
HEALTH PLAN MANAGEMENT SYSTEM
FORMULARY SUBMISSION MODULE & REPORTS
TECHNICAL MANUAL

MARCH 17, 2008

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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 for organizations offering the Medicare Part D benefit. As part of the overall Bid Submission process, an interface was originally established in CY 2006 to enable organizations to upload their Formulary submissions within HPMS. The CY 2007 and CY 2008 HPMS Formulary Submission Modules provided organizations with a series of enhancements and incorporated the use of a standard Formulary Reference File. The CY 2009 module includes updates to the Formulary Data Reference File, the Formulary File Format, Prior Authorization File, Formulary Reports and new functionality for supplemental file submissions. Supplemental file submissions include Gap Coverage, Free First Fill, Home Infusion Drug, Over the Counter, and Excluded Drug files.

Using the HPMS Formulary Submission Module, the user is able to submit one or more formulary files for a contract that contains all or a subset of drugs from the CMS provided Formulary Data Reference File. All subsequent resubmissions of a formulary file must be a complete resubmission of all proxy National Drug Codes (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 2009 HPMS Formulary Submission Module will be made available to organizations beginning March 28, 2008. Formulary Submissions are due by 11:59 PM EDT on April 21, 2008. Initial review of CY 2009 formularies will begin on April 22, 2008. It is anticipated that all formularies will undergo a preliminary review prior to the bid submission deadline of June 2, 2008, for CY 2009. 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 initial upload period, 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/or step therapy attachment).

On June 3rd, 2008, the Formulary Supplemental Submissions and Reports functionality will be released to support the submission of gap coverage, free first fill, home infusion drug, over-the-counter, and excluded drug supplemental files. Organizations must submit this supplemental information for each plan offering this coverage. The supplemental files cannot be loaded until the organization has successfully submitted their related bid(s). Details on the required file format are available in Appendix B. Details on the steps for submitting these files will be available in this manual on May 21, 2008.

The CY 2009 Formulary Reports module provides reports that can be used to monitor the status of your formulary submission. The available reports include the Formulary/Bid Contact Report and the Formulary Change Notification Report. More reports will become available to user at different periods throughout the year.

This document provides information and instructions to:

- Submit New Formulary
- Revise Formulary
- Delete Formulary
- Access/Generate Formulary Reports

NOTE: Supplemental file instructions for Gap Coverage, Free First Fill, Home Infusion, Excluded Drug, and Over the Counter will be available at a later time.

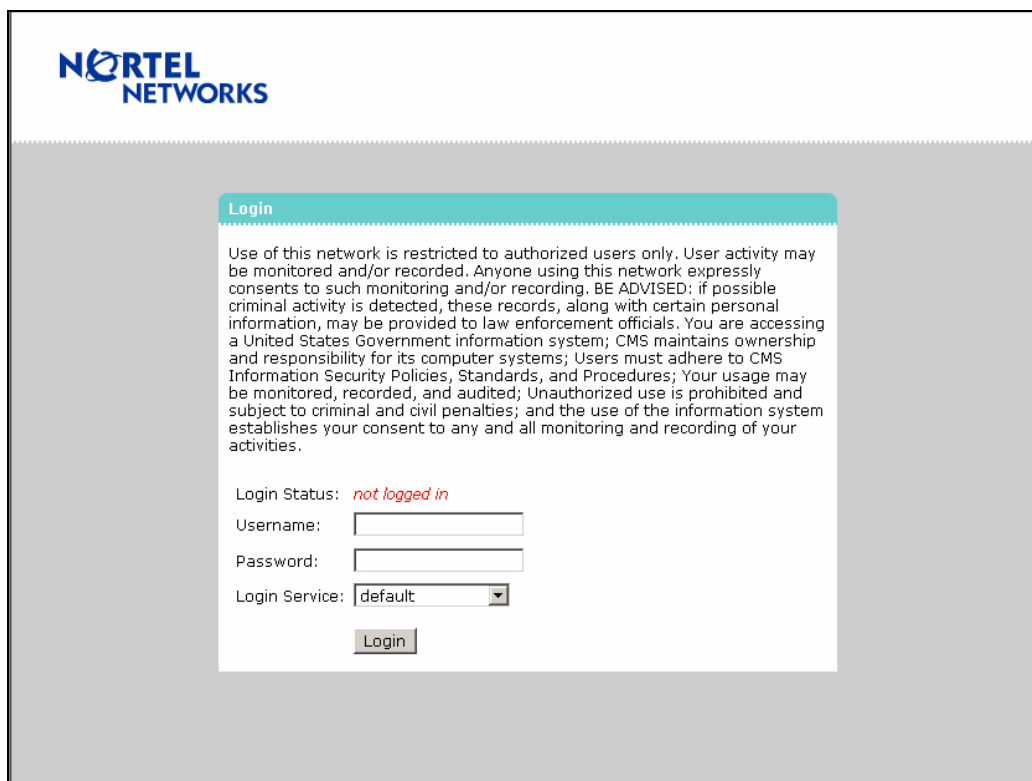
GETTING STARTED

The HPMS Part D Plan Reporting module is hosted on an Extranet site that can be accessed via the Internet using a Secure Sockets Layer (SSL) Virtual Private Network (VPN). All HPMS users with a valid CMS-issued HITS User ID and password can log into the HPMS. The URL for the CMS SSL VPN portal is <https://gateway.cms.hhs.gov>. The HPMS Part D Plan Reporting module continues to be accessible by dial-up or T1/leased line via the Medicare Data Communications Network (MDCN). The URL for MDCN access is <https://32.90.191.19>. Please contact your system administrator to access the MDCN network if the connection is not available.

Accessing HPMS Using the Internet:

Step 1: Launch a web browser (e.g., Internet Explorer) and enter the **CMS SSL VPN** gateway address <https://gateway.cms.hhs.gov> in the Address field.

Step 2: Log on with a valid CMS-issued HITS User ID and Password. (Screen below)



NORTEL NETWORKS

Login

Use of this network is restricted to authorized users only. User activity may be monitored and/or recorded. Anyone using this network expressly consents to such monitoring and/or recording. BE ADVISED: if possible criminal activity is detected, these records, along with certain personal information, may be provided to law enforcement officials. You are accessing a United States Government information system; CMS maintains ownership and responsibility for its computer systems; Users must adhere to CMS Information Security Policies, Standards, and Procedures; Your usage may be monitored, recorded, and audited; Unauthorized use is prohibited and subject to criminal and civil penalties; and the use of the information system establishes your consent to any and all monitoring and recording of your activities.

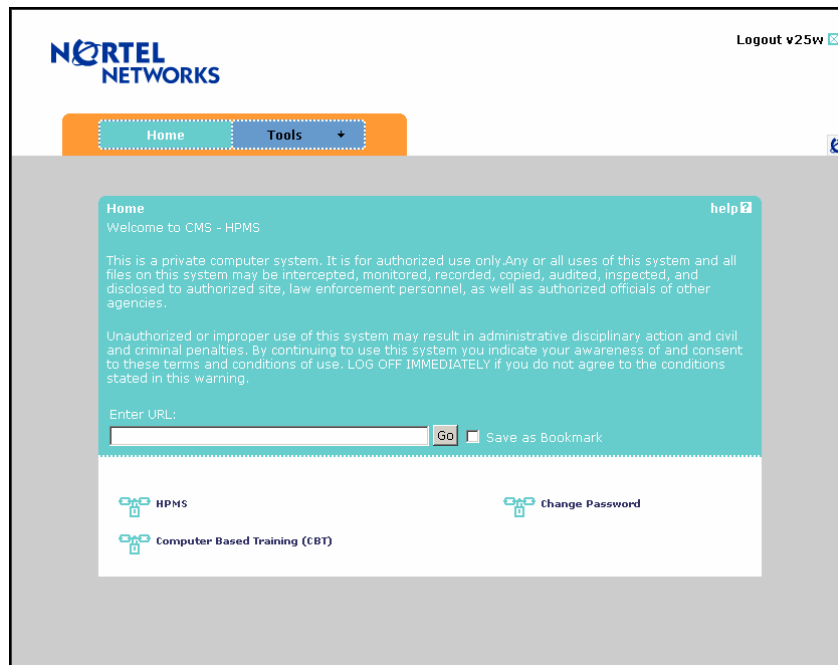
Login Status: *not logged in*

Username:

Password:

Login Service:

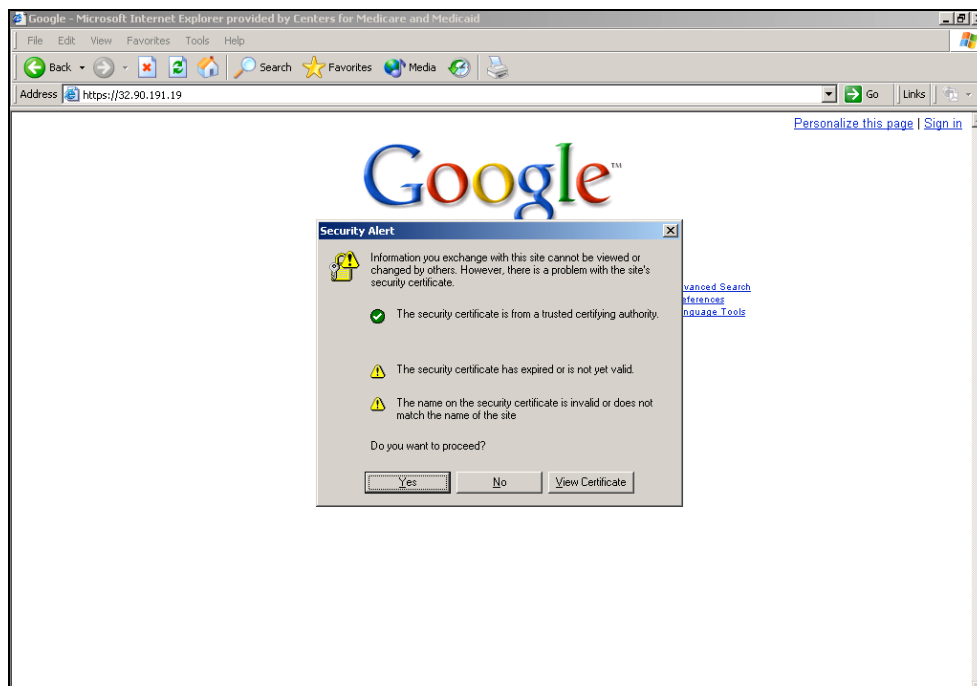
Step 3: Select “Login” to access the SSL VPN portal page. (Screen below) *Proceed to Step 5.*



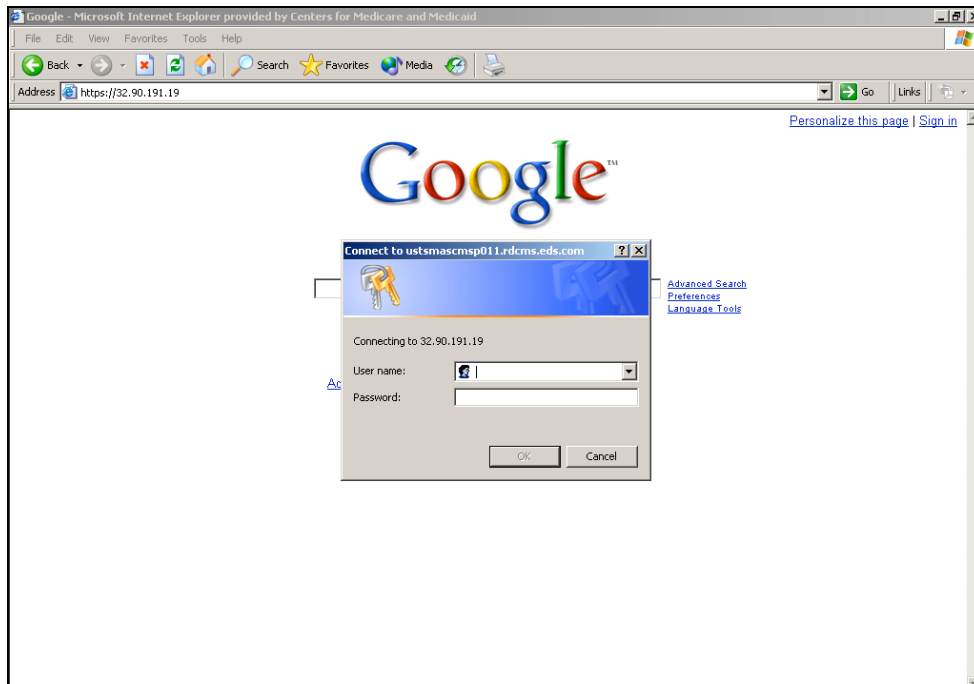
Accessing HPMS Using an MDCN lease line:

Step 4a: Launch a web browser (e.g., Internet Explorer) and enter the **CMS MDCN** access address <https://32.90.191.19> in the Address field.

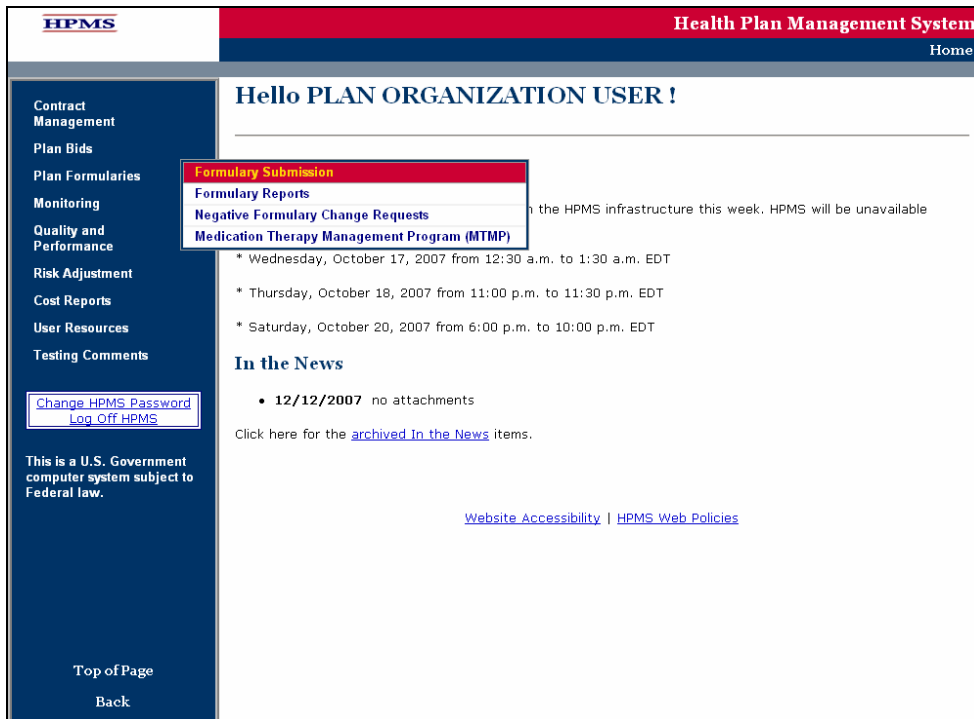
Step 4b: Select the “Yes” button on the Security Alert pop-up page. (Screen below)



Step 4c: Enter User Name using the following format –**hcfa.gov/xxxx**– where xxxx is your CMS-issued HITS User ID. Enter Password and select the “OK” button (screen below) to access the **HPMS Home Page**.



Step 5: Select the **HPMS** link from the SSL VPN portal page to access the **HPMS Home Page**. (Screen below)



GENERAL INFORMATION

The formulary submission process contains a series of web pages that will collect information from the submitter. **Prior to beginning the submission process, you must ensure that the Formulary Contact information in the Contract Management module is completed.** You will not be able to submit a formulary for a contract that does not have this information. The Formulary Contact as well as the Formulary Upload Contact (the submitter) will receive all email notifications regarding the status of the formulary.

Once the formulary contact information is complete, you will step thru the Formulary Submission module to provide information on:

- **Associated Contracts** – Identify contract number(s) (H#, R#, S#, E#) that will be using the uploaded formulary.
- **Formulary Name** – Assign a name to your formulary. This name will be used only within the HPMS to identify the specific formulary submission (100 characters maximum).
- **Formulary Classification System** – Identify the formulary classification as United States Pharmacopeia Model Guidelines (USP), American Hospital Formulary Service (AHFS), or another classification source (Other).
- **Number of Cost Share Tiers** – Identify the maximum number of tiers in the formulary. This value must equal the highest tier value indicated in the submitted formulary file. Acceptable values are 1-10. This value must also match the tier information provided in the corresponding Plan Benefit Package (PBP).
- **Quantity Limits Requirements** – Indicate if there are drugs in the formulary that have quantity limit restrictions. Additionally, the formulary file must identify the drugs that have the quantity limit restrictions.
- **Limited Access** – Indicate if there are drugs on the formulary in which access is limited to certain pharmacies. Drugs with this restriction must be identified in the formulary file.
- **Prior Authorization Requirements** – Indicate if there are drugs in the formulary that require prior authorization. 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** – Indicate if there are drugs in the formulary that require step therapy. 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.
- **Formulary Tier Information** – Specify information about each tier in the formulary.

The organization also should note that 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 Appendix A: CY 2009 Formulary File Record Layout. Appendix B: Upload File Formats provides additional narrative instruction for completing your formulary file and supplemental files. It is imperative that the formulary submission contains only those NDCs provided in the current CY 2009 Formulary Reference NDC File. All other NDCs will be rejected by the HPMS Formulary Validation Process and the formulary submission will fail.

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.

SUBMIT NEW FORMULARY

The Submit New Formulary function should be used to submit a formulary for the first time. This process will create a formulary ID for the CY 2009 formulary season in the following format: 00009xxx (e.g. 00009123). Please make note of the formulary ID as you will need this ID to submit subsequent updates to the formulary.

The process to submit a new formulary is as follows:

ASSOCIATE CONTRACTS TO FORMULARY

The Associate Contracts to Formulary page allows the user to associate one or more contracts to a formulary submission.

Step 1: Select **CY 2009** from the Formulary Submission page.

The screenshot shows the HPMS (Health Plan Management System) interface. The top navigation bar includes the HPMS logo and the text "Health Plan Management System" with a "Home" link. The main content area is titled "Formulary Submission" and contains two bullet points: "To Perform a Contract Year 2009 Formulary Submission, select the 'CY 2009' link." and "To Perform a Contract Year 2008 Formulary Submission, select the 'CY 2008' link." A left sidebar contains links for "CY 2009", "CY 2008", "Top of Page", and "Back".

Step 2: Select **Submit New Formulary** from the 2009 Formulary Submission Start Page.

HPMS	Health Plan Management System
	Home
<p>Submission</p> <p>Submit New Formulary</p> <p>Revise Formulary</p> <p>Delete Formulary</p> <p>Documentation</p> <p>Formulary Instructions</p> <p>Formulary Reference File</p> <p>Attachment 1 Example File</p> <p>Attachment 2 Example File</p> <p>OMB Clearance</p> <p style="text-align: center;">Top of Page</p> <p style="text-align: center;">Back</p>	<h2 style="text-align: center;">2009 Formulary Submission Start Page</h2> <p>You will use this module to perform the following:</p> <p>Submit New Formulary - Submit a new Formulary to CMS. This function will create a new Formulary ID.</p> <p>Revise Formulary Submit a revision for an existing formulary for one of the following two reasons:</p> <ul style="list-style-type: none"> • The formulary requires resubmission because it was rejected by the validation process or desk review has requested resubmission, or • The formulary was previously approved by desk review and now needs to be updated. <p>Delete Formulary - Delete a formulary that is no longer applicable.</p> <p>Formulary Instructions - View the instructions for the Formulary Submission Module and Formulary Reports Technical Manual.</p> <p>Formulary Reference File - Download a copy of the latest 2009 Formulary Reference File and NDC Crosswalk File.</p> <p>Attachment 1 Example File - View the Formulary Attachment File #1 referred to in the Formulary Instructions.</p> <p>Attachment 2 Example File - View the Formulary Attachment File #2 referred to in the Formulary Instructions.</p> <p>OMB Clearance - View OMB Clearance.</p> <hr/> <p>Go To: Select Contract Year</p>

Step 3: Select one or more contracts on the Associate Contracts to Formulary page to associate with the new Formulary ID.

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 Contract 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.

Contracts Associated with this Formulary			
Included	Contract Number	Contract Name	Formulary Contact
<input type="checkbox"/>	X0001	CHRONIC CARE2	-- UNASSIGNED --
<input type="checkbox"/>	X0002	CHRONIC CARE	-- UNASSIGNED --
<input type="checkbox"/>	X0003	AMY'S 2007 CHRONIC CARE	-- UNASSIGNED --
<input type="checkbox"/>	X0004	GREGS ES-PFFS	-- UNASSIGNED --
<input type="checkbox"/>	X0005	JB ESPDP	-- UNASSIGNED --
<input type="checkbox"/>	X0006	STEVE PDP 2006	-- UNASSIGNED --
<input type="checkbox"/>	X0007	STEVE 2008 NOI PDP TEST	-- UNASSIGNED --
<input type="checkbox"/>	X0008	JOE'S PDP	-- UNASSIGNED --
<input type="checkbox"/>	X0009	AMY'S 2008 PDP 800-SERIES ONLY2	-- UNASSIGNED --
<input type="checkbox"/>	X0010	GENERAL PROGRAMS, INC	-- 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: 0001
Name: John Test
E-mail: test@test.com

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

Step 4: Select the “Next” button to confirm the Contract Associations and move to the Formulary Information page.

FORMULARY INFORMATION

The Formulary Information page collects information about the formulary submissions including: Formulary Name; Formulary Classification System; Number of Tiers; Quantity Limit status; Limited Access status; Prior Authorization status; and Step Therapy status.

Step 1: Enter responses to all of the questions. All fields are required.

HPMS	Health Plan Management System
	Home

Formulary Submission

Formulary Information

*Required fields are marked with an asterisk.

*Formulary Name: (max. 100 Characters)
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.

*Indicate the Formulary Classification System for this formulary: USP AHFS Other

*Define number of Tiers: (max. 10 tiers)
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.

*Do any drugs in this formulary submission have Quantity Limits? Yes No

*Is access to any formulary drug restricted to certain pharmacies? Yes No

*Do any drugs in this formulary submission require Prior Authorization? Yes No

*Do any drugs in this formulary submission require Step Therapy? Yes No

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

Step 2: Select the “Next” button to confirm your entries and move to the Formulary Tier Information page.

FORMULARY TIER INFORMATION

The Formulary Tier Information page collects information about the tiers within the formulary. The page will automatically generate the number of tiers based on the information entered on the prior page. The tier information entered in the formulary submission module must correspond to the number of tiers that will be identified in the corresponding CY 2009 PBP software.

When developing the 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: Drugs within the Specialty Tier are exempt from tiering exceptions. Only one formulary tier can be designated as a Specialty Tier. In addition, only drugs that meet the cost criteria as outlined in the CY 2009 Call Letter may be included on a specialty tier.

NOTE: If “Other” is selected as the Anticipated Tier Name, the user must enter data in the “Other Anticipated Tier Name” field.

Step 1: For each tier, indicate the Tier Name, Specialty Tier designation, and Drug Types.

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Formulary Submission

Formulary Tier Information

Formulary Name: New Name

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	Specialty Tier	Tier Drug Types
Tier 1	Generic	Specialty Tier? <input type="radio"/> Yes <input 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 type="checkbox"/> Non-Preferred Brand
Tier 2	Generic	Specialty Tier? <input type="radio"/> Yes <input 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 type="checkbox"/> Non-Preferred Brand

Back Next

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

Step 2: Select the “Next” button to confirm your information and move to the Upload Files page.

UPLOAD FILES

The Upload Files page allows the user to upload the Formulary File, Prior Authorization File, and Step Therapy File, if required. The page will determine what needs to be uploaded based upon your prior responses.

It is imperative that the files are in the following format:

Formulary File [See Appendix A, Appendix B (available in this manual), Attachment 1 Example File and Attachment 2 Example File (available on the Formulary Submission Start Page) for additional assistance] – ASCII Tab delimited text file, e.g. *formulary123.txt*

NOTE: Attachment 1 (and 2) Example Files provides sample records for a formulary.

Prior Authorization – (See Appendix B for additional assistance) – ASCII Tab delimited text file, e.g. *formularyPA.txt*

Step Therapy – Microsoft Word file, e.g. *steptherapy123ST.doc*

Step 1: Enter the name of the Formulary Text File (Tab delimited .txt only) in the “Formulary File” field. If you are unsure of the file name and/or location, click on the "Browse" button to locate and attach the file.

Formulary Resubmission

Upload Files

Formulary Name: New Name

- 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. The Prior Authorization File must be a tab-delimited text 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. The Step Therapy File must be a MS Word File.
- Step 4.** Click on the "Upload" button to send the file to HPMS.
- Step 5.** Wait until the file transfer is complete. Your browser will automatically be directed to the appropriate page once the file(s) are received.
- Step 6.** 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:

 Browse...

PRIOR AUTHORIZATION FILE

Select Prior Authorization File for upload:

 Browse...

STEP THERAPY FILE

Select Step Therapy File for upload:

 Browse...

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

Step 2: Enter the name of the Prior Authorization File (Tab Delimited Text File) in the “Prior Authorization File” field. If you are unsure of the file name and/or location, click on the "Browse" button to locate and attach the file. If “No” was selected for the prior authorization question from the Formulary Information page, this field will not be displayed.

Step 3: Enter the name of the Step Therapy File (MS-Word only) in the “Step Therapy File” field. If you are unsure of the file name and/or location, click on the "Browse" button to locate and attach the file. If “No” was selected for the step therapy question from the Formulary Information page, this field will not be displayed.

Step 4: Select the “**Upload**” button to submit the files and to continue to the Verify Submission page. Please wait until the file transfer is complete before attempting to navigate further.

VERIFY SUBMISSION

The submitter must verify the information entered during the submission process to complete the upload and submit the information to CMS. If anything is incorrect, you may use the “**Back**” button to return to prior pages and correct the information.

Formulary Submission

Verify Submission

Please note that your data has not yet been submitted.

Formulary Name: Test Name
 Formulary ID: 00000016
 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.

Once your files have been uploaded, HPMS will send to you a confirmation email and you will also be directed to a Submission Confirmation page confirming the receipt of your upload. Depending on the size of your files, this may take some time. If you never receive any confirmation of your upload, please contact the HPMS Help Desk at either 1-800-220-2028 or hpms@cms.hhs.gov.

Contract(s) Associated with Formulary: X0001, X0002, X0003, X0004

Contacts to be notified of this formulary submission			
	User ID	Name	E-mail
Upload User	Login1	John Test	test@test.com
X0001	n/a	John Test	test@test.com
X0002	n/a	John Test	test@test.com
X0003	n/a	John Test	test@test.com
X0004	n/a	John Test	test@test.com

Formulary Classification System used for this formulary: USP

Number of Tiers: 5

Tier Level	Anticipated Tier Name	Specialty Tier?	Tier Drug Types
1	Generic	YES	Brand
2	Generic	NO	Preferred Generic
3	Generic	NO	Non-Preferred Generic
4	Generic	NO	Preferred Brand
5	Generic	NO	Brand

Formulary includes drugs that have Quantity Limits? YES

Formulary includes drugs that have Pharmacy Restrictions? 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:\Documents and Settings\text.txt
Prior Authorization File	C:\Documents and Settings\text.txt
Step Therapy File	C:\Documents and Settings\text.doc

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

Step 1: Review the information for correctness.

Step 2:

Select the **“Submit”** button to send the submission to CMS for review. The Submission Confirmation page will display.

OR

Select the “**Back**” button to correct the information by returning to the appropriate pages.

SUBMISSION CONFIRMATION

The Submission Confirmation page provides a status of the successful upload and the unique Formulary ID assigned to your submission. This Formulary ID must be used for all subsequent resubmissions. This page will also generate an email to both the Formulary and the Formulary Upload Contact identified on this page acknowledging receipt of the submission and the assigned Formulary ID.

After receiving the uploaded formulary file the HPMS will perform a series of validation edits. At the close of the validation process, a second e-mail will be sent to the designated formulary contacts. This e-mail will either indicate that the formulary was successfully validated or it will identify errors detected during the validation process. If errors were detected, the formulary submission will be rejected. The email will list a maximum of 200 error messages. You must correct the formulary and resubmit using the Revise Formulary function.

Step 1: Review the information and **MAKE NOTE OF YOUR ASSIGNED FORMULARY ID.**

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Formulary Submission

Submission Confirmation

Formulary Name: Test Name
Formulary ID: 00000016
Formulary Version: 1

Your formulary information was received. The formulary contacts listed below will receive an email that the formulary submission was received.

The HPMS will now perform a series of validation edits on the formulary submission. At the close of the validation process, a second email will be sent to the formulary contacts listed below. This email will either indicate a successful formulary upload or identify the errors detected during validation. If errors were detected, the formulary submission will be rejected. Once the errors are corrected, the formulary can be resubmitted.

	User ID	Name	E-mail
Upload User	Login1	John Test	test@test.com
X0001	n/a	John Test	test@test.com
X0002	n/a	John Test	test@test.com
X0003	n/a	John Test	test@test.com
X0004	n/a	John Test	test@test.com

OK

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

Step 2: Select the “**OK**” button to return to the Formulary Submission Start Page.

REVISE A FORMULARY

Use the Revise Formulary functionality to update existing formularies. You are only permitted to update a formulary that has a status of “Resubmission Requested” or “Rejected by Validation.” Formularies that are “Approved” can be updated during the assigned update windows. The user may indicate whether changes to the Step Therapy and Prior Authorization Supplemental Files are required during this process.

The Formulary Resubmission–Select a Formulary page groups formularies into three categories:

- Resubmission – formularies that are eligible for resubmission either due to a validation failure or because a reviewer requested a resubmission.
- Updates – approved formularies that are eligible for resubmission during a scheduled update window.
- In Process – formularies that are in desk review and are NOT eligible for resubmission.

Step 1: Select the **Revise Formulary** link from the 2009 Formulary Submission Start Page.

Step 2: Select the formulary you wish to update.

Formulary Resubmission

Select a Formulary

These formularies are available for selection. TO VIEW THE STATUS OF ALL VERSIONS OF A FORMULARY, PLEASE UTILIZE THE FORMULARY STATUS HISTORY REPORT.

Resubmissions

These formularies are available for resubmission. If the Submission Status is "Successfully Validated," then a resubmission should only be performed if the plan believes changes are necessary. Otherwise, all other formularies below 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	Contract(s) User is Unable to Access
<input type="radio"/>	00000001	Formulary 1	1	Rejected by Validation	X0001	
<input type="radio"/>	00000002	Formulary 2	1	Rejected by Validation	X0001	
<input type="radio"/>	00000003	Formulary 3	5	Successfully Validated	X0001	
<input type="radio"/>	00000004	Formulary 4	6	Rejected by Validation	X0001	
<input type="radio"/>	00000005	Formulary 5	1	Rejected by Validation	X0001	
<input type="radio"/>	00000006	Formulary 6	10	Rejected by Validation	X0001	
<input type="radio"/>	00000007	Formulary 7	11	Successfully Validated	X0001	
<input type="radio"/>	00000008	Formulary 8	2	Rejected by Validation	X0001	
<input type="radio"/>	00000009	Formulary 9	2	Rejected by Validation	X0001	
<input type="radio"/>	00000010	Formulary 10	1	Rejected by Validation	X0001	
<input type="radio"/>	00000011	Formulary 11	1	Rejected by Validation	X0001	

In Process

These formularies are currently unavailable for revision.

Formulary ID	Formulary Name	Version	Submission Status	Contract(s) Associated with Formulary	Contract(s) User is Unable to Access
00000001	Formulary #1A	1	In Desk Review	X0004	

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

Step 3: Select the **“Update”** button to access the Formulary Resubmission’s Associate Contracts to Formulary page.

Step 4: Respond to the questions as instructed in the **Submit New Formulary** section of the manual.

NOTE: The user may not change the following fields when resubmitting if the formulary has been in Approved status: Formulary Classification System, Number of Tiers, Quantity Limits, Prior Authorization, and Step Therapy. In addition, the system will not allow the user to change the information on the Drug Tier Information page once the formulary has been in Approved status.

NOTE: The user may indicate if changes are required for the Prior Authorization and Step Therapy files from the Formulary Resubmission – Upload Files page.

Step 5: Upload files as instructed in the **Submit New Formulary** section of the manual.

HPMS Health Plan Management System Home

Formulary Resubmission

Upload Files

Formulary Name: T
Formulary ID: 00000016
Formulary Version: 1

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. The Prior Authorization File must be a tab-delimited text 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. The Step Therapy File must be a MS Word File.

Step 4. Click on the "Upload" button to send the file to HPMS.

Step 5. Wait until the file transfer is complete. Your browser will automatically be directed to the appropriate page once the file(s) are received.

Step 6. 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: Browse...

PRIOR AUTHORIZATION FILE
 Use previously uploaded copy of the Prior Authorization File [View Previous File](#)
 Select Prior Authorization File for upload:

STEP THERAPY FILE
 Use previously uploaded copy of the Step Therapy File [View Previous File](#)
 Select Step Therapy File for upload:

Back Upload

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

Step 6: Continue the upload process on the Verify Submission and Confirmation pages as instructed in the **Submit New Formulary** section of the manual.

DELETE FORMULARY

The **Delete Formulary** functionality allows the user to delete existing formularies that have never been approved. You should only delete a formulary if you are certain that it is obsolete. Eligible formularies are listed under the heading “Resubmissions – Available for deletion.” The page also provides a list of formularies that are “Approved” or “In Process” for user reference. You cannot delete these formularies.

Step 1: Select the **Delete Formulary** link from the 2009 Formulary Submission Start Page.

Step 2: Select the formulary you wish to delete and click the “**Delete**” button.

HPMS
Health Plan Management System
Home

Delete Formulary Submission

Select a Formulary

These formularies are available for selection. TO VIEW THE STATUS OF ALL VERSIONS OF A FORMULARY, PLEASE UTILIZE THE FORMULARY STATUS HISTORY REPORT.

Resubmissions - Available for deletion

Select One	Formulary ID	Formulary Name	Version	Submission Status	Contract(s) Associated with Formulary	Contract(s) User is Unable to Access
<input type="radio"/>	00000001	Formulary 1	1	Rejected by Validation	X0001	
<input type="radio"/>	00000002	Formulary 2	1	Rejected by Validation	X0001	
<input type="radio"/>	00000003	Formulary 3	5	Successfully Validated	X0001	
<input type="radio"/>	00000004	Formulary 4	6	Rejected by Validation	X0001	
<input type="radio"/>	00000005	Formulary 5	1	Rejected by Validation	X0001	
<input type="radio"/>	00000006	Formulary 6	11	Successfully Validated	X0001	
<input type="radio"/>	UUUUUUU7	Formulary 7	2	Rejected by Validation	XUUU1	
<input type="radio"/>	00000008	Formulary 8	2	Rejected by Validation	X0001	
<input type="radio"/>	00000009	Formulary 9	1	Rejected by Validation	X0001	
<input type="radio"/>	00000010	Formulary 10	1	Rejected by Validation	X0001	
<input type="radio"/>	00000011	Formulary 11	1	Successfully Validated	X0001	

In Process

These formularies are currently unavailable for revision.

Formulary ID	Formulary Name	Version	Submission Status	Contract(s) Associated with Formulary	Contract(s) User is Unable to Access
00000007	Formulary #2A	16	Uploaded, but not Processed	X0001	
00000022	Formulary #3A	1	Uploaded, but not Processed	X0001	
00000024	Formulary #4A	1	Uploaded, but not Processed	X0001	
00000091	Formulary #5A	1	In Desk Review	X0001	

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

Step 3: Review the page carefully and select the “Delete” button to finalize the deletion.

HPMS
Health Plan Management System
Home

Delete Formulary Submission

Confirm Deletion

Please note that your data has not yet been deleted.

Formulary Name: test dmh 2008 tenth
Formulary ID: 00000007

Please carefully review the Formulary information before deleting this Formulary. Select the "Delete" button to delete your Formulary Information.

Contracts Covered by Formulary: X0001, X0002

Contact(s) to be notified of this formulary deletion			
	User ID	Name	E-mail
Upload User	Login1	John Test	test@test.com
X0001	n/a	John Test	test@test.com
X0002	n/a	John Test	test@test.com

Therapeutic Category/Class Database Source Type: USP
Number of Cost Share Tiers: 10
Formulary includes drugs that need Prior Authorization? YES
Formulary includes drugs associated with a Step Therapy Management plan? YES

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

Step 4: Select the “OK” button to return to the Formulary Submission Start Page.

HPMS
Health Plan Management System
Home

Delete Formulary Submission

Deletion Confirmation

Formulary Name: test dmh 2008 tenth
Formulary ID: 00000007

Your formulary information was successfully deleted. The formulary contacts listed below will receive an email confirming the successful deletion of this formulary.

Contact(s) to be notified of this formulary deletion			
	User ID	Name	E-mail
Upload User	Login1	John Test	test@test.com
X0001	n/a	John Test	test@test.com
X0002	n/a	John Test	test@test.com

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

SUPPLEMENTAL SUBMISSIONS AND REPORTS

This section will be provided in a May 21, 2008 update of this manual. The functionality for submission of these files is scheduled to be released on June 3, 2008. Upload of these files is due on June 9, 2008.

The final file format layouts for the below files are available within Appendix B.

Please note that Supplemental Submissions and Reports will support the submission of the following supplemental files:

- Gap Coverage;
- Free First Fill;
- Home Infusion Drug;
- Over the Counter Drug; and
- Excluded Drug.

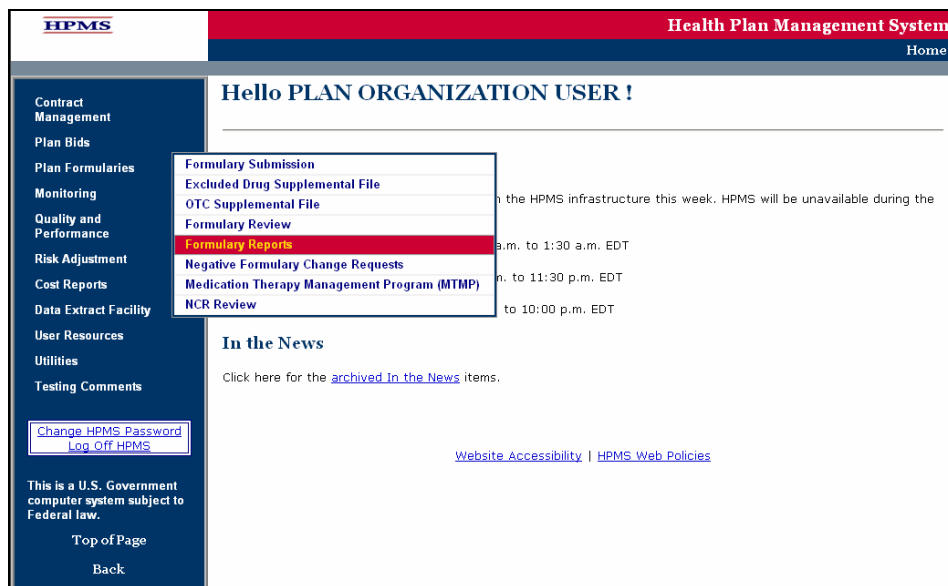
FORMULARY FILE REPORTS

The Formulary Reports functionality provides users access to a variety of formulary-related information to assist users in the formulary submission process. This section provides detailed information on the following reports:

- Formulary/Bid Contact Report
- Formulary Change Notification Report

The Formulary Reports are available from the Plan Formularies link on the HPMS Home Page.

Step 1: Hover over the **Plan Formularies** link in the left-hand navigation bar to view the flyout menu. Select the **Formulary Reports** link to access the Formulary Reports by Contract Year.



Step 2: Select the **CY 2009** link from the Formulary Reports page.



FORMULARY/BID CONTACT REPORT

The **Formulary/Bid Contact Report** provides contact information at the “Contract Level” and “Plan Level” for one or more contract(s). The report includes Name, Address, Phone Number, Fax Number, and Email Address for the following contract contacts:

- CEO;
- CFO;
- Medicare Compliance Officer;
- Marketing Contact;
- Bid Primary Contact; and
- Formulary Contact.

The Plan Level information displays the Plan ID, Name, Address, Phone Number, Fax Number, and Email Address for the following contacts:

- Bid Actuary Contact;
- Bid PBP Contact;
- Certifying Actuary – MA Bid; and
- Certifying Actuary – Part D Bid.

Step 1: Select “**Formulary/Bid Contact Report**” from the Contract Year 2009 – Select a Report page.

The screenshot shows the HPMS (Health Plan Management System) interface. At the top, there is a red header with the HPMS logo on the left and the text 'Health Plan Management System' on the right. Below the header is a dark blue navigation bar with a 'Home' link. The main content area is white and features the heading 'Contract Year 2009'. Below this heading is a note: 'NOTE: The instructions for the reports are available within the Formulary Submission Module and Reports Technical Manual (from the Formulary Submission Start Page)'. A section titled 'Select a Report' contains a list of report options. The 'Formulary/Bid Contact Report' is highlighted in blue. Below the list are 'Back' and 'Next' buttons. At the bottom of the page, there is a 'Go To:' link pointing to 'Select Contract Year'.

Step 2: Select the desired Contract Number(s) from the Formulary/Bid Contact Report selection criterion page and click on the “Next” button.

Step 3: View the details of the Formulary/Bid Contact Report.

IMPORTANT NOTE: If the information from the Formulary/Bid Contact Report is incorrect, please update the “Contact Information” in the HPMS **Contract Management Module**.

This report was generated using the following search criteria.

Contract(s): X0003

Contract Number: X0003
Organization Name: ESPFFS ORG SS
Organization Type: Employer/Union
Formulary(s):
 00000016 - Test Name

Contract Level					
CEO	CFO	Medicare Compliance Officer	Marketing Contact	Bid Primary Contact	Formulary
Ms. Jane Test 123 Elm Street Suite 1000 Arlington VA 22201 Phone: 555-555-5555 Fax: 555-555-5556 Email: test@test.com	Ms. Jane Test 123 Elm Street Suite 1000 Arlington VA 22201 Phone: 555-555-5555 Fax: 555-555-5556 Email: test@test.com	Ms. Jane Test 123 Elm Street Suite 1000 Arlington VA 22201 Phone: 555-555-5555 Fax: 555-555-5556 Email: test@test.com	Ms. Jane Test 123 Elm Street Suite 1000 Arlington VA 22201 Phone: 555-555-5555 Fax: 555-555-5556 Email: test@test.com	Ms. Jane Test 123 Elm Street Suite 1000 Arlington VA 22201 Phone: 555-555-5555 Fax: 555-555-5556 Email: test@test.com	Ms. Jane Test 123 Elm Street Suite 1000 Arlington VA 22201 Phone: 555-555-5555 Fax: 555-555-5556 Email: test@test.com

Plan Level				
Plan ID	Bid Actuary Contact	Bid PBP Contact	Certifying Actuary - MA Bid	Certifying Actuary Bid
001	Not Found	Ms. Jane Test 123 Elm Street Suite 1000 Arlington VA 22201 Phone: 555-555-5555 Fax: 555-555-5556 Email: test@test.com	Not Found	Not Found

[Back](#)

Go To: [Select Report Page](#) [Select Contract Year](#)

FORMULARY CHANGE NOTIFICATION REPORT

The Formulary Change Notification Report provides a comparison of data between two submitted formularies. The user has a capability to compare the content of two submissions from one formulary or differences between two different formularies. The report displays summary comparison information and provides details on the Base Formulary, Comparison Formulary, and the Differences between the two.

The summary comparison information includes:

- Formulary Name;
- Review Status;
- Formulary Type;
- Contract(s);
- Database Source (Formulary Classification);
- Number of Cost Share Tiers;
- Anticipated Tier Names;
- Limited Access (Y/N);
- Prior Authorization (0-3);
- Prior Authorization File Name;
- Quantity Limit (Y/N);
- Step Therapy (0-2); and
- Step Therapy File Name.

In addition, the user may access the attachment files (Prior Authorization File, and Step Therapy File) by clicking on the available links. Please note that the files are available only if they were submitted by the organizations.

The “In Base Formulary,” “In Comparison Formulary,” and “Formulary Difference” sections of the report display the following drug-related information for a selected Base Formulary ID/Version and comparison Formulary ID/Version:

- Formulary ID;
- Version;
- NDC;
- Brand Name;
- Generic Name;
- Dosage Form;
- Strength;
- Route of Administration;
- Cost Share Tier Level Value;
- Unique Quantity Limit Amount;
- Unique Quantity Limit Days;
- Prior Authorization (0-3);
- Therapeutic Category;
- Therapeutic Class;
- Step Therapy (0-2); and
- Number of Step Therapy Groups.

Step 1: Select “**Formulary Change Notification Report**” from the Contract Year 2009 – Select a Report page.

The screenshot shows the HPMS Health Plan Management System interface. At the top, there is a red header with the HPMS logo and the text 'Health Plan Management System' and 'Home'. Below the header, the page title is 'Contract Year 2009'. A note states: 'NOTE: The instructions for the reports are available within the Formulary Submission Module and Reports Technical Manual (from the Formulary Submission Start Page)'. Under the heading 'Select a Report', a list of reports is displayed, with 'Formulary Change Notification Report' highlighted in blue. Other reports include Formulary Activity Report, Formulary/Bid Contact Report, Formulary Contract Year Comparison Report, Formulary Crosswalk Report, Formulary Potential Duplicates Report, Formulary Potential Negative Change Report, Formulary Status History Report, Formulary Summary Report, Formulary Therapeutic Class and Category Name Change Report, Formulary Unattached Report, and Formulary Upload Failure Report. At the bottom, there are 'Back' and 'Next' buttons and a 'Go To: [Select Contract Year](#)' link.

Step 2: Select the desired Base Formulary ID and Version (this will populate based on the selected Formulary ID) as well as **Comparison Formulary ID and Version** from the Formulary Change Notification Report selection criteria page.

The screenshot shows the HPMS Health Plan Management System interface for the 'Formulary Reports 2009' section. The page title is 'Formulary Reports 2009' and the sub-heading is 'Formulary Change Notification Report'. There are two dropdown menus for 'Base Formulary ID' (value: 00000002) and 'Comparison Formulary ID' (value: 00000008). Below each dropdown is a 'Version:' label and a text box. The left text box contains 'Version 5 - Successfully Validated' and 'Version 4 - Successfully Validated'. The right text box contains 'Version 11 - Successfully Validated'. At the bottom, there are 'Back' and 'Next' buttons and a 'Go To: [Select Contract Year](#)' link.

Step 3: Click on the “**Next**” button to review the report.

Formulary Reports 2009

Formulary Change Notification Report

This report was generated using the following search criteria.

Formulary IDs: 00000002 To 00000008
Compare: Version 5 To Version 11

[Back](#)

FORMULARY COMPARISON

	Formulary ID: 00000002 Version 5	Formulary ID: 00000008 Version 11
Formulary Name	KFormulary	2008 tenth with fixes PA desc
Review Status	Successfully Validated	Successfully Validated
Formulary Type	Original	Original
Contract(s)	EMP SPONSORED	INSURANCE SERVICES COMPANY
Database Source	AHFS	USP
Number of Cost Share Tiers	4	10
Anticipated Tier Names	Generic, Generic, Non-Preferred Generic, Other	Other
Limited Access (Y/N)	Yes	Yes
Prior Authorization (0-3)	Prior Authorization Applies	Prior Authorization Applies
Prior Authorization File	Prior Authorization File - Version 5	Prior Authorization File - Version 11
Quantity Limit (Y/N)	Yes	Yes
Step Therapy (0-2)	Not Part or a Step Therapy Program	Step Therapy Applies
Step Therapy File	N/A	Step Therapy File - Version 11

[Jump To: Formulary Differences](#)

In Base Formulary

Formulary ID: 00000002
Version : Version 5

Formulary ID	Version	NDC	Brand Name	Generic Name	Dosage Form	Strength	Route of Administration	Cost Share Tier Level Value	Unique Quantity Limit Amount	Unique Quantity Limit Days
00000002	5	00100001400	ZIAGEN	ABACAVIR SULFATE	TABS	10 MG	ORAL	3		
00000002	5	00100001400	ZIAGEN	ABACAVIR SULFATE	TABS	20 MG	ORAL	3		

[Jump To: Top](#)

In Comparison Formulary

Formulary ID: 00000008
Version : Version 11

Formulary ID	Version	NDC	Brand Name	Generic Name	Dosage Form	Strength	Route of Administration	Cost Share Tier Level Value	Unique Quantity Limit Amount	Unique Quantity Limit Days
00000008	11	00000000023	ACCUPRIL	QUINAPRIL HCL	TABS	10 MG	ORAL	3		
00000008	11	00000000023	ACCUPRIL	QUINAPRIL HCL	TABS	20 MG	ORAL	3		

[Jump To: Top](#)

[Jump To: In Base Formulary](#)

[Jump To: In Comparison Formulary](#)

FORMULARY DIFFERENCES

Formulary IDs: 00000002 To 00000008
Compare: Version 5 To Version 11

Formulary ID	Version	NDC	Brand Name	Generic Name	Dosage Form	Strength	Route of Administration	Cost Share Tier Level Value	Unique Quantity Limit Amount	Unique Quantity Limit Days	Prior Authorization (0-3)	Therapeutic Category	Therapeutic Class	Step Therapy (0-2)
70 Drugs Compared - All Drug information is the same between Formulary 00000002, Version 5 and Formulary 00000008, Version 11														

[Back](#)

[Go To: Select Report Page](#) [Select Contract Year](#)

NOTE: The user may click on the Prior Authorization File and/or the Step Therapy File to view the submission.

APPENDIX A: CY 2009 FORMULARY FILE RECORD LAYOUT

Required File Format = ASCII File - Tab Delimited
Do not include a header record
Filename extension should be “.TXT”

<u>Field Name</u>	<u>Field Type</u>	<u>Field Length</u>	<u>Field Description</u>	<u>Sample Field Value(s)</u>
Proxy_NDC	CHAR Always Required	11	11-Digit National Drug Code	00000333800
Tier_Level	CHAR Always Required	2	Defines the Cost Share Tier Level 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 level options available to data entry users in the Plan Benefit Package software.	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	CHAR Always Required	1	Defines the Drug Type Label for the drug. Enter the label value for the Drug Type from the defined list of labels.	1 = Generic 2 = Preferred Generic 3 = Non-Preferred Generic 4 = Brand 5 = Preferred Brand 6 = Non-Preferred Brand
Quantity_Limit_YN	CHAR Always Required	1	Does the drug have a quantity limit restriction?	0 = No Quantity Limits 1 = Quantity Limits Apply
Quantity_Limit_Amount	NUM Sometimes Required	7	If Yes to Quantity_Limit_Amount_Y N, enter the quantity limit unit amount for a given number of days. The units for this amount must be defined by a unit measure e.g. number of tablets, number of milliliters, number of grams, etc. Do not enter the number of syringes, bottles, or packages. If the Quantity_Limit_YN field is 0 = No, then leave	9

<u>Field Name</u>	<u>Field Type</u>	<u>Field Length</u>	<u>Field Description</u>	<u>Sample Field Value(s)</u>
			this field blank. The maximum logical number that will be accepted is "9999.99".	
Quantity_Limit_Days	NUM Sometimes Required	3	Enter the number of days associated with the quantity limit. If the Quantity_Limit_YN field is 0 = No, then leave this field blank The maximum logical number that will be accepted is "999"	60 (e.g. 9 tablets every 60 days)
Prior_Authorization_Type	CHAR Always Required	1	Is prior authorization required for the drug?	0 = No Prior Authorization 1 = Prior Authorization Applies 2 = Prior Authorization Applies to New Starts Only 3 = Part D vs. Part B Prior Authorization Only
Prior_Authorization_Group_Desc	CHAR Sometimes Required	100	Description of the drug's prior authorization group as it will appear on the submitted prior authorization attachment. The group name may represent a drug category or class or may simply be the name of the drug if no other grouping structure applies. If response to Prior_Authorization_Type = 0 (No) or 3 (Part D vs. Part B), then leave this field blank.	Antiemetics
Limited_Access_YN	CHAR Always Required	1	Is access to this drug limited to certain pharmacies?	1 = Yes 0 = No
Therapeutic_Category_Name	CHAR Always Required	100	Enter the name of the category for the drug.	Analgesics
Therapeutic_Class_Name	CHAR Always Required	100	Enter the name of the class for the drug.	Opioid Analgesics
Step_Therapy_Type	CHAR Always Required	1	Does step therapy apply to this drug?	0 = Not Part of a Step Therapy Program 1 = Step Therapy

<u>Field Name</u>	<u>Field Type</u>	<u>Field Length</u>	<u>Field Description</u>	<u>Sample Field Value(s)</u>
			Note: Prerequisite (Step 1) drugs should also have a value of 1 in this field.	Applies 2 = Step Therapy Applies to New Starts Only
Step_Therapy_Total_Groups	NUM Sometimes Required	2	Enter the total number of step therapy drug treatment groups in which the drug is included. If response to Step_Therapy_Type = 0 (No), then leave this field blank. The maximum logical number that will be accepted is "99."	3
<p>The remaining two fields described below should be repeated as a group or unit in the file. For example, for a given drug used in multiple Step Therapy programs, the values for Step_Therapy_Group_Desc = "CHF Therapy" and Step_Therapy_Step_Value = 4 should be included in adjacent columns in the file. Likewise, the values for Step_Therapy_Group_Desc = "Angina Therapy" and Step_Therapy_Step_Value = 1 should be included in additional adjacent columns in the file. Likewise, the values for Step_Therapy_Group_Desc = "CVD Therapy" and Step_Therapy_Step_Value = 5 should be included in additional adjacent columns in the file.</p>				
Step_Therapy_Group_Desc	CHAR Sometimes Required	100	Description of step therapy drug treatment group. Field should be repeated in the record based upon number of groups declared in Step_Therapy_Total_Groups. If response to Step_Therapy_Type = 0 (No), then leave this field blank. Note: For a given NDC, each Group Description must be unique.	Step_Therapy_Group_Desc = "CHF Therapy" Step_Therapy_Group_Desc = "Angina Therapy" Step_Therapy_Group_Desc = "CVD Therapy"
Step_Therapy_Step_Value	NUM Sometimes Required	2	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_Total_Groups AND in the same order as Step_Therapy_Group_Desc If response to	Step_Therapy_Step_Value = 4 (e.g. Step 4 of 6) Step_Therapy_Step_Value = 1 (e.g. Step 1 of 3) Step_Therapy_Step_Value = 5 (e.g. Step 5 of 5)

<u>Field Name</u>	<u>Field Type</u>	<u>Field Length</u>	<u>Field Description</u>	<u>Sample Field Value(s)</u>
			<p>Step_Therapy_Type = 0 (No), then leave this field blank.</p> <p>The range of valid accepted values is 1 to 99.</p>	

Please Note: Certain characters are restricted from HPMS. The submitted file will be rejected if any of the following characters are included in any field: 1) greater than sign (>), 2) less than sign (<), 3) semi-colon (;), and 4) ampersand (&).

APPENDIX B: UPLOAD FILE FORMATS

FORMULARY FILE INSTRUCTIONS

The formulary file must be created in an ASCII File Tab delimited format and contain one proxy NDC record for each drug offered with an organization's benefit plan(s). The Appendix A: Formulary File Record Layout is provided for your reference. Please note that only proxy NDCs provided in the CY 2009 Formulary Reference NDC File maybe uploaded. All other NDCs will be rejected by the HPMS Formulary Validation Process.

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.

NOTE: Attachment 1 (and 2) Example Files (located on the Formulary Submission Start Page) provides sample records for a formulary.

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.

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 CY 2009 Formulary Reference NDC File. Proxy NDCs should only be entered once in this formulary file.

Field 2 – Tier Level:

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:

REQUIRED: Enter a drug type label value associated with the drug. Include a value of 1 to 6 only. A number outside of this range will result in an update error.

Field 4 – Quantity Limit 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. Examples of quantity limits include the following:

- Simvastatin 80mg tablets - 30 tablets/30 days
- Risedronate 35mg tablets - 5 tablets/30 days
- Latanoprost 0.005% drops – 2.5 ml/30 days
- Albuterol HFA MDI – 17 grams/30days

Field 5 - Quantity_Limit_Amount:

CONDITIONAL: If the **Quantity_Limit_YN** field is 0, then leave this field blank by providing a tab delimiter. If the **Quantity_Limit_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 tablets or the number of grams 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_YN** field is 0, then leave this field blank by providing a tab delimiter. If the **Quantity_Limit_YN** field is 1, include the quantity limit day amount for this drug. For example, for a quantity limit that includes 9 tablets every 60 days, this field should indicate a value of 60.

Field 7 – Prior_Authorization_Type:

REQUIRED: This value should be set to value of 0 through 3, where 0 = No Prior Authorization, 1 = Prior Authorization Applies, 2 = Prior Authorization Applies to New Starts Only, and 3 = Part D vs. Part B Prior Authorization Only. 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 or greater for this field. If these values are inconsistent, an upload error will result.

Please note that the intent of the PA Type 2 is for identification of applicable six class drugs that require PA during the initial formulary review and approval process. These values should not change after initial formulary approval. The addition of this new type will not result in modification of the submission or review of negative formulary change requests during the plan year.

Field 8 – Prior_Authorization_Group_Desc:

CONDITIONAL: If Prior Authorization Type is 0 or 3, then leave this field blank. If Prior Authorization Type is 1 or 2, then include the description of the drug’s prior authorization group as it will appear on the Prior Authorization Attachment. The group name may represent a drug category or class or may be the name of the drug if no other grouping structure applies. Proxy NDCs should only be grouped together if the prior authorization criteria are the same for all NDCs within that group description.

Field 9 – Limited_Access_YN:

REQUIRED: The value should be set to 0 or 1, where 0 = No and 1 = Yes. Set the value to 1 if access to the drug is limited to certain pharmacies; otherwise set the value to 0 to indicate that the drug is not restricted to certain pharmacies.

NOTE: If the user selected “Yes” to the limited access 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 10 – Therapeutic_Category_Name:

REQUIRED: Enter the name of the category for this drug.

Field 11 – Therapeutic_Class_Name:

REQUIRED: Enter the name of the class for this drug.

NOTE: If the classification system you have chosen, such as the USP Model Guidelines, provides a category name but no class name, the category name should be repeated in this field.

Field 12 – Step_Therapy_Type:

REQUIRED: This value should be set to a value of 0, 1, or 2, where 0 = Not Part of a Step Therapy Program, 1 = Step Therapy Applies, and 2 = Step Therapy Applies to New Starts Only.

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 or greater for this field. If these values are inconsistent, an upload error will result.

Please note that the intent of the ST Type 2 is for identification of applicable six class drugs that require ST during the initial formulary review and approval process. These values should not change after initial formulary approval. The addition of this new type will not result in a modification of the submission or review of negative formulary change requests during the plan year.

Field 13 – Step_Therapy_Total_Groups:

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** = 1 or greater. If step therapy does not apply to a given drug, then leave this field blank by providing a tab delimiter.

Field 14 – Step_Therapy_Groups_Desc:

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_Total_Groups**. If Step Therapy does not apply to this drug, then leave this field blank by providing a tab delimiter.

Field 15 – Step_Therapy_Step_Value:

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. Prerequisite (Step 1) drugs should be indicated by a value of 1. This field should be repeated in the record (in an additional column) based upon number of groups declared in **Step_Therapy_Total_Groups** AND in the same order as **Step_Therapy_Group_Desc**. For example, if an NDC has 3 step therapy treatment groups declared in the Step_Therapy_Total_Groups field, then three sets of values should be defined for Step_Therapy_Group_Desc and Step_Therapy_Step_Value as follows:

Step Therapy Treatment Group 1 Values –
 Step_Therapy_Group_Desc = “CHF Therapy”
 And
 Step_Therapy_Step_Value = 4

Step Therapy Treatment Group 2 Values –
 Step_Therapy_Group_Desc = “Angina Therapy”
 And
 Step_Therapy_Step_Value = 2

Step Therapy Treatment Group 3 Values –
 Step_Therapy_Group_Desc = “CVD Therapy”
 And
 Step_Therapy_Step_Value = 5

PRIOR AUTHORIZATION FILE INSTRUCTIONS AND RECORD LAYOUT

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 a Tab Delimited Text File and field entries should be as succinct as possible. Provider questions, diagrams, and decision trees are not permitted. Further, if a drug has quantity limit restrictions, the applicable values must be entered on the formulary flat file, not the PA file. Consistent with the definition of a Part D drug, you must not list any uses for drugs within the document that are not FDA-approved or supported in the compendia. Please refer to the Field Descriptions below for details. References or citations are not required. When an optional field is left blank must be represented by a tab delimiter.

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
Prior_Authorization_Group_Desc	CHAR Always Required	100	Description of the prior authorization group as it appears on the submitted formulary file. This field must exactly

Field Name	Field Type	Field Length	Field Description
			<p>match the value entered in the Prior_Authorization_Group_Desc field on the Formulary File.</p> <p>The group name may represent a drug category or class or may be the name of the drug if no other grouping structure applies. Proxy NDCs should only be grouped together if the prior authorization criteria are the same for all NDCs within that group description.</p>
Covered_Uses	CHAR Always Required	3000	<p>Enter <u>both</u> the FDA-approved and off-label indications for which the drug(s) will be covered.</p> <p>At a minimum, you must enter the following in this field: “All FDA-approved indications not otherwise excluded from Part D.”</p> <p>You may enter the statement “All medically accepted indications not otherwise excluded from Part D” if the PA will be approved for all non-excluded off-label uses in addition to the labeled indications.</p> <p>If only certain off-label uses will be approved by prior authorization, you should list the specific uses following the “All FDA-approved indications not otherwise excluded from Part D” statement.</p>
Exclusion_Criteria	CHAR Optional	2000	Describe any criteria (e.g. comorbid diseases, laboratory data, etc.) that would result in the exclusion of coverage for an enrollee.
Required_Medical_Information	CHAR Optional	2000	Enter laboratory, diagnostic, or other medical information required for initiation or continuation of the drug(s).
Age_Restrictions	CHAR Optional	500	Enter age limitations or restrictions required for prior authorization approval.
Prescriber_Restrictions	CHAR Optional	500	Description of prescriber attribute necessary for PA to be considered, e.g. specialist in a field or registered under a certain program.
Coverage_Duration	CHAR Always Required	100	Enter the duration for which the prior authorization will be approved.

Field Name	Field Type	Field Length	Field Description
Other_Criteria	CHAR Optional	3000	Enter any other relevant criteria.

Please Note: Certain characters are restricted from HPMS. The submitted file will be rejected if any of the following characters are included in any field: 1) greater than sign (>), 2) less than sign (<), 3) semi-colon (;), and 4) ampersand (&).

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.

Note: This attachment should be written in Arial or Times New Roman font with font size of 10-12 point.

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. Angiotensin II receptor blockers). These names must match the corresponding Step Therapy Group Descriptions entered on the formulary file. The medications or medication classes should be listed alphabetically with the associated page number. For example:

<u>Summary Page</u>	
Angiotensin II receptor blockers	Page 1
Non-sedating antihistamines	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 Angiotensin II receptor blockers and page 2 would contain the criteria for Non-sedating antihistamines, and so on.

Please note that since the OTC drugs that may be the first step in a Step Therapy program cannot be represented on the formulary file, you must identify these drugs within the Step Therapy File. These drugs should be listed with “OTC” following the drug name (e.g. loratadine OTC).

Only on-formulary Part D drugs or OTCs paid for out of Part D administrative costs can be included in the Step Therapy document.

GAP COVERAGE, FREE FIRST FILL, AND HOME INFUSION RECORD LAYOUT

Required File Format = ASCII File
Do not include a header record
Filename extension should be “.TXT”

Field Name	Field Type	Maximum Field Length	Field Description	Sample Field Value(s)
Proxy_NDC	CHAR Always Required	11	11-Digit National Drug Code Note: The NDCs included in this file must be a subset of the NDCs submitted in the Formulary file.	00000333800

Please Note: Certain characters are restricted from HPMS. The submitted file will be rejected if any of the following characters are included in any field: 1) greater than sign (>), 2) less than sign (<), 3) semi-colon (;), and 4) ampersand (&).

EXCLUDED DRUG RECORD LAYOUT

Required File Format = ASCII File - Tab Delimited
Do not include a header record
Filename extension should be “.TXT”

Field Name	Field Type	Maximum Field Length	Field Description	Sample Field Value(s)
NDC	CHAR Always Required	11	11-Digit National Drug Code	00000333800
Drug_Name	CHAR Always Required	200	Enter the name of the drug.	Diazepam
Strength	CHAR Always Required	200	Enter the strength of the drug.	5 MG
Dosage_Form	CHAR Always Required	25	Enter the dosage form.	TABS

Field Name	Field Type	Maximum Field Length	Field Description	Sample Field Value(s)
Route_of_Administration	CHAR Always Required	25	Enter the route of administration.	ORAL
Tier	CHAR Always Required	2	Defines the Cost Share Tier Level 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 level options available to data entry users in the Plan Benefit Package software.	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 Level 10
Quantity_Limit_YN	CHAR Always Required	1	Does the drug have a quantity limit restriction?	0 = No Quantity Limits 1 = Quantity Limits Apply
Quantity_Limit_Amount	NUM Sometimes Required	7	If Yes to Quantity_Limit_Amount_YN, enter the quantity limit unit amount for a given number of days. The units for this amount must be defined by a unit measure e.g. number of tablets, number of milliliters, number of grams, etc. If the Quantity_Limit_YN field is 0 = No, then leave this field blank. The maximum logical number that will be accepted is "9999.99".	30
Quantity_Limit_Days	NUM Sometimes Required	3	Enter the number of days associated with the quantity limit.	30 (e.g. 30 tablets every 30 days)

Field Name	Field Type	Maximum Field Length	Field Description	Sample Field Value(s)
			<p>If the Quantity_Limit_YN field is 0 = No, then leave this field blank</p> <p>The maximum logical number that will be accepted is “999”</p>	
Capped_Benefit_YN	CHAR Always Required	1	Does the drug have a capped benefit limit?	0 = No 1 = Yes
Capped_Benefit_Quantity	NUM Sometimes Required	7	<p>If Capped_Benefit_YN field is 1 = Yes, enter the capped benefit limit unit amount for a given prescription or time period. The units for this amount may be defined by a unit measure e.g. number of tablets, number of milliliters, number of grams, etc.</p> <p>If the Capped_Benefit_YN field is 0 = No, then leave this field blank</p> <p>The maximum logical number that will be accepted is “9999.99”.</p>	365
Capped_Benefit_Days	NUM Sometimes Required	3	<p>Enter the number of days associated with the capped benefit limit.</p> <p>If the Capped_Benefit_YN field is 0 = No, then leave this field blank</p> <p>The maximum logical number that will be accepted is “999”</p>	365 (e.g. 365 tablets every 365 days)
Prior_Authorization_YN	CHAR Always Required	1	Is prior authorization required for the drug?	1 = Yes 0 = No
Prior_Authorization_Desc	CHAR Sometimes Required	1500	<p>Description of the drug’s prior authorization.</p> <p>If response to Prior_Authorization_YN = 0 (No), then leave this field blank.</p>	

Field Name	Field Type	Maximum Field Length	Field Description	Sample Field Value(s)
Step_Therapy_YN	CHAR Always Required	1	Does step therapy apply to this drug?	1 = Yes 0 = No
Step_Therapy_Desc	CHAR Sometimes Required	500	Description of step therapy. If response to Step_Therapy_YN = 0 (No), then leave this field blank.	

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OVER THE COUNTER RECORD LAYOUT

Required File Format = ASCII File - Tab Delimited

Do not include a header record

Filename extension should be “.TXT”

Field Name	Field Type	Maximum Field Length	Field Description	Sample Field Value(s)
NDC	CHAR Always Required	11	11-Digit National Drug Code	00000333800
Drug_Name	CHAR Always Required	200	Enter the name of the drug.	Claritan
Strength	CHAR Always Required	200	Enter the strength of the drug.	10 MG
Dosage_Form	CHAR Always Required	25	Enter the dosage form.	TABS
Route_of_Administration	CHAR Always Required	25	Enter the route of administration.	ORAL

Please Note: Certain characters are restricted from HPMS. The submitted file will be rejected if any of the following characters are included in any field: 1) greater than sign (>), 2) less than sign (<), 3) semi-colon (;), and 4) ampersand (&).

APPENDIX C: CONTACT INFORMATION

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