Formulary IDs to apply the changes to.
Select All	Allows you to select all items, one or multiple to apply change.
Submission Date	Display Only. The data for this field is pre-populated.
Issue	Display Only. The data for this field is pre-populated.
Detail 1	Display Only. The data for this field is pre-populated.
Detail 2	Display Only. The data for this field is pre-populated.

Field	Definition
Detail 3	Display Only. The data for this field is pre-populated.
Resubmission? (Yes/No)	Display Only. The data for this field is pre-populated.
Resubmission Comment/Justification	Display Only. The data for this field is pre-populated.

Select one or more Formulary ID's. Multiple selection of Formulary ID's is possible by hitting the CTRL key and selecting multiple Formulary ID's from the list box.

You may click on the "Select All" check box to select all the Submitted Justifications (or) click on the check box corresponding to each Submitted Justification to apply selected Justification(s) to other formularies.

You may click on the "Submit" button to apply the Justification(s) to the selected formularies. If there are errors during submission, they will be displayed on the error log. If there are no error messages, a message will notify you that the submission was successful.

You may click on the "Reset" button to refresh your screen and reset all the fields.

You may click on the "Back to Home" button to be routed back to the home page.

You may click on the "Export Errors to Excel" button to view the errors in MS Excel. The error log will include all the failed validations while processing a selected Submitted Justification to apply to another formulary.

The error log will export to excel and contain the following fields:

Date/Time stamp (within title)

FRID

Issue

Detail 1

Detail 2

Detail 3

Error

5 Reports

Via the **Outlier Justification Submission module**, you will be able to access a history report for all CMS identified formulary issues that have ever been available for justification. You will be able to access the History Report by selecting the “Reports” link from the left navigation bar. The History Report will allow you to select one or multiple formularies and the report will open in Microsoft Excel.

Exhibit 8 Report Selection Page

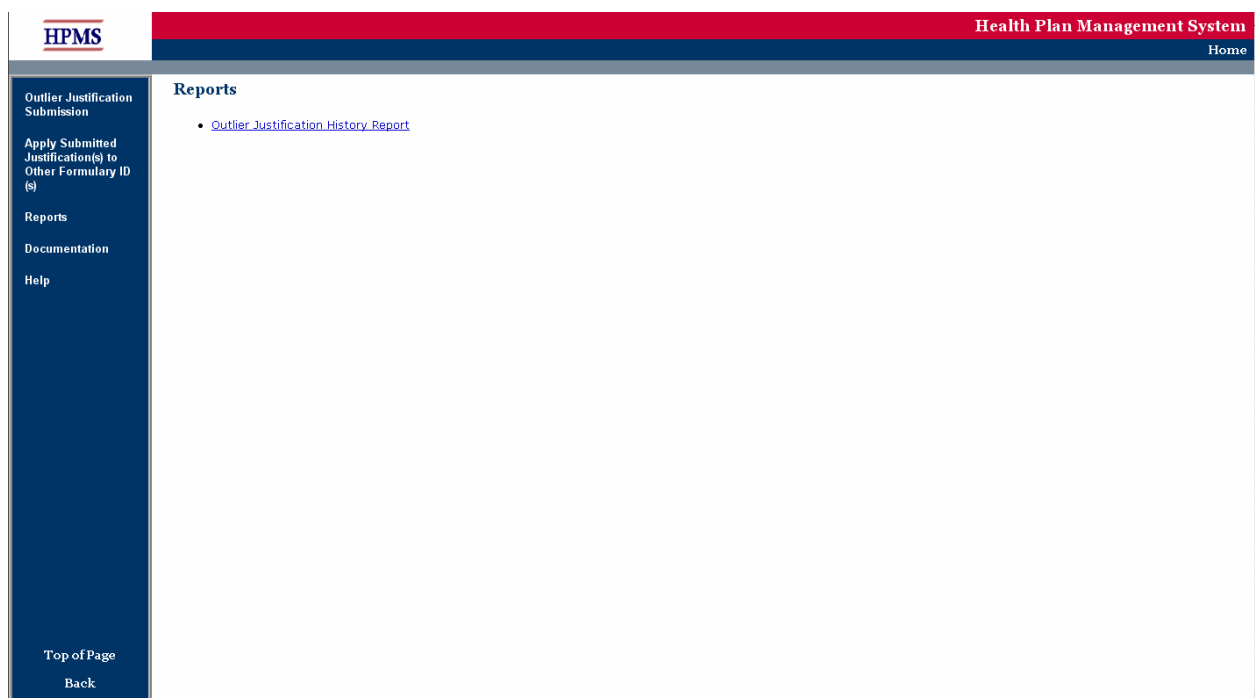


Exhibit 9 Outlier Justification History Report - Selection Page

HPMS

Health Plan Management System
Home

Outlier Justification Submission

Apply Submitted Justification(s) to Other Formulary ID(s)

Reports

Documentation

Help

Top of Page

Back

Outlier Justification History Report - Selection Page

Select Formulary

1. Select Formulary ID.
2. Click Next.

Formulary ID:

Select one or more Formulary IDs

00008020
00008022
00008023
00008028
00008036
00008086
00008100
00008103

Next

The following fields are available on the **Outlier Justification History Report** Selection Page.

Field	Definition
Formulary ID	A list box with Formulary IDs. You may select one or many. If none are selected, the system will display all. Note: this list will display all formularies the user has access to based on Contract and User access. If a formulary is selected which does not have an Outlier Justification Submission History, a “No Records Found” message will be displayed.

Please complete the following steps to view search results:

1. Select one or many Formulary IDs. Use the CTRL key to select multiple formularies.
2. Click the “Next” button to view search results in Microsoft Excel.

Note: If no formularies are selected and you click the “Next” button, all Formulary IDs in the list will be displayed in the Excel file.

The following fields are displayed in the **Outlier Justification History Report** (Excel):

Field	Definition
Formulary ID – Version	Displays the Formulary ID and Version for the Outlier Justification(s).
Issue	Displays the Issue which generated the Outlier.
Submission Date	Displays the date the Outlier Justification was submitted for CMS evaluation.
Detail 1	Displays the first Detail Level associated with the Issue.
Detail 2	Displays the second Detail Level associated with the Issue.
Detail 3	Displays the third Detail Level associated with the Issue.
Resubmission (Y/N)	Displays the Resubmission Yes or No selection for the Outlier.
Resubmission Comment/Justification	Displays the Resubmission Comment or Justification Comment for the Outlier.
Gate Open Date	Displays the date the “Gate” for Outlier Justification was opened.
Gate Close Date	Displays the date the “Gate” for Outlier Justification was closed.

6 Documentation

Via the OJS module, you will be able to access an on-line **Outlier Justification Submission User Manual**. This document is in Portable Document Format (PDF) format. In order to read this document you will need Adobe Reader. This program is available for download from the following link <http://www.adobe.com/products/acrobat/readstep2.html>.

Exhibit 10 Documentation

HPMS		Health Plan Management System
		Home
Outlier Justification Submission	Outlier Justification Submission Documentation	
Apply Submitted Justification(s) to Other Formulary ID(s)	User Manual [332K, PDF]	
Reports		
Documentation		
Help		
Top of Page		
Back		