

HEALTH PLAN MANAGEMENT SYSTEM

Medicare Part D Prescription Drug Formulary Technical Manual

March 15, 2006

Introduction

Since Contract Year (CY) 2006, the Health Plan Management System (HPMS) has provided various utilities to support the submission, review, and approval of the Bid and Formulary Submission processes for organizations offering the Medicare Part D benefit.

As part of the overall Bid Submission process, an interface was originally established in Contract Year (CY) 2006 to enable organizations to upload their Formulary submissions within HPMS. The new CY 2007 HPMS Formulary Submission Module will provide organizations with the means to upload their Formulary File and supplemental data, for review and approval by CMS as a part of the Bid Submission process for CY 2007. The CMS Division of Provider Data (DPD) has been tasked with the development and maintenance of the HPMS Formulary Submission Module, which will allow organizations to submit their formularies electronically.

Using the HPMS Formulary Submission Module, the user will submit one or more formulary files for a contract. All subsequent resubmissions of a formulary file should be a complete resubmission of all proxy NDCs in the formulary. That is, resubmitted formulary files should NOT include just the changes to the original formulary file submission, but rather an entire new version of the formulary file.

The CY 2007 HPMS Formulary Submission Module will be made available to organizations beginning March 27, 2006. Initial review of CY 2007 formularies will begin April 18, 2006. It is anticipated that all formularies will be approved prior to the bid submission deadline of June 5, 2006, for CY 2007. It is highly recommended that organizations submit their formulary file(s) as early as possible during the upload time frame. Uploading earlier in this time frame will provide organizations with adequate time to address potential upload problems and submit corrected formulary file(s). An organization may resubmit their formulary as many times as necessary during the upload time frame, however, only the final successful submission will be processed for CMS review. Organizations implementing a drug formulary must provide a formulary file, along with the applicable supporting documentation (e.g. prior authorization attachment and step therapy attachment).

Section I: General Formulary Information

During the upload process, organizations will provide the following general information for each formulary submission in the HPMS interface:

- Associated Contracts – Users will indicate which contract number(s) (H#, R#, S#, E#) will be utilizing a specific formulary.
- Formulary Upload Contact – The person who uploads the formulary submission for the organization and will work with HPMS staff to resolve any technical issues.
- Formulary Contact - The organization will confirm the Formulary Contact identified in the Contract Management Module in HPMS. This person will be the main formulary contact during review and approval and throughout the contract year.
- Formulary Name – This name will be used internally to reference the specific formulary submission (100 character maximum).
- Formulary Classification System – Organizations will indicate the source type for this formulary. The options for this selection are United States Pharmacopeia (USP), American Hospital Formulary Service (AHFS), or a plan defined source.
- Number of Cost Share Tiers – This value must equal the highest value indicated in the formulary file (1-10). This value must also correspond to the tiers identified in the Plan Benefit Package (PBP) software submitted by June 5, 2006.
- Quantity Limits Requirements – If there are quantity limit restrictions for certain drugs, the organization should select “Yes” in the HPMS interface. Additionally, the formulary file must identify the drugs that have quantity limit restrictions.
- Prior Authorization Requirements – If prior authorization is required for certain drugs, the organization should select “Yes” in the HPMS interface. Additionally, the formulary file must identify the drugs that require prior authorization and the organization must upload a supporting file detailing the prior authorization criteria.
- Step Therapy Management Program – If one or more drugs are included in a step therapy management program, the organization should select “Yes” in the HPMS interface. Additionally, the formulary file must identify the drugs that are part of the step therapy management program and the organization must upload a supporting file detailing the step therapy requirements.

IMPORTANT NOTE: When uploading a new formulary, a unique 8-digit identifier will be assigned to each formulary submission. This ID will be prominently displayed on the HPMS screen. It is critical that the formulary upload user retain the Formulary ID for future reference. CMS will utilize this ID throughout the life cycle of the formulary.

Section II: Formulary File Creation Instructions

The formulary file must be created in an ASCII File Tab Delimited format and must contain one proxy NDC record for each drug offered within an organization's benefit plan(s). The record layout is provided in Section III: Formulary Record Layout. Note that only proxy NDCs provided in the Formulary Reference NDC File may be uploaded. All other NDCs will be rejected by the HPMS Formulary Validation Process.

The general process that the user will complete to submit their plan's drug formulary information is documented in the following sections:

Section One consists of a description, accompanied by screen shots, of how to submit a new formulary file from the "Formulary Submission Start Page" and assign contracts to Formulary IDs from the "Associate Contracts to Formulary Page"

Section Two consists of a description, accompanied by screen shots, of the general formulary-level data entered on the "Formulary Information Page" as well as the tier-level information that is entered on the "Formulary Tier Information Page"

Section Three consists of a step-by-step description of how to upload the various files associated with your formulary submission including:

- The formulary flat file in text format
- If relevant, a prior authorization file in MS-Word format
- If relevant, a step therapy file in MS-Word format

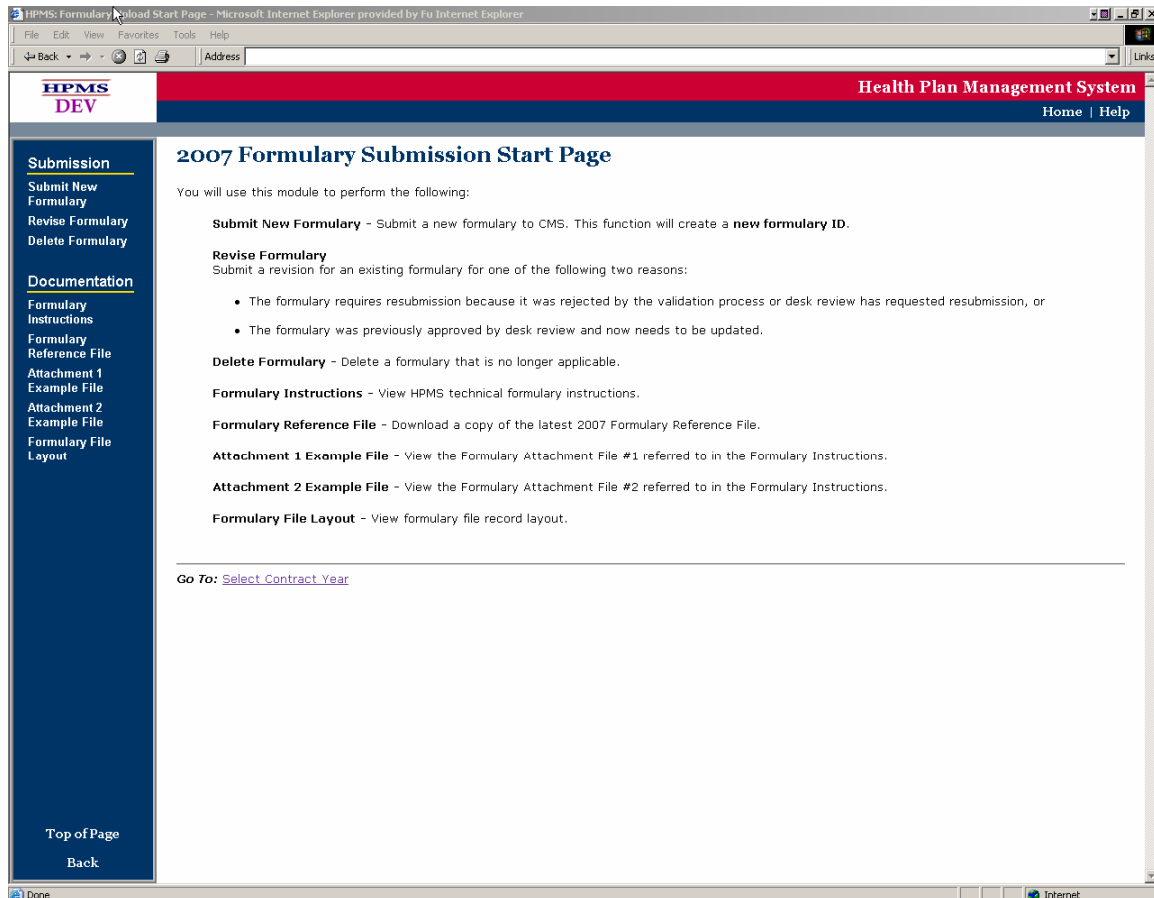
Section Four consists of a description of how to verify the completeness of the information to be submitted prior to upload

Section Five consists of a general description of the results of the Formulary Submission process

Section Six consists of a general description of the Formulary Resubmission process

Section II-1: Formulary Submission Start Page

To submit a new formulary file to CMS, the user must select the option “Submit New Formulary” from the left hand navigation bar on the 2007 Formulary Submission Start Page. This module will create a new Formulary ID.



Selecting the “Submit New Formulary” option will take the user to the “Associate Contracts to Formulary” page.

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File Edit View Favorites Tools Help

Back Address Links

HPMS
DEV

Health Plan Management System
Home | Help

Formulary Submission

Associate Contracts to Formulary

Select one or more contracts to associate with this formulary. If you are unable to select a contract because the Formulary Contact is unassigned or there is no email address, please go to the Contract Management Module to update this information.

NOTE: Prior to contract bid approval, the formulary/contract association can be updated by selecting or deselecting the checkbox beside a contract. Once a contract bid is approved, the formulary/contract association selections can no longer be changed.

Included	Contract Number	Contract Name	Formulary Contact
<input type="checkbox"/>	H0303	PACIFICARE OF ARIZONA, INC	H0303 FormularyContact kfinch@cmshsgov.com
<input checked="" type="checkbox"/>	H1032	WELL CARE HMO, INC.	-- UNASSIGNED --
<input type="checkbox"/>	H1047	HUMANA INSURANCE COMPANY	H1047 FormularyContact tommyslo@gmail.com
<input checked="" type="checkbox"/>	H2462	HEALTHPARTNERS	-- UNASSIGNED --
<input type="checkbox"/>	H4564	MOLLI'S 1876 COST ORG SS	Mollika Phlong phlong@nerdvana.fu.com
<input type="checkbox"/>	H5505	SHAWN'S HMO ORG SS	Shawn Larson larson@nerdvana.fu.com
<input type="checkbox"/>	H5522	TIA'S HMOPOS ORG SS	Tia Henderson thenderson@nerdvana.fu.com
<input checked="" type="checkbox"/>	H5533	UPMC HEALTH NETWORK	-- UNASSIGNED --
<input type="checkbox"/>	H9104	TAKEKO'S CONTINUING CARE ORG SS	Takeko Kamagawa KUMAGAWA@nerdvana.fu.com
<input checked="" type="checkbox"/>	S5915	SCOTT AND WHITE HEALTH PLAN	-- UNASSIGNED --

Please verify that your email address is correct. This email address will be used to communicate the status of this formulary submission. If you need to update your email address, please go to the User Account Maintenance Module and make this change before submitting your formulary information.

Formulary Upload Contact
User ID: jk50
Name: Tommy Lo
E-mail: lo@nerdvana.fu.com

Back Next

Go To: [Formulary Submission Start Page](#) [Select Contract Year](#)

On this page, the user will select one or more contracts to associate with the Formulary ID. To do so, the Formulary Contact must first be assigned. If you are unable to select a contract because the Formulary Contact is unassigned or there is no email address, please go to the Contract Management Module to update the Formulary Contact information.

IMPORTANT NOTE: Prior to contract bid approval, selecting or deselecting the checkbox beside a contract can update the contract-to-formulary association. Once a contract bid is approved, the contract-to-formulary association selections can no longer be deselected.

Section II-2: Formulary Information Screen

Selecting the “Next” button from the “Associate Contracts to Formulary” page will display the “Formulary Information” page. To continue through the process, enter the name of the formulary and enter the other formulary-level data required as part of the formulary upload process.

The screenshot shows a web browser window titled "HPMS: Formulary Submission - Microsoft Internet Explorer provided by Fu Internet Explorer". The browser's address bar is empty. The page has a red header bar with "HPMS DEV" on the left and "Health Plan Management System" on the right, with "Home | Help" links. Below the header, the page title is "Formulary Submission" and the sub-title is "Formulary Information". A horizontal line separates the header from the form content. The form contains several fields and instructions:

- A note: "*Required fields are marked with an asterisk."
- A text input field for "Formulary Name" containing "TestFormulary", with a "(max. 100 Characters)" label. Below it is a note: "NOTE: This is a descriptive name you can use to help identify a formulary. This name can be as simple as Formulary 1, Formulary 2, etc."
- A radio button group for "Indicate the Formulary Classification System for this formulary:" with options: ☒ USP, ☐ AHFS, and ☐ Other, Plan Defined.
- A text input field for "Define number of Tiers" containing "3", with a "(max. 10 tiers)" label. Below it is a note: "NOTE: If all drugs are contained in a single tier, please enter '1' as the value for this field. Please ensure this entry corresponds to the number of tiers to be entered in the Plan Benefit Package (PBP) software."
- A radio button group for "Do any drugs in this formulary submission have Quantity Limits?" with options: ☒ Yes and ☐ No.
- A radio button group for "Do any drugs in this formulary submission require Prior Authorization?" with options: ☒ Yes and ☐ No.
- A radio button group for "Do any drugs in this formulary submission require Step Therapy?" with options: ☒ Yes and ☐ No.
- At the bottom left are "Back" and "Next" buttons.
- At the bottom right is a "Go To:" section with links: [Formulary Submission Start Page](#) and [Select Contract Year](#).

The “Next” button at the bottom of the “Formulary Information” page will take you to the “Formulary Tier Information” page shown below. The number of tiers displayed on the page should be the same as the number of tiers defined on the “Formulary Information” page. Please ensure that this number corresponds to the number of tiers that will be identified in the Plan Benefit Package (PBP) software.

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File Edit View Favorites Tools Help

Back Address Links

HPMS DEV **Health Plan Management System** Home | Help

Formulary Submission

Formulary Tier Information

Formulary Name: Test Formulary

Excluded Drug Tiers: If your formulary submission contains one or more exclusive cost share tiers for Excluded Drugs Only, then please describe your Excluded Drugs Only tier(s) last in the list of Formulary Tier Information that you enter below. See the Technical Instructions for additional details about the order in which tiers should be described in your formulary.

A Specialty Tier is defined as a tier that includes high cost and unique drugs that are exempt from tiering exceptions.

Tier Level	Anticipated Tier Name	Tier Includes	Specialty Tier	Tier Drug Types
Tier 1	Generic 'Other' Anticipated Tier Name	<input checked="" type="radio"/> Part D Only <input type="radio"/> Excluded Drugs Only (e.g., barbiturates, benzodiazepines) <input type="radio"/> Combination	Specialty Tier? <input type="radio"/> Yes <input checked="" type="radio"/> No	<input checked="" type="checkbox"/> Generic <input checked="" type="checkbox"/> Preferred Generic <input checked="" type="checkbox"/> Non-Preferred Generic <input type="checkbox"/> Brand <input type="checkbox"/> Preferred Brand <input type="checkbox"/> Non-Preferred Brand
Tier 2	Brand 'Other' Anticipated Tier Name	<input checked="" type="radio"/> Part D Only <input type="radio"/> Excluded Drugs Only (e.g., barbiturates, benzodiazepines) <input type="radio"/> Combination	Specialty Tier? <input type="radio"/> Yes <input checked="" type="radio"/> No	<input type="checkbox"/> Generic <input type="checkbox"/> Preferred Generic <input type="checkbox"/> Non-Preferred Generic <input checked="" type="checkbox"/> Brand <input checked="" type="checkbox"/> Preferred Brand <input type="checkbox"/> Non-Preferred Brand
Tier 3	Non-Preferred Brand 'Other' Anticipated Tier Name	<input checked="" type="radio"/> Part D Only <input type="radio"/> Excluded Drugs Only (e.g., barbiturates, benzodiazepines) <input type="radio"/> Combination	Specialty Tier? <input type="radio"/> Yes <input checked="" type="radio"/> No	<input type="checkbox"/> Generic <input type="checkbox"/> Preferred Generic <input type="checkbox"/> Non-Preferred Generic <input type="checkbox"/> Brand <input type="checkbox"/> Preferred Brand <input checked="" type="checkbox"/> Non-Preferred Brand

Back Next

Go To: [Formulary Submission Start Page](#) [Select Contract Year](#)

Enter the information related to the tiers included in the formulary (i.e., for each tier, the Tier Name or “Other” Anticipated Tier Name, whether the tier is a specialty tier or not, and the types of drugs in the tier).

When developing their formulary tier structure, plans should utilize standard industry practices. Tier 1 should be considered the lowest cost-sharing tier available to beneficiaries. Any and all subsequent tiers within the formulary structure should be higher cost-sharing tiers in ascending order. For example, drugs in Tier 3 should have a higher cost-share for beneficiaries than drugs in Tier 2.

IMPORTANT NOTE: A Specialty Tier is defined as a tier that includes drugs that are high cost and unique. Drugs within the Specialty Tier are exempt from tiering exceptions.

Section II-3: Formulary Submission – Upload Files Screen

Selecting the “Next” button from the “Formulary Tier Information” page will take the user to the “Upload Files” screen. Based on the information entered on previous pages, the application will request the following files for upload:

- Formulary File
- Prior Authorization File
- Step Therapy File

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File Edit View Favorites Tools Help

Back Forward Stop Home Links

Address

HPMS
DEV

Health Plan Management System
Home | Help

Formulary Submission

Upload Files

Formulary Name: Test Formulary

Step 1. Enter the name of the Formulary Text File (.txt) that you would like to upload. If you are unsure of the file name and/or location, click on the "Browse" button to locate the file.

Step 2. Enter the name of the Prior Authorization File that you would like to upload. If you are unsure of the file name and/or location, click on the "Browse" button to locate the file. Must be a MS Word File.

Step 3. Enter the name of the Step Therapy File that you would like to upload. If you are unsure of the file name and/or location, click on the "Browse" button to locate the file. Must be a MS Word File.

Step 4. Enter the name of the Notes File that you would like to upload. If you are unsure of the file name and/or location, click on the "Browse" button to locate the file. Must be a MS Word File.

Step 5. Click on the "Upload" button to send the file to HPMS.

Step 6. Wait until the file transfer is complete. Your browser will automatically be directed to the appropriate page once the file(s) are received.

Step 7. You will be directed to a verification page. The verification page allows you to confirm that your formulary information is correct before your data is submitted.

FORMULARY FILE
Select Formulary File for upload:

PRIOR AUTHORIZATION FILE
Select Prior Authorization File for upload:

STEP THERAPY FILE
Select Step Therapy File for upload:

NOTES FILE
☐ There is no Notes File to include
☒ Select Notes File for upload:

Go To: [Formulary Submission Start Page](#) [Select Contract Year](#)

Enter the name of the Formulary Text File (.txt) that you would like to upload. If you are unsure of the file name and/or location, click on the "Browse" button to locate and attach the file. The formulary file must be a tab delimited text file.

If “No” was selected for the prior authorization or step therapy questions on the “Formulary Information” page, then the field associated with these questions will not be displayed. If “Yes” was selected for the prior authorization question, then enter the name of the prior authorization file that you would like to upload. The prior authorization file must be an MS-Word file. If “Yes” was selected for the step therapy question, then enter the name of the step therapy file that you would like to upload. The step therapy file must be an MS-Word file. Again, if you are

unsure of the file name and/or location for either of these files, click on the "Browse" button to locate and attach the appropriate file.

When all files have been identified, click on the "Upload" button to submit the files. Your browser will automatically be directed to the appropriate page once the file(s) are received. Please wait until the file transfer is complete before attempting to navigate further.

Section II-4: Formulary Submission – Verify Submission Screen

Prior to completion of the upload process, the “Verify Submission” screen will be displayed, which will allow the user to confirm that they have answered the questions on the prior pages correctly for this formulary upload. If the information is correct, select the “Submit” button to submit your formulary and related information and files. If any information is incorrect, select the “Back” button at the bottom of the page to return to the appropriate screen to correct your information.

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File Edit View Favorites Tools Help

Back Forward Stop Home Address Links

HPMS DEV **Health Plan Management System** Home | Help

Formulary Submission

Verify Submission

Please note that your data has not yet been submitted.

Formulary Name: Test Formulary
Formulary ID: 00007081
Formulary Version: 1

Please verify that the information entered is correct. Select the "Submit" button to submit your Formulary Information. If any information is incorrect, please select the "Back" button at the bottom of the page to correct your information.

Contracts Covered by Formulary: H1047, H5505

Contacts to be notified of this formulary submission			
	User ID	Name	E-mail
Upload User	jk50	Tommy Lo	lo@nerdvana.fu.com
H1047	n/a	H1047 FormularyContact	tommyslo@gmail.com
H5505	n/a	Shawn Larson	larson@nerdvana.fu.com

Formulary Classification System used for this formulary: USP

Number of Tiers: 3

Tier Level	Anticipated Tier Name	Tier Includes	Specialty Tier?	Tier Drug Types
1	Generic	Part D Only	NO	Generic, Preferred Generic, Non-Preferred Generic
2	Brand	Part D Only	NO	Brand, Preferred Brand
3	Non-Preferred Brand	Part D Only	NO	Non-Preferred Brand

Formulary includes drugs that have Quantity Limits? YES

Formulary includes drugs that require Prior Authorization? YES

Formulary includes drugs that require Step Therapy? YES

Files to be Uploaded	
Title	File Name
Formulary File	C:\formulary.txt
Prior Authorization File	C:\formulary_priorauth.doc
Step Therapy File	C:\formulary_steptherapy.doc
Notes File	C:\formulary_notes.doc

Back Submit

Go To: Formulary Submission Start Page Select Contract Year

IMPORTANT NOTE: Please note that your data has NOT yet been submitted for upload when this screen is displayed.

Section II-5: Formulary Submission – Submission Confirmation Screen

This page is displayed once the files have been successfully uploaded and the answers to the questions have been stored in the HPMS database. A unique Formulary ID will be assigned to each new formulary created once the initial upload is completed. This Formulary ID will be used for all subsequent submissions with incremental version changes for each successful resubmission. Selecting “OK” will return the user to the HPMS Home Page.

The screenshot shows a web browser window titled "HPMS: Formulary Submission - Microsoft Internet Explorer provided by Fu Internet Explorer". The address bar is empty. The page has a red header bar with the HPMS logo on the left and "Health Plan Management System" on the right, with "Home | Help" links. Below the header, the page title is "Formulary Submission" and the sub-title is "Submission Confirmation".

Formulary Name: Test Formulary
Formulary ID: 00007081
Formulary Version: 1

Your formulary information was successfully uploaded and the formulary contacts listed below will receive a confirmation e-mail.

Please note your formulary ID. You will need this ID in order to make an update or revision later. The Formulary ID will also appear in your confirmation e-mail.

The HPMS will now perform a series of validation edits on the formulary submission. At the close of the validation process, a second e-mail will be sent to the formulary contacts listed below. This e-mail will either indicate a successful formulary validation or identify the errors detected. If errors were detected, the formulary submission will be rejected. Once the errors are corrected, the formulary can be re-submitted using the Revise Formulary function.

Contacts notified of this formulary submission			
	User ID	Name	E-mail
Upload User	jk50	Tommy Lo	lo@nerdvana.fu.com
H1047	n/a	H1047 FormularyContact	tommyslo@gmail.com
H5505	n/a	Shawn Larson	larson@nerdvana.fu.com

OK

Go To: [Formulary Submission Start Page](#) [Select Contract Year](#)

IMPORTANT NOTE: Receipt of this page confirms that your formulary information was successfully uploaded. The formulary contacts displayed on this page will receive a confirmation e-mail documenting receipt by HPMS of the uploaded file(s) and will include the Formulary ID associated with the submission. Users should NOTE their Formulary ID as they will need this ID in order to make a later update or revision.

After receiving the uploaded formulary file, HPMS will perform a series of validation edits. At the close of the validation process, a second e-mail will be sent to the formulary contacts listed on this page. This e-mail will either indicate that the formulary was successfully validated or identify errors detected in the validation process. If errors were detected, then the formulary submission will be rejected. The system will communicate 200 errors at a time. Once the errors are corrected, the formulary can be re-submitted using the Revise Formulary function.

Section II-6: Formulary Re-submission – Select a Formulary Screen

This page will display if the user selects the “Revise Formulary” link from the navigation bar on the left side of the “Formulary Submission Start Page”. Users should select from the list of formularies available for resubmission. Once a formulary is selected and the user clicks on “Update”, the user is taken to the “Associate Contracts to Formulary” screen specified above in Section II-1. Only formularies with a submission status of “Resubmission Requested” or “Rejected by Validation” are generally available for revision. Approved formularies will appear on this page but are only available for revision during the designated update cycles.

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File Edit View Favorites Tools Help

HPMS DEV Health Plan Management System Home | Help

Formulary Re-Submission

Select a Formulary

Resubmissions

These formularies require resubmission because they have been either rejected by the validation process or desk review has requested resubmission.

Select One	Formulary ID	Formulary Name	Version	Submission Status	Contract(s) Associated with Formulary
<input type="radio"/>	00007001	Tommy Test 200702061633	1	Resubmission Requested	H1047

In Process

These formularies are currently unavailable for revision.

Formulary ID	Formulary Name	Version	Submission Status	Contract(s) Associated with Formulary
00007081	Test Formulary	1	Uploaded, but not Processed	H1047, H5505
00007040	Tommy 200602161018	2	Successfully Validated	H1047
00007060	Tommy d200602221411	1	Successfully Validated	H0303
00007061	Tommy 200602221413	1	Successfully Validated	H0303
00007062	Tommy 200602221416	1	Successfully Validated	H0303, H1047
00007063	Tommy 200602221419	1	Successfully Validated	H0303
00007000	Tommy Test 200702061629	2	Sent to Desk Review	H0303

Go To: [Formulary Submission Start Page](#) [Select Contract Year](#)

Section III: Formulary File Record Layout

2007 Formulary File Record Layout

Required File Format = ASCII File - Tab Delimited

Do not include a header record

Filename extension should be “.TXT”

Field Name	Field Type	Field Length	Field Description	Sample Field Value(s)
Proxy NDC	CHAR NOT NULL	11	11-Digit National Drug Code	00000333800
Tier_Level_Value	CHAR NOT NULL	2	Defines the Cost Share Tier Level Value Associated with the drug. Assumption is that the drug is assigned to only one tier value. These values are consistent with the selection of tier value options available to data entry users in the Plan Benefit Package software. If no Tier Level Value applies, enter ‘1’ as the value for this field.	1 = Tier Level 1 2 = Tier Level 2 3 = Tier Level 3 4 = Tier Level 4 5 = Tier Level 5 6 = Tier Level 6 7 = Tier Level 7 8 = Tier Level 8 9 = Tier Level 9 10 = Tier Level 10
Drug_Type_Label_Value	CHAR NULL	1	Defines the Drug Type Label Value for the drug. Enter the label value for the Drug Type from the defined list of labels in the instructions (currently not applicable)	1 = n/a (reserved for later use) 2 = n/a (reserved for later use)
Quantity_Limit_Amount_YN	CHAR NOT NULL	1	Does the drug have a quantity limit restriction?	1 = Yes 0 = No
Quantity_Limit_Amount	NUM NULL	7	If Yes to Quantity_Limit_Amount_YN, enter the quantity limit unit amount for a given prescription or time period. The units for this amount may be defined as number of pills, number of injections, etc. If the drug does not have a quantity limit restriction, then leave this field blank. The maximum logical number that will be accepted is “9999.99”.	1000.75
Quantity_Limit_Days	NUM NULL	3	Enter the number of days associated with the quantity limit.	60 (e.g. 9 pills every 60 days) (e.g. 9 injections every 60 days)

Field Name	Field Type	Field Length	Field Description	Sample Field Value(s)
			<p>If the Quantity_Limit_Amount_YN field is 0 = No, then leave this field blank</p> <p>The maximum logical number that will be accepted is “999”</p>	
Prior_Authorization_YN	CHAR NOT NULL	1	Is prior authorization required for the drug?	1 = Yes 0 = No
Therapeutic_Category_Name	CHAR NOT NULL	100	<p>If an AHFS or plan-defined classification structure was chosen, enter the name of the category for the drug.</p> <p>Formularies using the USP classification system should leave this field blank.</p>	Analgesics
Therapeutic_Class_Name	CHAR NOT NULL	100	<p>If an AHFS or plan-defined classification structure was chosen, enter the name of the class for the drug.</p> <p>Formularies using the USP classification system should leave this field blank.</p>	Opioid Analgesics
Step_Therapy_YN	CHAR NOT NULL	1	<p>Does step therapy apply to this drug?</p> <p>The only drugs that should be marked as “Yes” are those that require additional drugs to be used first.</p> <p>Step one level drugs in a step therapy algorithm should be marked “No”.</p>	1 = Yes 0 = No
Step_Therapy_Type_Group_Num	NUM NULL	2	<p>Enter the total number of step therapy drug treatment groups in which the drug is included.</p> <p>If response to Step_Therapy_YN = 0 (No), then leave this field blank.</p> <p>The maximum logical number that will be accepted is “99”.</p>	3

Field Name	Field Type	Field Length	Field Description	Sample Field Value(s)
<p>The remaining two fields described below should be repeated as a group or unit in the file.</p> <p>For example, for a given drug used in multiple Step Therapy programs, the values for Step_Therapy_Type_Group_Desc_1 = “CHF Therapy” and Step_Therapy_Type_Group_Step_1 = 4 should be included in adjacent columns in the file. Likewise, the values for Step_Therapy_Type_Group_Desc_2 = “Angina Therapy” and Step_Therapy_Type_Group_Step_2 = 1 should be included in additional adjacent columns in the file. Likewise, the values for Step_Therapy_Type_Group_Desc_3 = “CVD Therapy” and Step_Therapy_Type_Group_Step_3 = 5 should be included in additional adjacent columns in the file.</p>				
Step_Therapy_Type_Group_Desc_X	CHAR NULL	100	<p>Description of step therapy drug treatment group. Field should be repeated in the record based upon number of groups declared in Step_Therapy_Type_Group_Num</p> <p>If response to Step_Therapy_YN = 0 (No), then leave this field blank.</p>	<p>Step_Therapy_Type_Group_Desc_1 = “CHF Therapy”</p> <p>Step_Therapy_Type_Group_Desc_2 = “Angina Therapy”</p> <p>Step_Therapy_Type_Group_Desc_3 = “CVD Therapy”</p>
Step_Therapy_Type_Group_Step_X	NUM NULL	2	<p>Identifies the step number or level within the sequence for the Step Therapy Group. Field should be repeated in the record based upon the number of groups declared in Step_Therapy_Type_Group_Num AND in the same order as Step_Therapy_Type_Group_Desc_X</p> <p>Since only second level drugs will be flagged as requiring step therapy, all numbers in this field should be 2 or greater</p> <p>If response to Step_Therapy_YN = 0 (No), then leave this field blank.</p> <p>The range of valid accepted values is 2 to 99.</p>	<p>Step_Therapy_Type_Group_Step_1 = 4 (e.g. Step 4 of 6)</p> <p>Step_Therapy_Type_Group_Step_2 = 1 (e.g. Step 1 of 3)</p> <p>Step_Therapy_Type_Group_Step_3 = 5 (e.g. Step 5 of 5)</p>

Section IV: Formulary File Field-by-Field Instructions

The following is a “field by field” description of how to structure your formulary file for upload into HPMS. Please note that every field is labeled either “Required”, “Optional” or “Conditional”. The conditional fields should be populated if the condition is met as outlined below. When an optional and/or conditional field is left blank, the blank must be represented by a tab delimiter.

The upload validation edits are explained in further detail within each field description. A formulary will be rejected if the validation edits are not met.

Further clarification regarding the development of the supporting documents for the formulary file is provided in Section V – Formulary File Examples. Section V provides an illustration of the formulary layout of the prior authorization and step therapy documents in MS-Word.

Field 1 – Proxy NDC:

REQUIRED: Each record should include an 11-digit proxy NDC associated with the formulary. The list of acceptable proxy NDCs can be found in the Formulary Reference NDC File. Proxy NDCs should only be entered once in this formulary file.

Field 2 – Tier_Level_Value:

REQUIRED: Enter the cost share tier level value associated with the drug. Include a value from 1 to 10 only. A number outside of this range will result in an upload error. If cost share tiering does not apply, include the value “1” in this field.

NOTE: The maximum value entered for this field may NOT be greater than the value entered for the number of cost share tiers in the HPMS Formulary Submission Data Entry Web Interface. If these values are inconsistent, an upload error will result.

Field 3 – Drug_Type_Label_Value:

OPTIONAL: This field is reserved for later use. It should be left null during the initial formulary uploads by entering a tab delimiter.

Field 4 – Quantity_Limit_Amount_YN:

REQUIRED: This field should be set to a value of 0 or 1, where 0 = No and 1 = Yes. Set the value to 1 if the drug has a restriction on the quantity that is available; otherwise set the value to 0 if there are no restrictions other than a one-month supply. Examples of quantity limits include the following:

- Imitrex 50mg tablets - 9 tablets/30 days
- Actonel 35mg tablets - 5 tablets/30 days
- Diflucan 150mg tablets - 1 tablet/prescription

NOTE: If the user selected **Yes** to the Quantity Limit question in the HPMS Data Entry Web Interface, then one or more NDC records must have a value of 1 for this field. If these values are inconsistent, an upload error will result.

Field 5 - Quantity_Limit_Amount:

CONDITIONAL: If the **Quantity_Limit_Amount_YN** field is 0, then leave this field blank by providing a tab delimiter. If the **Quantity_Limit_Amount_YN** field is 1, include the quantity limit unit amount. The unit amount for this field refers to unit values such as the number of pills or the number of injections for the drug. For example, for a quantity limit that includes 9 tablets every 60 days, this field should indicate a value of 9.

Field 6 - Quantity_Limit_Days:

CONDITIONAL: If the **Quantity_Limit_Amount_YN** field is 0, then leave this field blank by providing a tab delimiter. If the **Quantity_Limit_Amount_YN** field is 1, include the quantity limit day amount for this drug. For example, for a quantity limit that includes 9 pills every 60 days, this field should indicate a value of 60. If there is a quantity limit per prescription (e.g. 1 tablet per prescription), the field should indicate the value of the prescription limit.

Field 7 – Prior_Authorization_YN:

REQUIRED: This value should be set to value of 0 or 1, where 0 = No and 1 = Yes. Set the value to 1 if the drug requires prior authorization; otherwise set the value to 0 to indicate that a prior authorization is NOT required. **NOTE:** If the user selected **Yes** to the Prior Authorization question in the HPMS Data Entry Web Interface, then one or more NDC records must have a value of 1 for this field. If these values are inconsistent, an upload error will result.

Field 8 – Therapeutic_Category_Name:

CONDITIONAL: If the formulary is using an AHFS or a plan-defined classification structure, then all records must include a value for the **Therapeutic_Category_Name** field or an upload error will result. Formularies using the USP classification structure must leave this field blank by entering a tab delimiter.

Field 9 – Therapeutic_Class_Name:

CONDITIONAL: If the formulary is using an AHFS or a plan-defined classification structure, then all records must include a value for the **Therapeutic_Class_Name** field or an upload error will result. Formularies using the USP classification structure must leave this field blank by entering a tab delimiter.

Field 10 – Step_Therapy_Type_Group_YN:

REQUIRED: This value should be set to a value of 0 or 1, where 0 = No and 1 = Yes. Set the value to 1 if the drug requires step therapy; otherwise set the value to 0 to indicate that step therapy is NOT required. Only drugs that are step two or above should be marked with a value of Yes.

NOTE: If the user selected **Yes** to the Step Therapy question in the HPMS Data Entry Web Interface, then one or more NDC records must have a value of 1 for this field. If these values are inconsistent, an upload error will result.

Field 11 – Step_Therapy_Type_Group_Num:

CONDITIONAL. This field should include a value that indicates the number of step therapy drug treatment groups in which the drug is a member. The value included in this field may not exceed 2 digits in length. This field should contain a value if

Step_Therapy_Type_Group_YN = 1 (Yes). If step therapy does not apply to a given drug, then leave this field blank by providing a tab delimiter.

Field 12 – Step_Therapy_Type_Group_Desc_X:

CONDITIONAL: If the user selects **Yes** to having one or more drugs with step therapy management in the HPMS Data Entry Web Interface, then the user must provide a description of the step therapy drug treatment group. This field should be repeated in the drug record (in an additional column) based upon the number of groups declared in **Step_Therapy_Type_Group_Num**. If Step Therapy does not apply to this drug, then leave this field blank by providing a tab delimiter.

Field 13 – Step_Therapy_Type_Group_Step_X:

CONDITIONAL: If the user selects **Yes** to having one or more drugs with step therapy management in the HPMS Data Entry Web Interface, then the user must include a value in this field that represents the unique step number within the sequence of steps for the treatment group identified in Field 12. If Step Therapy does not apply to this drug, then leave this field blank by providing a tab delimiter. This field should be repeated in the record (in an additional column) based upon number of groups declared in

Step_Therapy_Type_Group_Num AND in the same order as

Step_Therapy_Type_Group_Desc_X. For example, if an NDC has 3 step therapy treatment groups declared in the Step_Therapy_Type_Group_Num field, then three sets of values should be defined for Step_Therapy_Type_Group_Desc_X and Step_Therapy_Type_Group_Step_X as follows:

Step Therapy Treatment Group 1 Values –

Step_Therapy_Type_Group_Desc_1 = “CHF Therapy”

And

Step_Therapy_Type_Group_Step_1 = 4

Step Therapy Treatment Group 2 Values –

Step_Therapy_Type_Group_Desc_2 = “Angina Therapy”

And

Step_Therapy_Type_Group_Step_2 = 2

Step Therapy Treatment Group 3 Values –

Step_Therapy_Type_Group_Desc_3 = “CVD Therapy”

And

Step_Therapy_Type_Group_Step_3 = 5

Section V: Formulary Supporting Documentation

All attachments should be written in Arial or Times New Roman font with font size of 10-12 point.

Prior Authorization File Instructions

If a formulary has prior authorization for one or more drugs, then the formulary upload submission must include an attachment that describes the specific prior authorization criteria. The criteria should be provided in MS-Word format.

CMS requests that the prior authorization file be organized in the following format:

- Provide an initial summary page to organize the document, which should contain medication names (brand and/or generic) or medication classes that have prior authorization criteria (e.g. Proton pump inhibitors). The medications or medication classes should be listed alphabetically with the associated page number. For example:

Summary Page

Actiq	Page 1
COX-2 inhibitors	Page 2
Proton pump inhibitors	Page 3

- Following the summary page, each medication or medication class should be listed on the pages identified. For example:

Per the summary page in the previous example, page 1 of the attachment would contain the criteria for Actiq, page 2 would contain the criteria for COX-2 inhibitors, and page 3 would contain the criteria for Proton pump inhibitors.

- If prior authorization is being used administratively to help determine coverage under Part B vs. Part D, plans may create a separate table that lists all drugs under this category rather than listing each drug on the summary page.
- If prior authorization criteria only applies to beneficiaries who are initiating the drug for the first time (i.e. “new starts”), this should be noted at the drug/class level where the prior authorization criteria is applicable. In addition, on the summary page, please denote with an asterisk the drugs where a new start statement applies.

Step Therapy File Instructions

If a formulary has step therapy for one or more drugs, then the formulary upload submission must include an attachment that illustrates the detailed algorithms for all step therapy management programs in the formulary. The step therapy management algorithm file should be provided in MS-Word format.

CMS requests that the step therapy attachment be organized in the following format:

- Provide an initial summary page to organize the document, which should contain medication names (brand and/or generic) or medication classes that have step therapy criteria (e.g. Angiotension receptor blockers). The medications or medication classes should be listed alphabetically with the associated page number. For example:

Summary Page

Angiotension receptor blockers	Page 1
Proton pump inhibitors	Page 2

- Following the summary page, each medication or medication class should be listed on the pages identified. For example:

Per the summary page in the previous example, page 1 of the attachment would contain the criteria for Angiotension receptor blockers and page 2 would contain the criteria for Proton pump inhibitors.

- If step therapy criteria only applies to beneficiaries who are initiating the drug for the first time (i.e. “new starts”), this should be noted at the drug/class level where the step therapy criteria is applicable.

Section VI: List of Contacts

HPMS Technical Help Desk

1-800-220-2028

hpms@cms.hhs.gov

HPMS

Julia Heeter

410-786-6198

julia.heeter@cms.hhs.gov

Ana Nunez-Poole

410-786-3370

ana.nunezpoole@cms.hhs.gov

Formulary Content & Review Guidelines

Aaron Eaton

410-786-2058

aaron.eaton@cms.hhs.gov

Brian Martin

410-786-1070

brian.martin@cms.hhs.gov

Denise Von Rinteln

410-786-0157

denise.vonrinteln@cms.hhs.gov

Don Reese

410-786-6691

donald.reese@cms.hhs.gov

Kady Flannery

410-786-6722

kathleen.flannery@cms.hhs.gov