HEALTH PLAN MANAGEMENT SYSTEM

FORMULARY SUBMISSION MODULE & REPORTS

TECHNICAL MANUAL

MAY, 2022

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INTRODUCTION

Since the implementation of the Medicare Part D benefit, 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. The Formulary Submission Module in HPMS enables plans to submit one or more Formulary files for a contract that contains all or a subset of drugs from the Centers for Medicare & Medicaid Services (CMS) provided Formulary Reference File (FRF).

The purpose of the Formulary Submission Module & Reports Technical Manual is to provide step-by-step instructions on how to submit and revise plan formularies. It also provides instructions on:

- How to delete formularies no longer in use.
- How to submit and revise Formulary transition policies.
- How to submit Pharmacy and Therapeutic (P&T) Committee Attestations.
- How to submit Prior Authorization and Step Therapy (PA/ST) Attestations.
- How to submit PA/ST Criteria Change Request Files.
- How to submit supplemental files associated with a Formulary.
- How to submit Medicare-Medicaid Plans (MMP) Additional Demonstration Drug (ADD) Files.
- How to submit Value-Based Insurance Design (VBID) files associated with a Formulary.
- How to submit Part D Senior Savings Model Files.
- How to generate reports to monitor the status of Formulary, PA/ST, Indication-Based Coverage, Transition Policies, Attestations, Supplemental, Additional Demonstration Drug, Value-Based Insurance Design, and PA/ST Criteria Change Request submissions.

Key Formulary submission enhancements for Contract Year (CY) 2023 are:

- Introduced a new field named “Part B Prerequisite” on the Prior Authorization file layout.
- The Plan Sponsors will be able to withdraw PA/ST criteria change requests using the ‘Withdraw PA/ST Criteria Change Request’ hyperlink available on the ‘Submit or Withdraw PA/ST Criteria Change Request’ page.
- The Excluded Drug supplemental file submission must meet the following requirement: All the plans associated to a formulary that are offering excluded drugs coverage must be in the same tiers and offer the same drugs (refer to Appendix C for all file validations).
- The Part D Senior Savings Model supplemental file submission must meet the following requirement: The tier and cohort of an RxCUI in the supplemental file must be same as the tier associated to the cohort in the PBP.
- The new ‘Change Notification Report’ for Part D Senior Savings Model file can be accessed from Formulary Reports module.
- Part D Sponsors will be able to view the ‘Formulary Status’ associated to each supplemental file upload on all the supplemental change notification reports.
- The Two Drug Review report displays the ‘Contract IDs’ linked to a formulary.
- The export functionality on the VBID change notification report allows for exporting all sections of the report to Excel.

- Note on the Value-Based Insurance Design supplemental file submission: If beneficiary LIS cost sharing is waived for all Part D drugs across the tiers indicated on the VBID package tiers screen then submission of a VBID Supplemental File is not required.

The CY 2023 HPMS Formulary Submission module is available to organizations on May 13th, 2022. CY 2023 Formulary Submissions are due June 6th, 2022 at 11:59 PM Pacific Time (PT). It is highly recommended that organizations submit their Formulary files as early as possible during the upload timeframe. Uploading earlier in this time frame provides organizations with adequate time to address potential upload problems and submit corrected Formulary files before the deadline.

An organization may resubmit a Formulary as many times as necessary during the initial upload period. Only the last successful submission will be processed for CMS review. Organizations using a Formulary must provide a Formulary file, along with the applicable supporting documentation (e.g., Prior Authorization attachment, Step Therapy attachment or Indication-Based Coverage attachment).

The CY 2023 Formulary supplemental submission window opens on or about June 8, 2022 to support the submission of Partial Gap Coverage, Free First Fill, Home Infusion, Value-Based Insurance Design, Over the Counter, Excluded Drug, Additional Demonstration Drug and Part D Senior Savings Model supplemental files. Supplemental submissions are due by June 10th, 2022, 11:59 AM Eastern Time (ET).

Organizations must submit supplemental information for all the plans offering this coverage as specified in the PBP submission. Only one version of a supplemental file may be submitted for each file type per Formulary. Plans may only share a given Formulary and supplemental file type (e.g., partial gap coverage file) provided that the content of the supplemental file type is applicable to all plans that share the file. Users may submit their supplemental files as many times as necessary during the initial upload period. Only the last successful submission is processed for CMS review. The supplemental files cannot be loaded until the organizations have successfully submitted their related bids and they have migrated to "desk review" in the HPMS system (migration will occur on or about June 8th, 2022). Once your bid is in desk review, your required Supplemental file gates will automatically open for submission of your supplemental files.

Note: Formulary dates announced via subsequent HPMS emails supersede the dates mentioned in this document.

If you have any questions about accessing the HPMS Formulary Submission Module, contact the HPMS Help Desk at 1-800-220-2028 or hpms@cms.hhs.gov.

I. GETTING STARTED

ACCESSING HPMS

The HPMS Formulary Submission module is hosted on a secure site that you can access via the Internet.

CMS USER IDS

You must have a CMS-issued User ID and password approved for HPMS access in order to log into the system. You must also request that your contract numbers be associated with your user ID in order to submit your data.

To obtain a new CMS User ID you must fill out a CMS User ID request form. You can download and print the form from the following URL:
http://www.cms.hhs.gov/InformationSecurity/Downloads/EUAaccessform.pdf

Complete the form as follows:

- Section 1 – Check "New" as the type of request.
- Section 2 – Check "Medicare Advantage / Medicare Advantage with Prescription Drug / Prescription Drug Plan / Cost Contracts – Using HPMS Only" and complete the data entry fields, where applicable.
- Section 3 – Enter the contract numbers for which you need access for CY 2023.
- Section 4 – Check the first row beneath the "Default Non-CMS Employee" row (i.e., place a check in the Connect box of the third row). On the blank line beside your check mark, write "HPMS_P_CommlUser."
- Section 5 – State briefly why you require HPMS access.
- Section 6 – Leave blank.

Sign and date the Privacy Act Statement on page 3 of the form. Also, enter your name and Social Security Number at the top of page 3. This step is critical to ensuring the successful processing of your request.

If you are an existing HPMS plan user and need to associate a contract number to your current CMS User ID, please include the following information in an email to hpms_access@cms.hhs.gov:

- User Name,
- CMS User ID,
- Current Contract Numbers, and
- Contract Numbers to be added.

All questions related to HPMS user access should be directed to hpms_access@cms.hhs.gov.

How to Access HPMS Home Page Using the Internet

STEP 1
Open your web browser (e.g., Internet Explorer) and enter https://hpms.cms.gov in the Address bar. 4

STEP 2
Enter your CMS User ID and password and click the "Login" button (Exhibit 1).

Exhibit 1 – HPMS Login

NAVIGATION

Enter the Formulary Submission module by selecting from the horizontal, top navigation bar: Plan Formularies, then Formulary Submission or Formulary Reports.

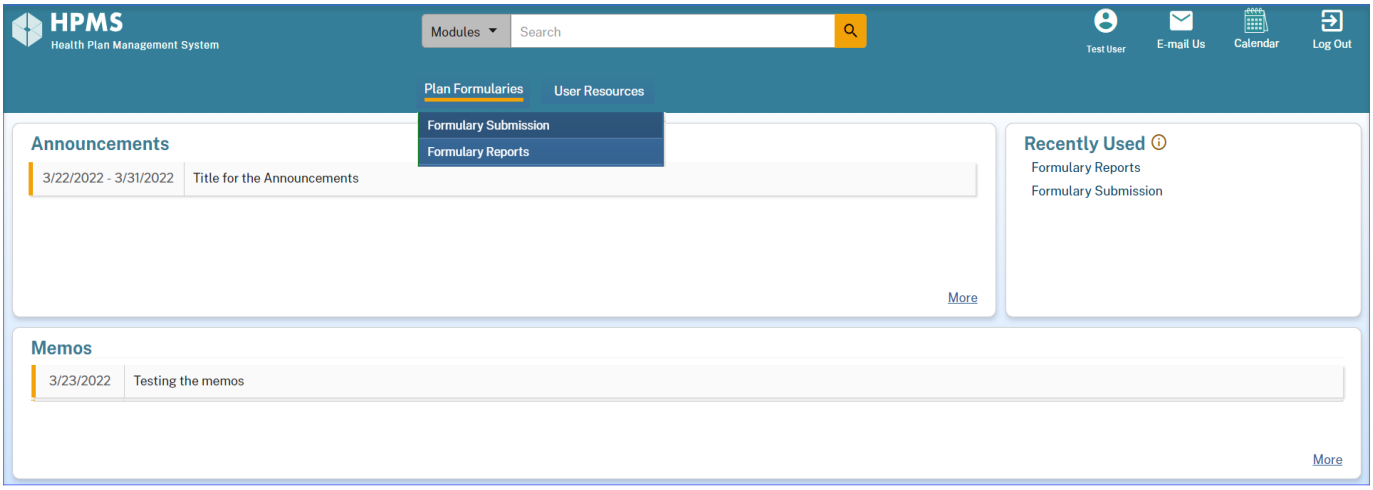
Once in the Formulary module, a collapsible navigation menu, on the left side of each page, provides links for each contract year that expand to provide the Formulary submission functions or reports for each year.

As navigation progresses through Formulary module, a breadcrumb trail displays starting from the left, beneath the top navigation menu. The trail tracks major milestones in navigation. Selecting a breadcrumb returns to that navigational milestone.

ACCESS HPMS FORMULARY SUBMISSION MODULE

STEP 1
To access the Formulary Submission Module, select **Plan Formularies** drop down from the HPMS top navigation bar. Then select the **Formulary Submission** menu item (Exhibit 2). This will take you to Formulary Submission Start Page.

Exhibit 2 – HPMS Home



STEP 2

On the Formulary Submission Start page, select the appropriate contract year from the collapsible navigation menu, on the left side of the page (Exhibit 3). This will take you to the **Formulary Submission Start** page (Exhibit 4).

Exhibit 3 – Formulary Submission Select Contract Year

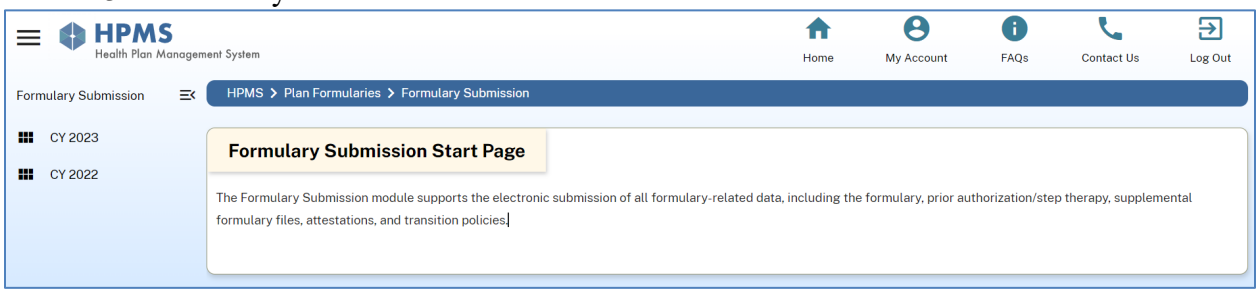
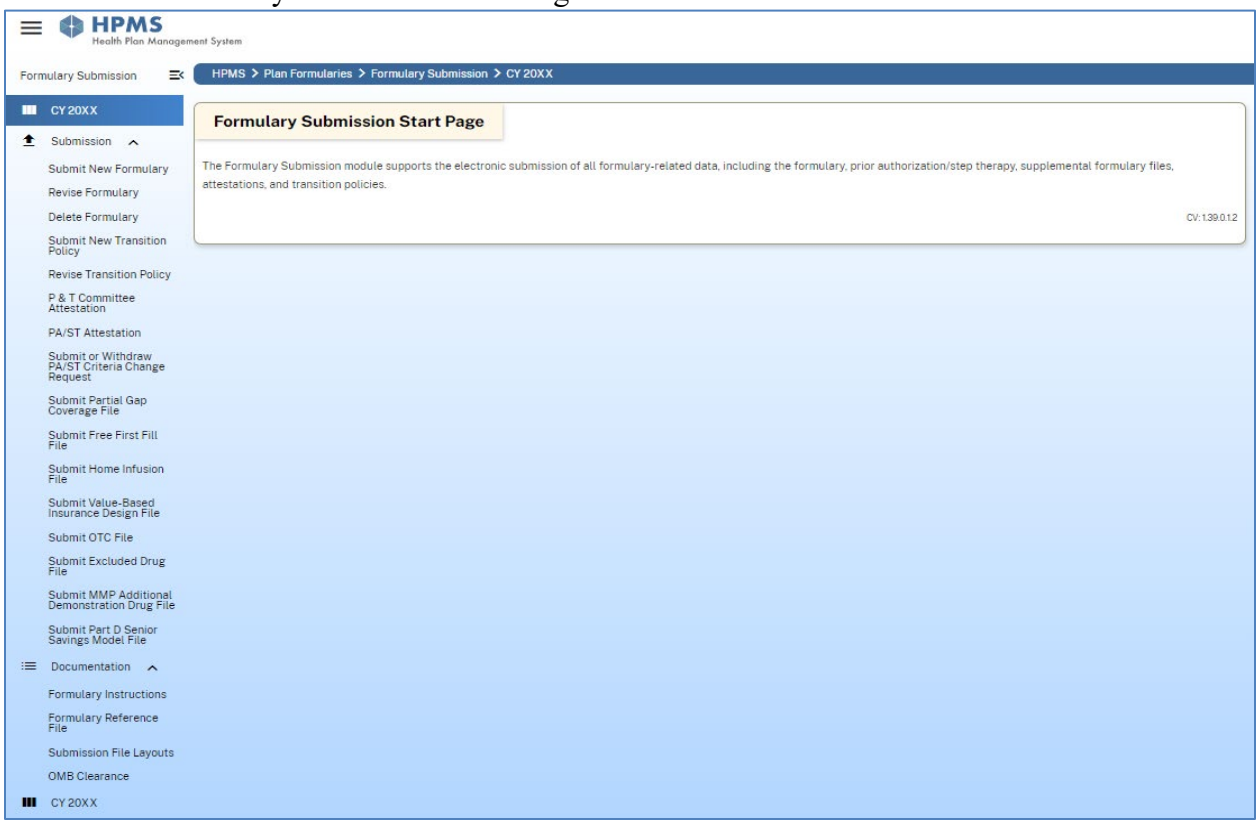


Exhibit 4 – Formulary Submission Start Page



BEFORE YOU BEGIN THE FORMULARY SUBMISSION PROCESS

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. Appendix C provides a subset of validation rules for the Formulary submission process.

The following functions are available from the left navigation menu of the CY 2023 Formulary Submission Start page (Exhibit 4)

Submit New Formulary: Submit a new Formulary to CMS. This function will create a new Formulary ID. When submitting Formulary file you may attach PA file, ST file and/or IBC file.

Revise Formulary: Submit a revision for an existing Formulary for one of the following reasons:

- The Formulary requires resubmission because it was rejected by the validation process or desk review has requested resubmission.
- The Formulary was previously approved by desk review and now needs to be updated.

- Revise PA/ST Criteria only (not the Formulary) when the Formulary was rejected by the validation process because of PA/ST validation errors or when CMS requested edits on existing criteria.
- Revise Indication-Based Coverage (IBC) only (not the Formulary) when the Formulary was rejected by the validation process because of IBC validation errors or when CMS requested re-submission on IBC file.

Delete Formulary: Delete a Formulary that is no longer applicable.

Transition Policy: Submit Formulary Transition Policy and Attestation.

Revise Transition Policy: Revise and resubmit Formulary Transition Policy.

P & T Committee Attestation: Submit Pharmacy and Therapeutic (P&T) Committee Attestations.

PA/ST Attestation: Submit Prior Authorization and Step Therapy (PA/ST) Attestations

Submit or Withdraw PA/ST Criteria Change Request File: Submit the PA/ST Criteria Change Request File to request gate opening for a PA/ST criteria. or Withdraw PA/ST Criteria Change Requests.
Submit Partial Gap Coverage File: Submit the Gap Coverage Supplemental File for Formularies that include Gap Coverage.

Submit Free First Fill File: Submit the Free First Fill Supplemental File for Formularies that include Free First Fill.

Submit Home Infusion File: Submit the Home Infusion Supplemental File for Formularies that include Home Infusion.

Submit OTC File: Submit the OTC Supplemental File for Formularies that include OTC drugs.

Submit Excluded Drug File: Submit the Excluded Drug Supplemental File for Formularies that include Excluded Drugs.

Submit MMP Additional Demonstration Drug File: Submit the Additional Demonstration Drug (ADD) File for Medicare-Medicaid formularies only.

Submit Value-Based Insurance Design File: Submit the **Value-Based Insurance Design** Supplemental File for Formularies that offer Value-Based Insurance Design benefit for at least one plan.

Submit Part D Senior Savings Model File: Submit the Part D Senior Savings Model file for the plans that offer Part D Senior Savings Model.

Documentation: Provides links to the following documents:

- **Formulary Instructions** – View the instructions for the Formulary Submission Module and Formulary Reports Manual.
- **Formulary Reference File** – Download a copy of the Formulary Reference File, Formulary Reference File Change Report, Related NDC Change Report, Contract Year RxCUI Crosswalk File, Over The Counter (OTC) Reference File, Additional Demonstration Drug (ADD) Reference File, Excluded Drug Reference File, and Indication Reference File.
- **Submission File Layouts** – View Formulary file, PA file, ST file, IBC file, PA/ST Criteria Change Request file, UMGD Criteria Response file (OJS module), Partial GAP Coverage file, Free First Fill file, Home Infusion file, Value-Based Insurance Design file, Excluded Drug file, Over The Counter (OTC) file, Additional Demonstration Drug (ADD) Reference file, and Part D Senior Savings Model file, record layouts.
- **OMB Clearance** – View Office of Management and Budget (OMB) Clearance

II. SUBMIT NEW FORMULARY

The Submit New Formulary function is used to submit a new Formulary. A new Formulary may only be submitted during the initial Formulary submission window. If you need to revise a previously submitted Formulary, you should use the Revise Formulary function (refer to Chapter III).

When submitting a new Formulary, you will:

1. **Select Formulary Plan Type –** Indicate whether you are a Medicare-Medicaid Plan.
2. **Associate Contracts to the Formulary** – Associate appropriate contracts with the Formulary.
3. **Provide Formulary Information** – Provide information about the Formulary submissions including: Formulary Name, Formulary Classification System, Number of Tiers, OTC as part of a Step Therapy Protocol status, Quantity Limit status, Limited Access status, Prior Authorization status, Step Therapy status, Indication-Based Coverage status, and Expedited Generic Substitution status.
4. **Provide Formulary Tier Information** – Provide information about the tiers within the Formulary.
5. **Upload Files** – Upload the full Formulary file, Prior Authorization File (if required), Step Therapy File (if required), and Indication-Based Coverage File (if required).
6. **Verify Submission** – Verify the correct information has been entered for your submission.
7. **Confirm the Submission** – Submit your Formulary and obtain your assigned Formulary ID and confirmation that your upload was successful.

STEP 1

Select Submit New Formulary from the Formulary Submission Start page. (If you need help getting to the Formulary Submission Start Page, see the sub-section entitled "How to Access the HPMS Formulary Submission module" in Chapter I). This will take you to the Formulary Plan Type page.

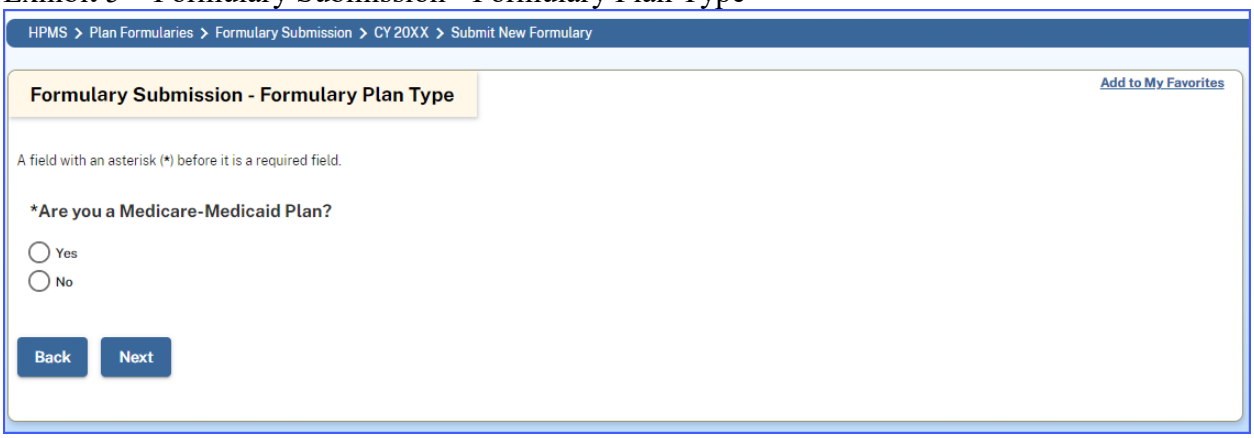
FORMULARY PLAN TYPE

The **Formulary Plan Type** page will allow you to indicate whether you are Medicare-Medicaid Plan.

STEP 1

On the **Formulary Plan Type** page (Exhibit 5), select 'yes' or 'no' to indicate whether you are a Medicare-Medicaid plan.

Exhibit 5 – Formulary Submission - Formulary Plan Type



STEP 2

Click the "Next" button. This will take you to the Associate Contracts to Formulary page.

ASSOCIATE CONTRACTS TO FORMULARY

The **Associate Contracts to Formulary** page will allow you to associate contracts to the Formulary submission.

In the previous step if you answered "Yes" for MMP, the system will display only MMP contracts for which you have access (Exhibit **7**). If you answered "No", the system will display all contracts other than MMP contracts for which you have access (Exhibit 6).

STEP 1

On the **Associate Contracts to Formulary** page, select one or more of the contracts listed on the page to associate with the new Formulary. If you cannot see one of your contracts, please refer to Section I – Getting Started. Also, review the Formulary upload contact information listed at the bottom of the page to ensure your current email address is in HPMS.

Note: A Formulary may only be associated with the contracts that belong to the same parent organization. If you select a contract with no parent organization, you will receive a warning message. Verify that all the contracts belong to the same parent organization before continuing with the submission.

Note: A specific Medicare-Medicaid Plan (MMP) Formulary can be associated with only one MMP contract. MMP formularies cannot be shared across contracts.

Exhibit 6 – Formulary Submission - Associate Contracts to Formulary

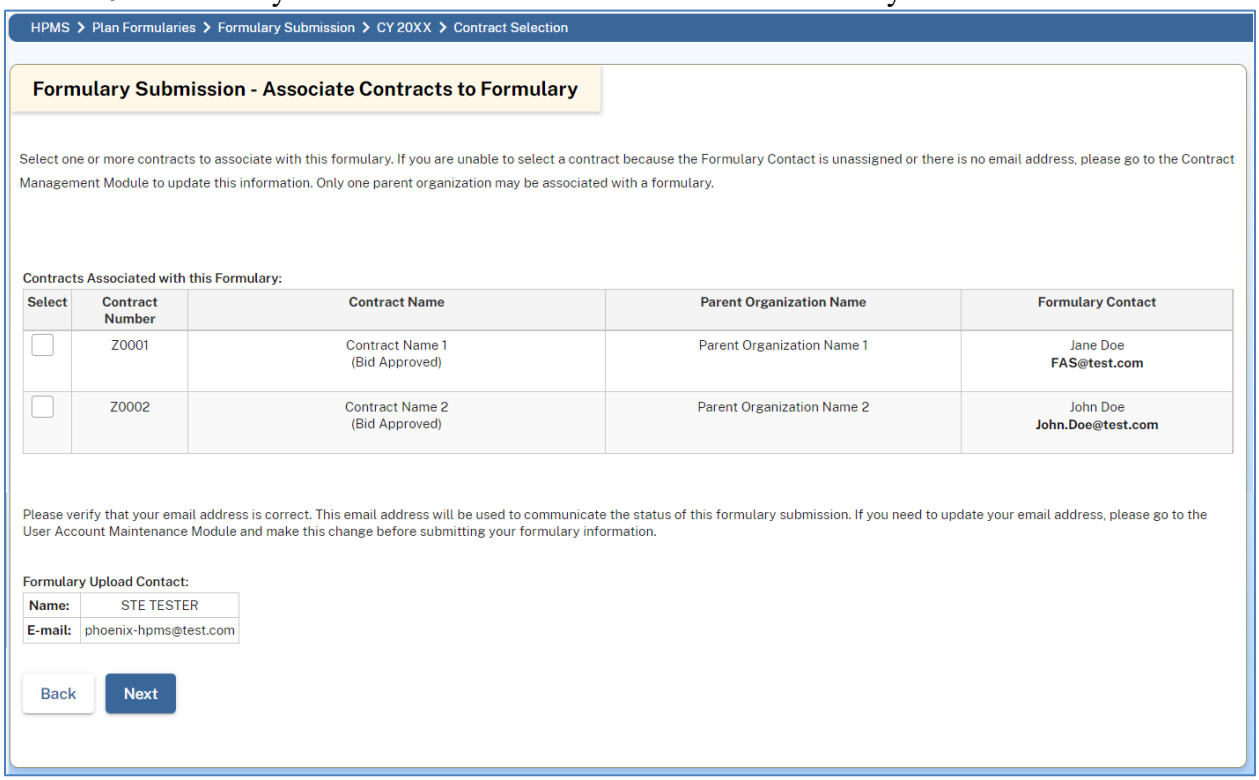
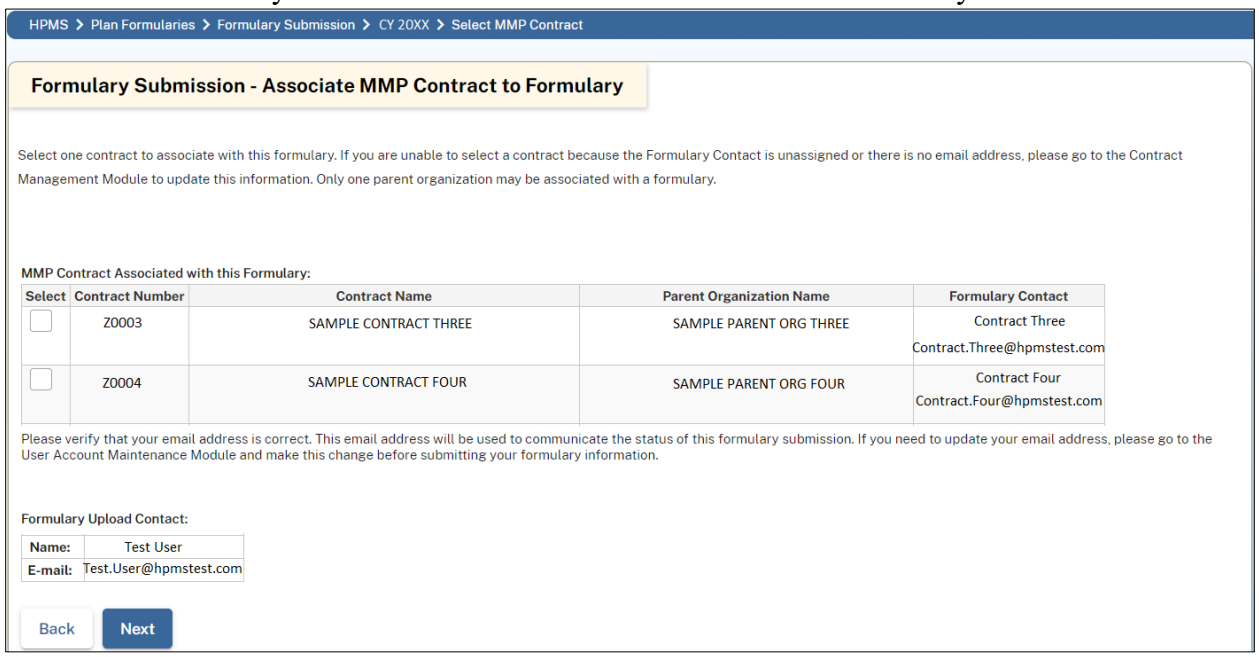


Exhibit 7 – Formulary Submission - Associate MMP Contract to Formulary



STEP 2

Click the "Next" button to confirm the Contract Associations. This will take you to the Formulary Information page.

FORMULARY INFORMATION

The **Formulary Information** page collects information about your Formulary submission including: the approved CY 2022 Formulary ID that closely resemble the current submission, Formulary Name, Formulary Classification System, Number of Tiers, OTC as part of a Step Therapy Protocol status, Quantity Limit status, Limited Access status, Prior Authorization status, Step Therapy status, Indication-Based Coverage and Expedited Generic Substitution.

STEP 1

On the **Formulary Information** page (Exhibit 8), respond to the questions. With the exception of the question about which Approved CY 2022 Formulary ID closely resembles the current submission, all fields are required.

When responding to the question about which Approved CY 2022 Formulary ID closely resembles the current submission, please be advised that you may identify a CY 2022 Formulary ID that was not associated with the contract in the previous year, as might be the case with MMPs, if it most closely resembles the Formulary you are currently submitting.

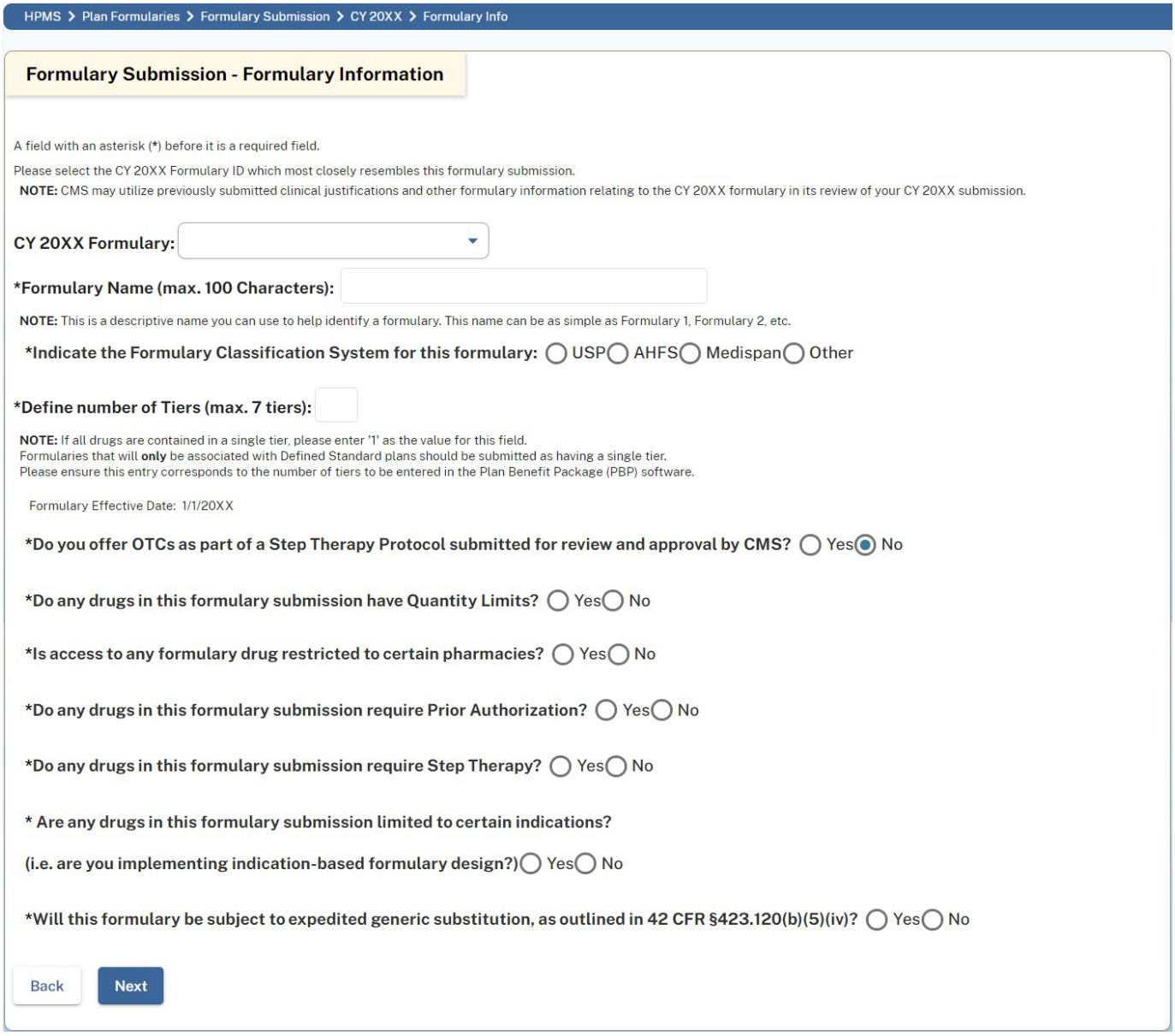
Select the Formulary Classification System for a Formulary. Options include USP, AHFS, Medispan, Other.

When defining the number of tiers, you may only define up to 7 tiers for Non-MMP formularies. MMP formularies can only have 2-6 tiers. MMP users will be restricted from entering 1 in the Number of Tiers field.

STEP 2

Click the "Next" button to confirm your entries and move to the Formulary Tier Information page.

Exhibit 8 – Formulary Submission - Formulary Information



FORMULARY TIER INFORMATION

The **Formulary Tier Information** page collects information about the tiers within the Formulary. The page will automatically generate the tier models based on the information you entered on the Formulary Information page and whether or not you indicated that you were a Medicare-Medicaid Plan. Formularies that will only be associated with Defined Standard plans must be submitted as having a single tier. The tier information that you enter in the Formulary submission module must correspond to the number of tiers that will be identified in the corresponding CY 2023 Plan Benefit Package (PBP) module, including plans offering an excluded drugs only tier (non-MMPs only).

Non-MMP plans only: When developing the Formulary tier structure, please use standard industry practices. Generally, Tier 1 should be considered the lowest cost-sharing tier available to beneficiaries. 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. However, please note that CMS implemented a Formulary tier structure standardization to improve the comparability of plan offerings for beneficiaries. Therefore, CMS will allow a fifth, sixth or seventh tier that provides a meaningful benefit offering such as a $0 vaccine-only tier or a low or $0 cost-sharing tier for special needs plans (SNP) targeting specific conditions.

Note: Drop-down options for fifth, sixth and seventh tier formularies will include the following:

- Vaccines
- Injectable tier
- Specialty tier
- Excluded drug only tier
- Select diabetic drugs
- Select care drugs

If a Formulary includes an excluded drug only tier, no FRF drug should be entered on the Formulary record layout as having that tier number.

Note: Based on the number of tiers defined in the Formulary questions section, Tier Information Page displays pre-defined Formulary tier models.

The tier models will be populated based on the plan type selected. MMP-specific tier models will be available for MMP formularies only. Non-MMP formularies will have regular tier models defined by CMS.

Although MMPs have the option to choose models ranging from 2-6 tiers, only Medicare tiers are included in the Formulary file. Non-Medicare tiers are placeholder tiers for state-required drugs that are not covered under Part D. All non-Part D drugs required by the State are submitted on the Additional Demonstration Drug file the first week of June.

STEP 1

On the **Formulary Tier Information** page (Exhibit 9 and Exhibit 10), select a tier model appropriate for your Formulary.

Exhibit 9 – Formulary Submission - Formulary Tier Information

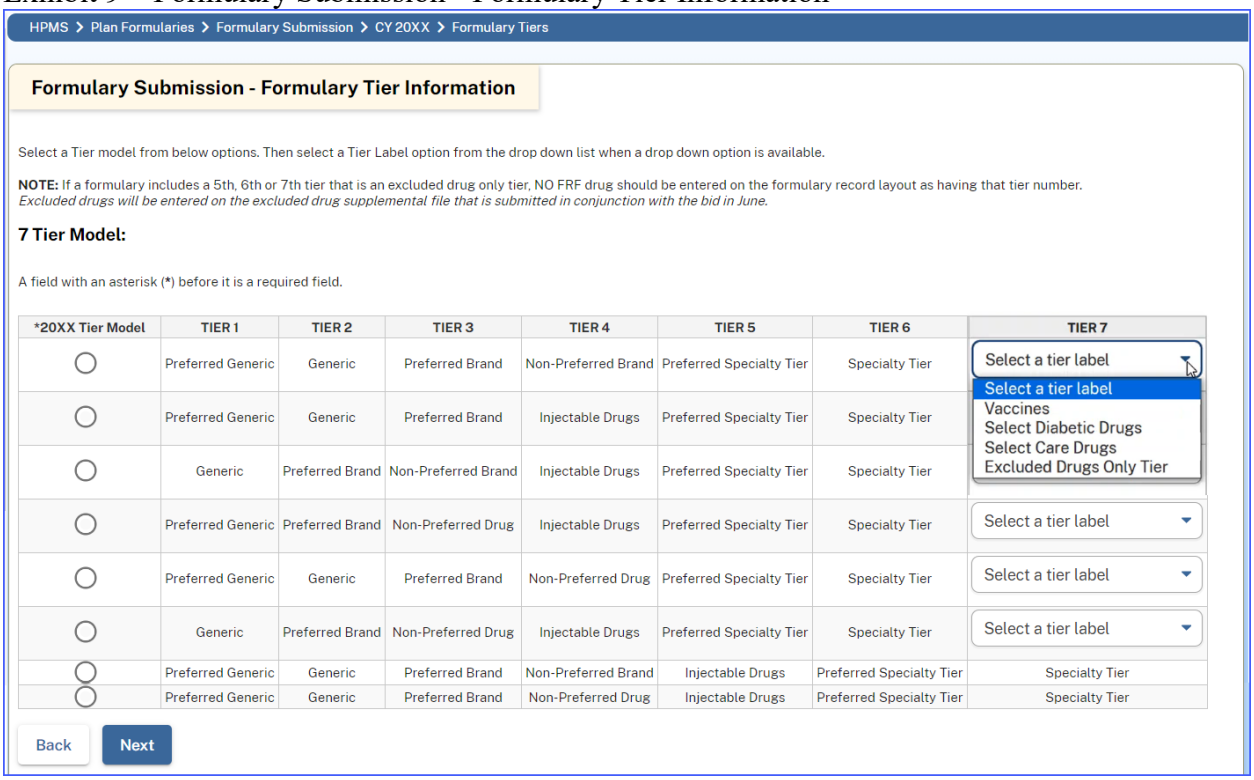
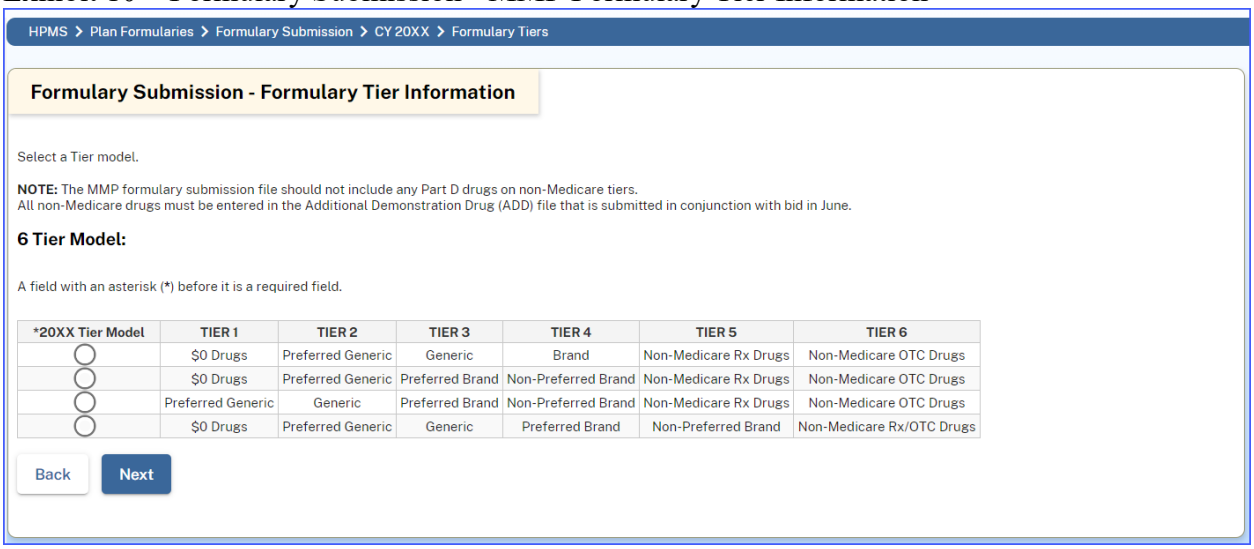


Exhibit 10 – Formulary Submission - MMP Formulary Tier Information



STEP 2

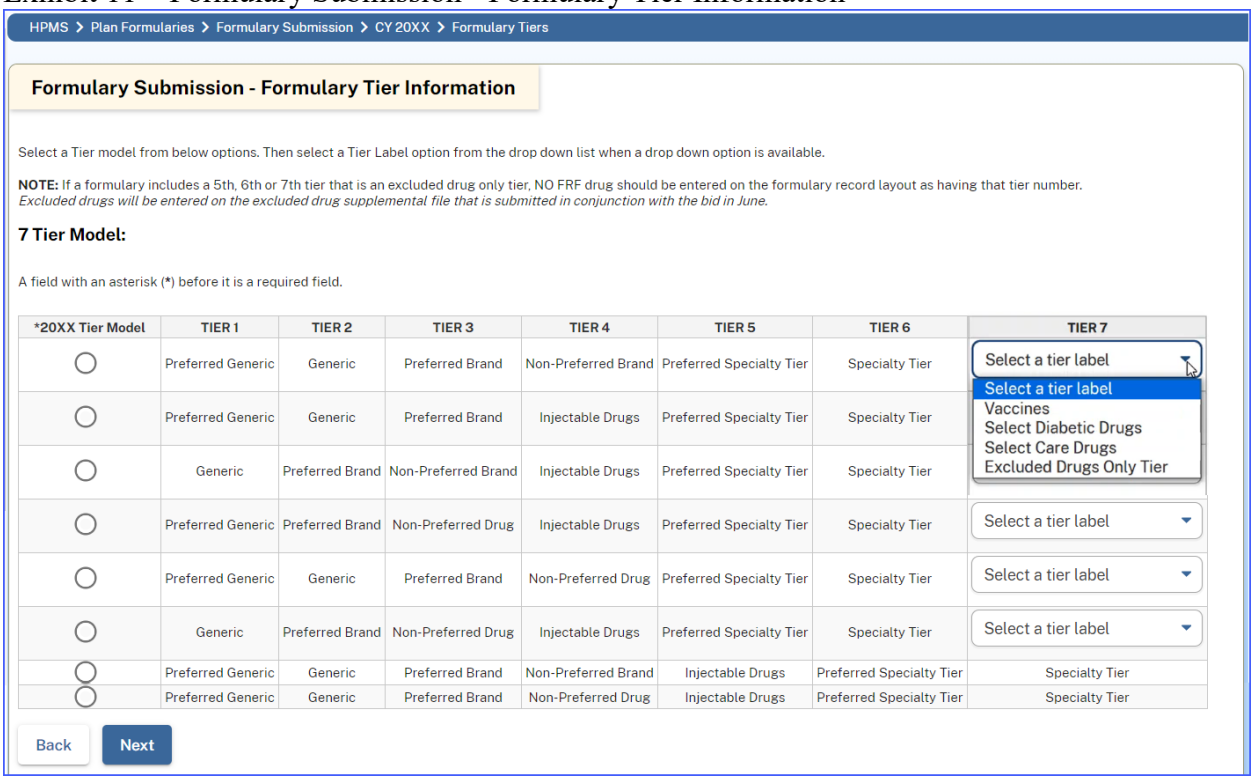
If your Formulary includes two to four tiers, skip to Step 3.

If your Formulary includes five, six or seven tiers, select the fifth, sixth or seventh tier (Exhibit 11) from the drop down option, if applicable.

STEP 3

Click the "Next" button to confirm your information and move to the Upload Files page.

Exhibit 11 – Formulary Submission - Formulary Tier Information



UPLOAD FILES

The **Upload Files** page allows you to specify the Formulary file, Prior Authorization File, Step Therapy File and Indication-Based Coverage you want to upload. The module will determine what you need to upload based on your responses on the Formulary Information page.

During initial submission, you will submit a full Formulary file, full PA, full ST and full IBC files if applicable. After initial submission, your Formulary and PA/ST files should include changes only. Even after initial submission, submit full IBC files only. To download all upload file instructions, click the **Submission File Layouts** link in the Documentation section of the Formulary Submission Start Page.

It is imperative that the files you are uploading be in the following formats:

- **Formulary file** - ASCII Tab delimited text file, e.g., *Formulary123*.txt
  During the initial submission period, the value of the change_type field must be "ADD" for all records in the file.
  For more information/assistance on the Formulary file layout, see Appendices A and B in this Manual.
- **Prior Authorization File** – ASCII Tab delimited text file, e.g., *FormularyPA*.txt
  During the initial submission period, the value of change_type field must be "ADD" for all records in the file.
  For more information/assistance on the Prior Authorization File, see Appendix B.
- **Step Therapy File** – ASCII Tab delimited text file, e.g., *steptherapy123ST*.txt

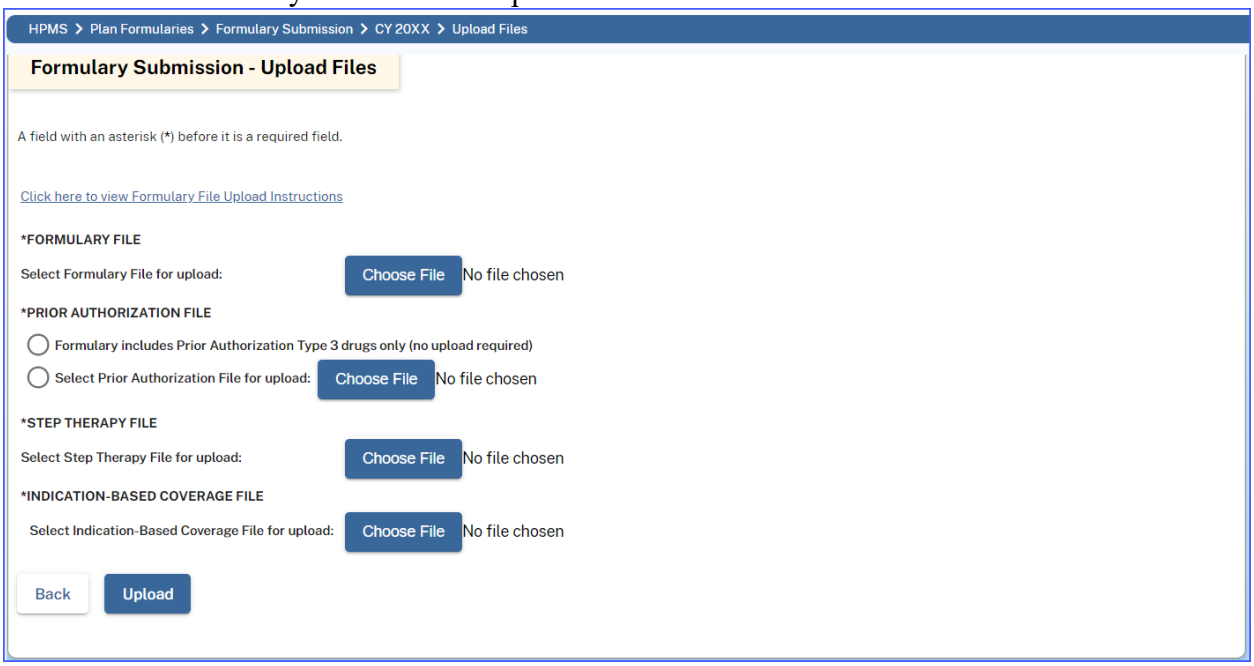
During the initial submission period, the value of change_type field must be "ADD" for all records in the file.
For more information/assistance on the Step Therapy File, see Appendix B.

- **Indication-Based Coverage File** – ASCII Tab delimited text file, e.g., ibc123.txt
  Do not include change_type field for IBC file.
  For more information/assistance on the Indication-Based Coverage File, see Appendix B.

STEP 1

On the **Upload Files** page (Exhibit 12), enter the full path and name of the Formulary Text File (Tab delimited .txt only) in the "Formulary file" field, e.g., c:\myFormularyfile.txt. If you are unsure of the file name or location, click the "Browse" button to locate and attach the file.

Exhibit 12 – Formulary Submission - Upload Files



STEP 2A

Select the "Formulary includes Prior Authorization Type 3 drugs only" radio button if the Formulary has PA Type 3 only. If this option is selected, no file upload is required. Skip to step 3.

STEP 2B

Select the "Select Prior Authorization File for Upload" radio button if the Formulary has PA Type 1 or 2. Enter the full path and name of the Prior Authorization File (Tab delimited .txt file only) in the "Prior Authorization File" field or click the "Browse" button to locate and attach the file (Exhibit 12).
Note: If you selected "No" for the prior authorization question from the Formulary Information page, this field will not be displayed.

STEP 3

Enter the full path and name of the Step Therapy File (Tab delimited .txt file only) in the "Step Therapy File" field or click the "Browse" button to locate and attach the file (Exhibit 12).

Note: If you selected "No" for the step therapy question from the Formulary Information page, this field will not be displayed.

STEP 4
Enter the full path and name of the Indication-Based Coverage File (Tab delimited .txt file only) in the "Indication-Based Coverage File" field or click the "Browse" button to locate and attach the file (Exhibit 12).
Note: If you selected "No" for the Indication-Based Coverage question from the Formulary Information page, this field will not be displayed.

STEP 5
Click the "Upload" button to prepare your files for submission to HPMS and to continue to the Verify Submission page. Please wait until the file transfer is complete before attempting to navigate further.

VERIFY SUBMISSION

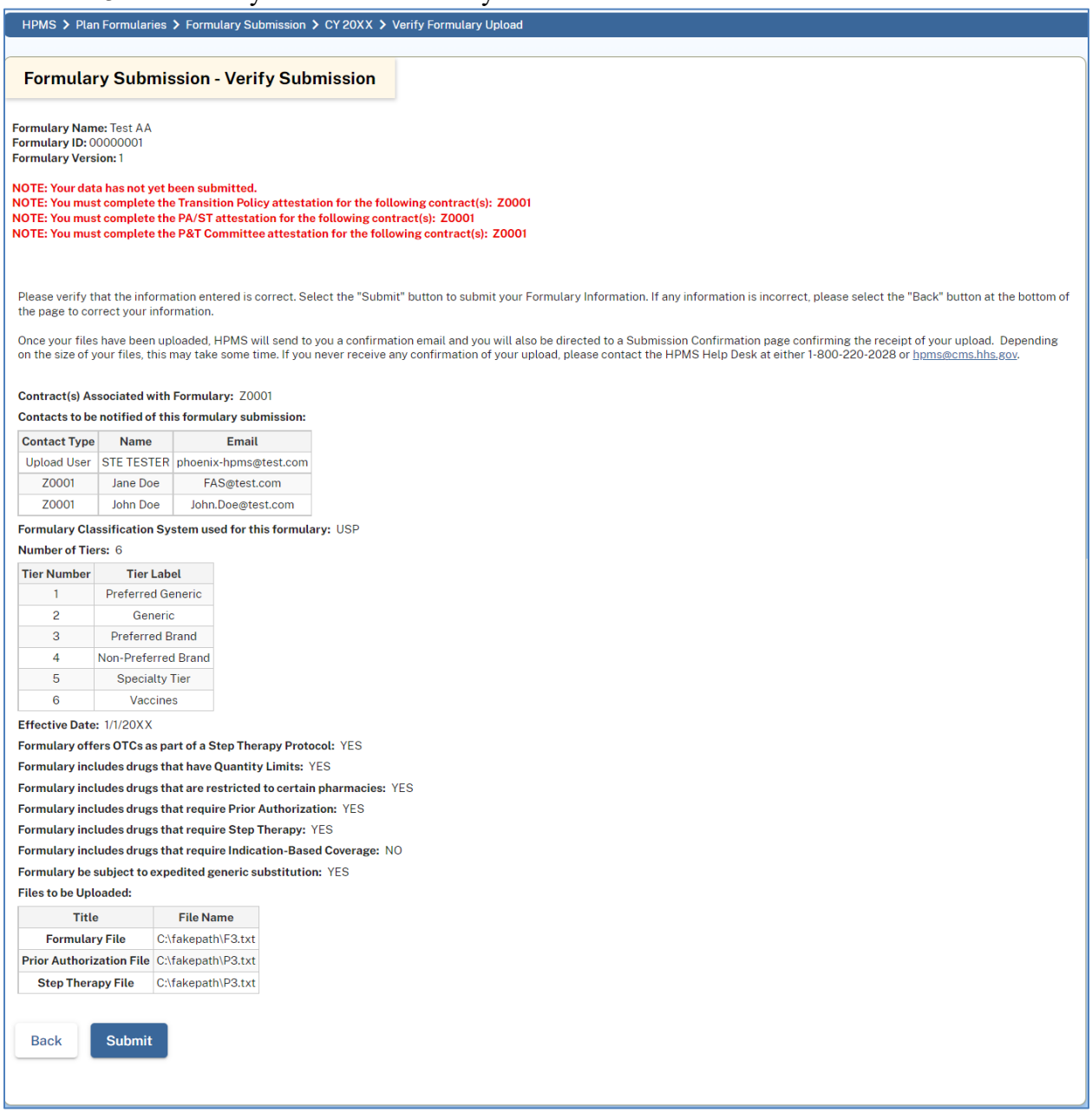
The **Verify Submission** page allows you to verify the information you entered during the submission process before you complete the upload and submit the information to CMS.

STEP 1
On the Verify Submission page (Exhibit 13), review the information for accuracy.

STEP 2A
If any information is incorrect, click the "Back" button to correct the information as necessary.

STEP 2B
If all information is correct, click the "Submit" button to send the submission to CMS for review. This will take you to the Submission Confirmation page.

Exhibit 13 – Formulary Submission - Verify Submission



HPMS > Plan Formularies > Formulary Submission > CY 20XX > Verify Formulary Upload

Formulary Submission - Verify Submission

Formulary Name: Test AA
Formulary ID: 00000001
Formulary Version: 1

NOTE: Your data has not yet been submitted.
NOTE: You must complete the Transition Policy attestation for the following contract(s): Z0001
NOTE: You must complete the PA/ST attestation for the following contract(s): Z0001
NOTE: You must complete the P&T Committee attestation for the following contract(s): Z0001

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: Z0001

Contacts to be notified of this formulary submission:

Contact Type	Name	Email
Upload User	STE TESTER	phoenix-hpms@test.com
Z0001	Jane Doe	FAS@test.com
Z0001	John Doe	John.Doe@test.com

Formulary Classification System used for this formulary: USP

Number of Tiers: 6

Tier Number	Tier Label
1	Preferred Generic
2	Generic
3	Preferred Brand
4	Non-Preferred Brand
5	Specialty Tier
6	Vaccines

Effective Date: 1/1/20XX

Formulary offers OTCs as part of a Step Therapy Protocol: YES

Formulary includes drugs that have Quantity Limits: YES

Formulary includes drugs that are restricted to certain pharmacies: YES

Formulary includes drugs that require Prior Authorization: YES

Formulary includes drugs that require Step Therapy: YES

Formulary includes drugs that require Indication-Based Coverage: NO

Formulary be subject to expedited generic substitution: YES

Files to be Uploaded:

Title	File Name
Formulary File	C:\fakepath\F3.txt
Prior Authorization File	C:\fakepath\P3.txt
Step Therapy File	C:\fakepath\P3.txt

Back Submit

SUBMISSION CONFIRMATION

The **Submission Confirmation** page confirms successful receipt of your submission and provides the unique Formulary ID assigned to your submission. This page will also generate an email to all Formulary Contacts and the Formulary Upload Contact identified on this page acknowledging receipt of the submission and the assigned Formulary ID.

Important: You should note the Formulary ID. You will need this ID for all subsequent resubmissions.

STEP 1

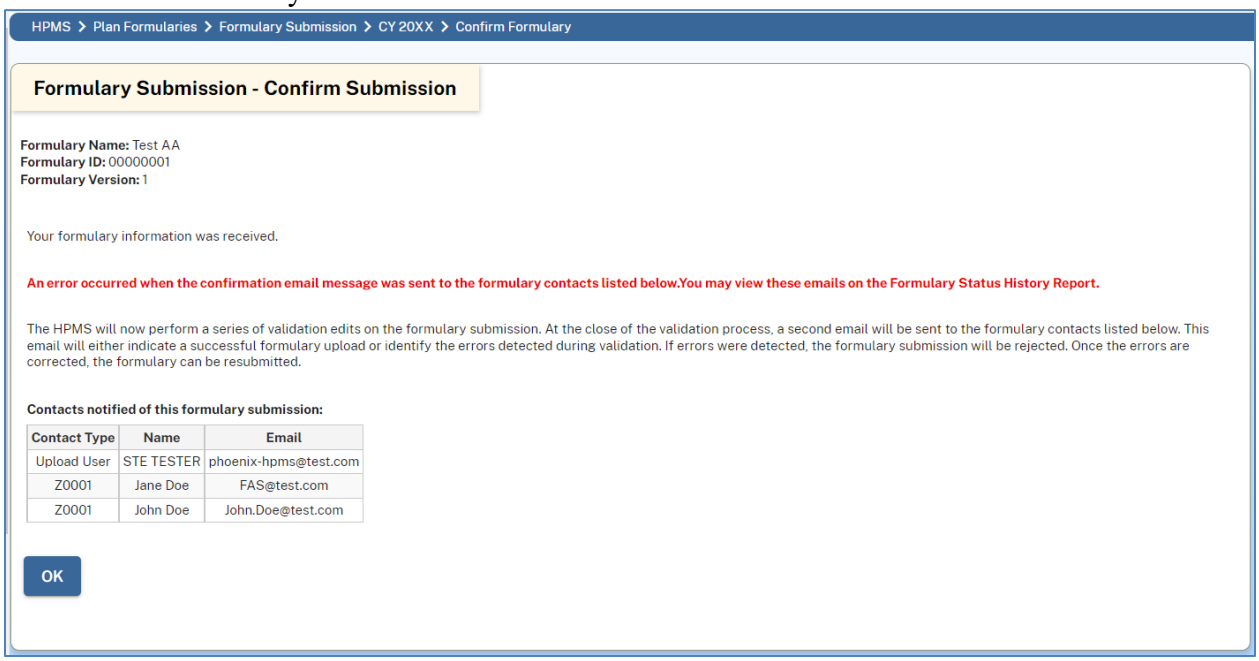
On the **Submission Confirmation** page (Exhibit 14), review the information. As explained above, MAKE NOTE OF YOUR ASSIGNED FORMULARY ID.

STEP 2

Click the "OK" button to return to the Formulary Submission Start Page.

At this point, you have finished submitting your new Formulary and need to wait for an email regarding the status of your submission. After receiving your submission, HPMS will perform a series of validation edits. At the close of the validation process, a follow-up email will be sent to the designated Formulary contacts. This email will indicate that the Formulary was successfully validated or 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 it using your assigned Formulary ID under the Revise Formulary function (refer to Chapter III).

Exhibit 14 – Formulary Submission - Confirm Submission



III. REVISE FORMULARY

The Revise Formulary functionality is used to update formularies and the necessary PA, ST and/or IBC files (if applicable) that have already been submitted to CMS via HPMS. This functionality can also be used to update a Formulary and PA, ST or IBC files before the initial submission deadline. You are only permitted to update a Formulary and PA, ST or IBC files during scheduled update windows and/or when a Formulary has a status of "Resubmission Requested" or "Rejected by Validation" ("How to Determine Formulary Submission Status" below). Formularies that are "Approved" may only be updated during the assigned update windows.

During initial submission, you must replace full files for the Formulary, PA, ST and IBC files.

After the initial submission period, you will upload only changes to the Formulary, PA and ST files (i.e., partial files) on the Revise Formulary page. Even after initial submission period, upload full IBC files only. If you are only making changes to your PA/ST criteria or IBC file, you do not need to upload a Formulary file.

After Bid submission, the Revise Formulary functionality may also be used to update certain existing supplemental files (if applicable), by indicating if the Formulary with an associated Partial Gap Coverage, Free First Fill, Home Infusion or Value-Based Insurance Design supplemental file requires a change to the previously uploaded supplemental file or to continue using the previously uploaded supplemental file. This functionality is only available if your Bid has passed all validation checks and has been "Sent to Desk Review (DR)." You can check the status of your Bid by reviewing the Bid Status History Report. The latest associated Partial Gap Coverage, Free First Fill, Home Infusion or Value-Based Insurance Design supplemental file must also be in the "In Desk Review" or "Approved" status.

DETERMINE YOUR FORMULARY SUBMISSION STATUS

As shown in Exhibit 4 select Revise Formulary from the Formulary Submission Start page. (If you need help getting to the Formulary Submission Start Page, see the sub-section entitled "Access HPMS Formulary Submission Module" in Chapter I). This will take you to the Formulary Resubmission-Select a Formulary page.

The **Formulary Resubmission–Select a Formulary** page (Exhibit 15) group's formularies into two categories:

> Resubmission/Updates – Formularies that are eligible for resubmission either due to a validation failure or because a reviewer requested a resubmission. Formularies that are approved by CMS and are available for update will be available in this category. This group also includes formularies eligible for resubmission during a scheduled window.
>
> In Process – Formularies that are in desk review.

Within each category, there is a table listing information about each Formulary. This table includes a column entitled "Submission Status." As noted above, you can only update formularies that have a submission status of "Resubmission Requested" or "Rejected by Validation." You can update formularies that are "Approved" during the assigned update

windows. Note: In the event CMS conducts a limited update window, formularies eligible for resubmission during the gate opening will show an "Approved" status.

In the Resubmission/Update category, there is a table listing columns entitled "Revise Formulary & PA/ST & IBC", "Revise PA/ST Only" and "Revise IBC Only."
If you are updating the Formulary file, click the Formulary ID hyperlink in the "Revise Formulary & PA/ST & IBC" column. This will allow you to upload changes to the Formulary file as well as changes to the PA/ST Criteria and IBC files.

If you are updating the PA/ST Criteria files only, click the Formulary ID hyperlink in the "Revise PA/ST Only" column.

If you are updating the IBC files only, click the Formulary ID hyperlink in the "Revise IBC Only" column.

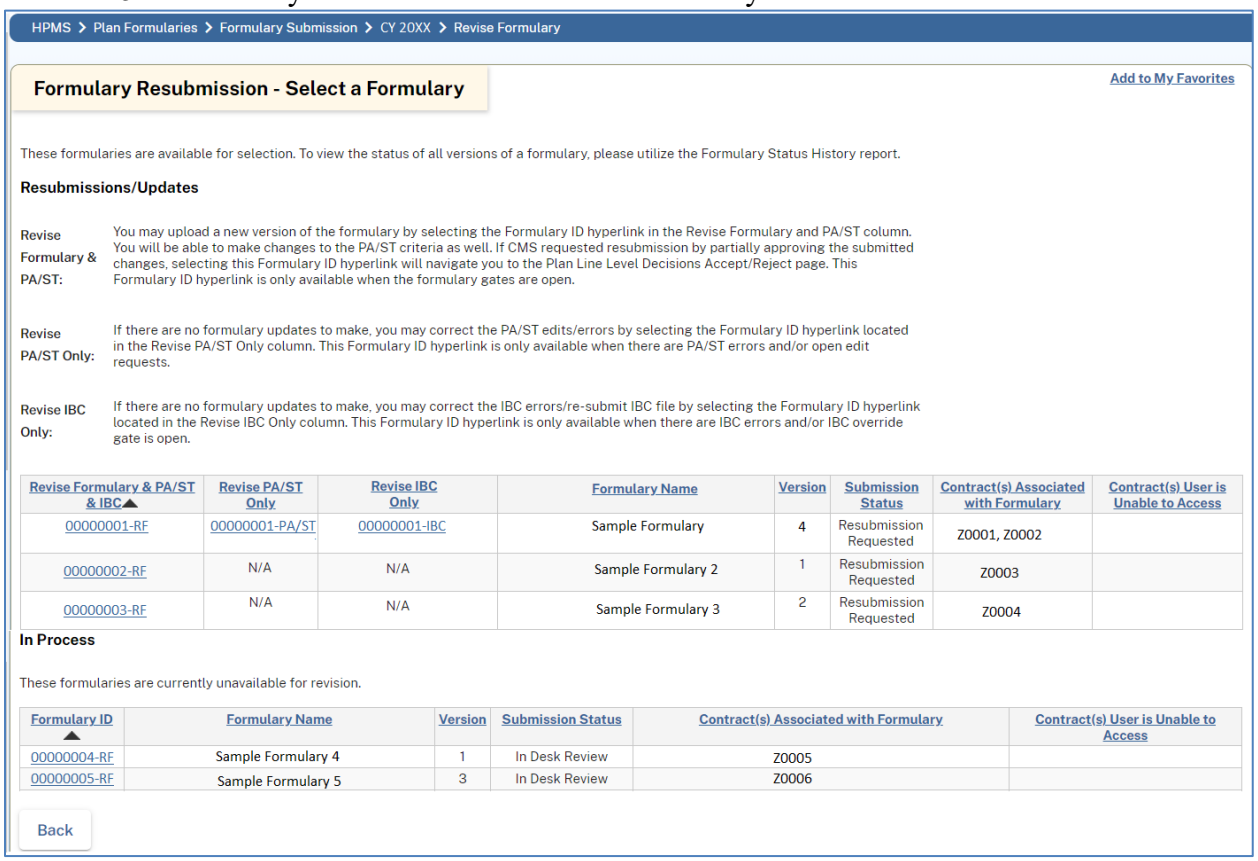
Hyperlinks in these columns will be enabled under the following situations.

Revise Formulary & PA/ST & IBC: Hyperlinks in this column will be enabled when the Formulary is in the status of "Resubmission Requested", "Rejected by Validation", or "Approved." You may upload a new version of the Formulary, PA, ST and IBC files by selecting this hyperlink. If CMS requested resubmission through the Line Level Decision process by partially approving the submitted changes, selecting this hyperlink will navigate you to the Plan Line Level Decisions Accept/Reject page.

Revise PA/ST Only: Hyperlinks in this column will be enabled when the Formulary is rejected because of PA/ST errors (or) when there are open edit requests. Selecting a hyperlink will navigate you to Revise PA/ST Criteria Upload page.

Revise IBC Only: Hyperlinks in this column will be enabled when the Formulary is rejected because of IBC errors (or) when there are re-submission requests. Selecting a hyperlink will navigate you to Revise IBC Upload page.

Exhibit 15 – Formulary Resubmission - Select a Formulary



REVISE FORMULARY & PA/ST & IBC

STEP 1

Select **Revise Formulary from the Formulary Submission** Start page. This will take you to the Formulary Resubmission – Select a Formulary page (Exhibit 15).

STEP 2A

On the **Formulary Resubmission - Select a Formulary** page, select "Revise Formulary & PA/ST & IBC" hyperlink for the Formulary you wish to update. This will take you to the Formulary Resubmission - Associate Contracts to Formulary page.

ASSOCIATE CONTRACTS TO FORMULARY

The **Formulary Resubmission - Associate Contracts to Formulary** page (Exhibit 16) will allow you to associate one or more of your contracts to the Formulary resubmission.

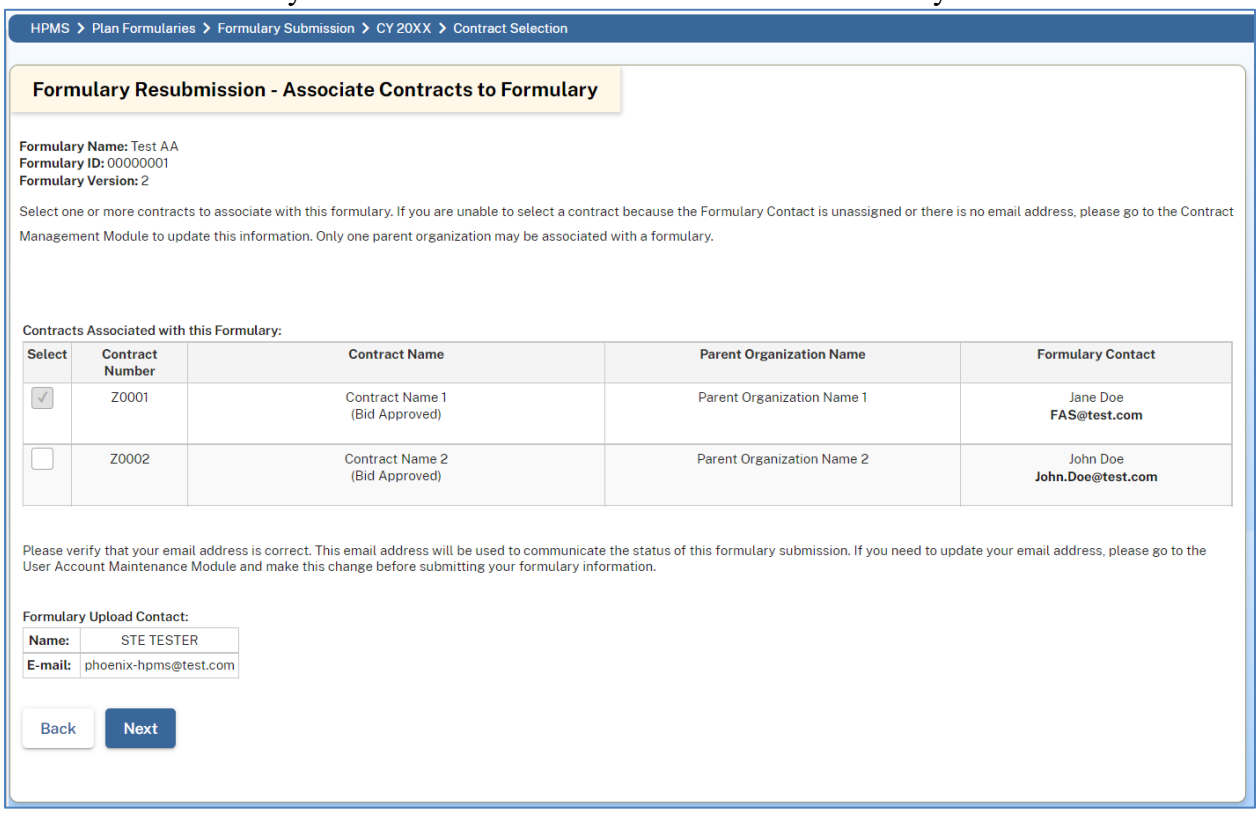
Note: When revising a Formulary, you cannot add or remove a contract from a Formulary association after the CMS-specified due date.

STEP 1

On the **Formulary Resubmission - Associate Contracts to Formulary** page, select one or more of the contracts listed on the page to associate with the Formulary.

Note: A Formulary may only be associated to the contracts that belong to the same parent organization. If you select a contract with no parent organization, you will receive a warning message. Verify that all the contracts belong to the same parent organization before continuing with the submission.

Exhibit 16 – Formulary Resubmission - Associate Contracts to Formulary



STEP 2

On the **Formulary Resubmission - Associate Contracts to Formulary** page, click the "Next" button to confirm the Contract Associations. This will take you to the Formulary Resubmission - Formulary Information page.

FORMULARY INFORMATION

The **Formulary Resubmission - Formulary Information** page collects information about your Formulary resubmissions including: Formulary Name, Formulary Classification System, Number of Tiers, Quantity Limit status, Limited Access status, Prior Authorization status, Step Therapy status, Indication-Based Coverage and Expedited Generic Substitution.

Note: Values in fields cannot be changed after certain conditions apply as follows:

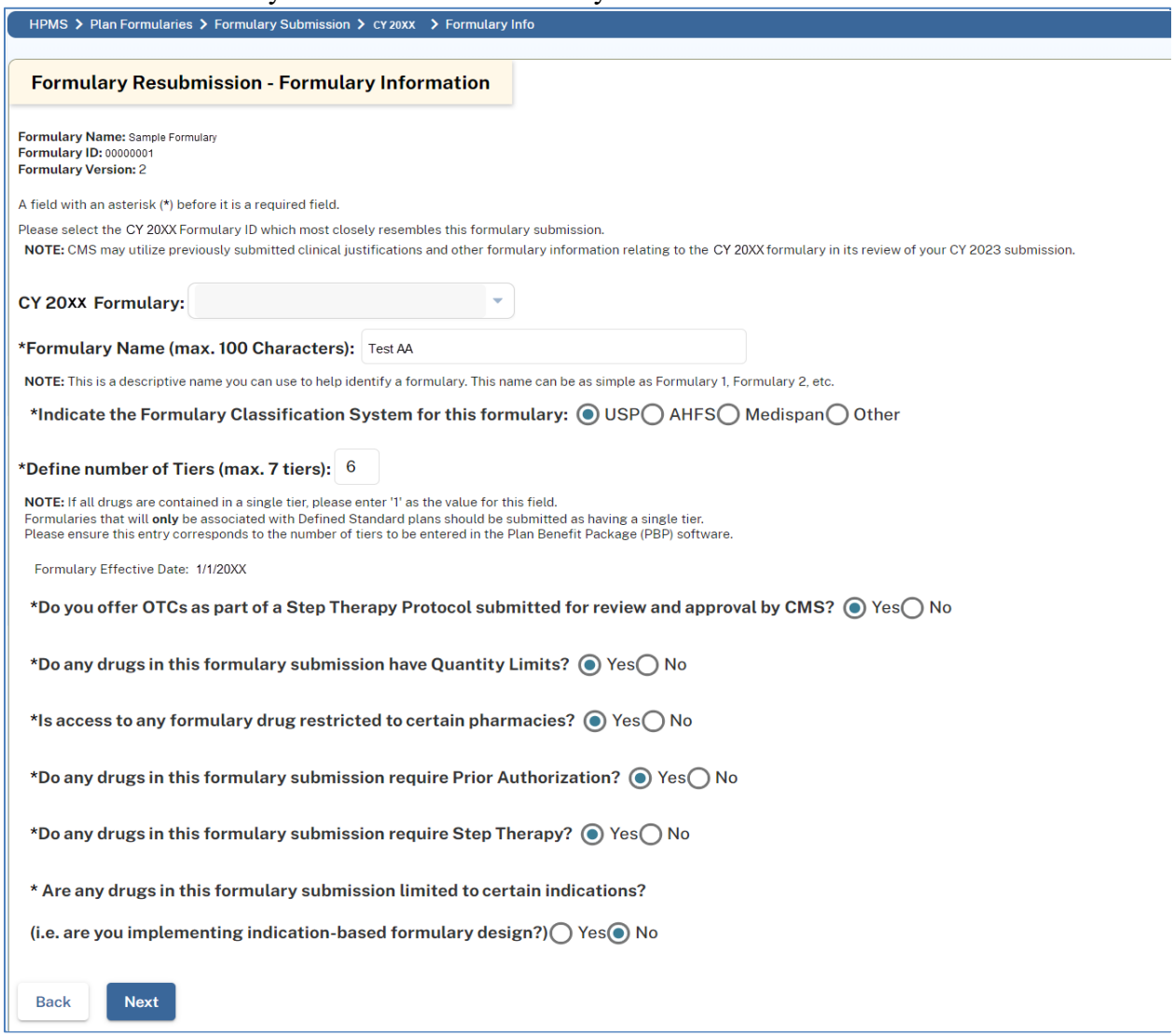
1. **Prior Year Formulary:** After initial Formulary submission period is closed.
2. **Formulary Classification System:** After prior version of the Formulary is approved.
3. **Define Number of Tiers:** After prior version of the Formulary is approved
4. **Do you offer OTC as a part of Step Therapy Protocol submitted for review and approval by CMS? :** After OTC supplemental file initial submission period is closed.
5. **Are any drugs in the Formulary submission limited to certain indications? :** After IBC file submission period is closed for approved formularies only.

6. **Will this Formulary be subject to expedited generic substitution, as outlined in 42 CFR 423.120(b)(5)(iv)? :** After initial Formulary submission period is closed.

STEP 1

On the **Formulary Resubmission - Formulary Information** page (Exhibit 17), enter any changes to the answers previously provided.

Exhibit 17 – Formulary Resubmission - Formulary Information



STEP 2

Click the "Next" button to confirm your changes and move to the Formulary Resubmission - Formulary Tier Information page.

FORMULARY TIER INFORMATION

The **Formulary Resubmission - Formulary Tier Information** page collects information about the tiers within the Formulary. **Note:** The system will not allow you to change the information on the Formulary Tier Information page once the Formulary has been approved.

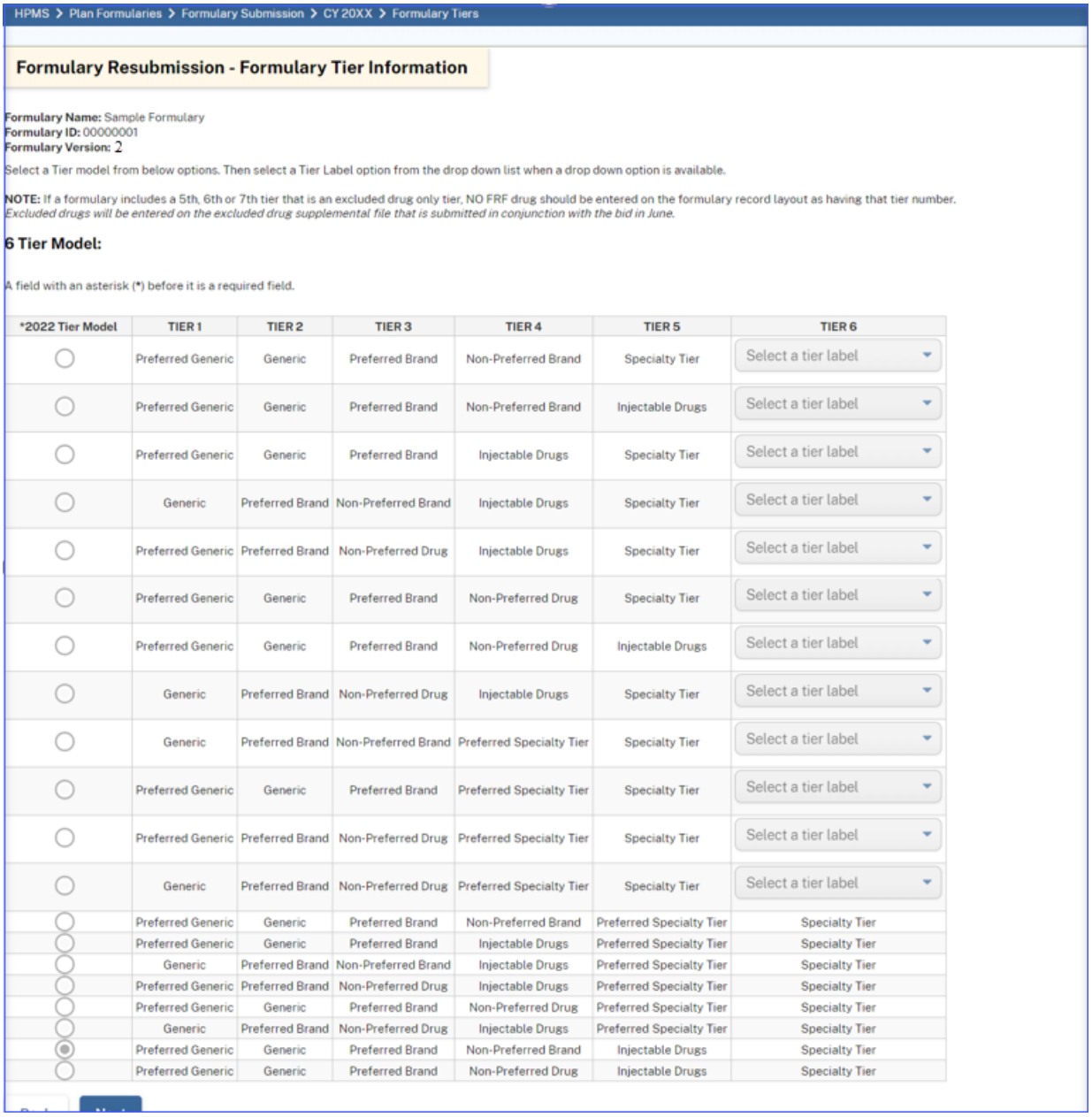
STEP 1
On the **Formulary Tier Information** page (Exhibit 18), select a tier model appropriate for your Formulary. MMPs will have a similar screen.

STEP 2
If your Formulary includes 2-4 tiers, skip to Step 3.
If your Formulary includes 5, 6 or 7 tiers, select a drop-down option for 5th, 6th or 7th tier (non-MMP models) if applicable.

STEP 3
Click the "Next" button to confirm your information and move to the Upload Files page.

Note: Note that the tier information entered in the Formulary submission module must correspond to the number of tiers and model that will be identified in the corresponding CY 2023 PBP software.

Exhibit 18 – Formulary Resubmission - Formulary Tier Information



HPMS > Plan Formularies > Formulary Submission > CY 20XX > Formulary Tiers

Formulary Resubmission - Formulary Tier Information

Formulary Name: Sample Formulary
Formulary ID: 00000001
Formulary Version: 2

Select a Tier model from below options. Then select a Tier Label option from the drop down list when a drop down option is available.

NOTE: If a formulary includes a 5th, 6th or 7th tier that is an excluded drug only tier, NO FRF drug should be entered on the formulary record layout as having that tier number. *Excluded drugs will be entered on the excluded drug supplemental file that is submitted in conjunction with the bid in June.*

6 Tier Model:

A field with an asterisk (*) before it is a required field.

*2022 Tier Model	TIER 1	TIER 2	TIER 3	TIER 4	TIER 5	TIER 6
○	Preferred Generic	Generic	Preferred Brand	Non-Preferred Brand	Specialty Tier	Select a tier label
○	Preferred Generic	Generic	Preferred Brand	Non-Preferred Brand	Injectable Drugs	Select a tier label
○	Preferred Generic	Generic	Preferred Brand	Injectable Drugs	Specialty Tier	Select a tier label
○	Generic	Preferred Brand	Non-Preferred Brand	Injectable Drugs	Specialty Tier	Select a tier label
○	Preferred Generic	Preferred Brand	Non-Preferred Drug	Injectable Drugs	Specialty Tier	Select a tier label
○	Preferred Generic	Generic	Preferred Brand	Non-Preferred Drug	Specialty Tier	Select a tier label
○	Preferred Generic	Generic	Preferred Brand	Non-Preferred Drug	Injectable Drugs	Select a tier label
○	Generic	Preferred Brand	Non-Preferred Drug	Injectable Drugs	Specialty Tier	Select a tier label
○	Generic	Preferred Brand	Non-Preferred Brand	Preferred Specialty Tier	Specialty Tier	Select a tier label
○	Preferred Generic	Generic	Preferred Brand	Preferred Specialty Tier	Specialty Tier	Select a tier label
○	Preferred Generic	Preferred Brand	Non-Preferred Drug	Preferred Specialty Tier	Specialty Tier	Select a tier label
○	Generic	Preferred Brand	Non-Preferred Drug	Preferred Specialty Tier	Specialty Tier	Select a tier label
○	Preferred Generic	Generic	Preferred Brand	Non-Preferred Brand	Preferred Specialty Tier	Specialty Tier
○	Preferred Generic	Generic	Preferred Brand	Injectable Drugs	Preferred Specialty Tier	Specialty Tier
○	Generic	Preferred Brand	Non-Preferred Brand	Injectable Drugs	Preferred Specialty Tier	Specialty Tier
○	Preferred Generic	Preferred Brand	Non-Preferred Drug	Injectable Drugs	Preferred Specialty Tier	Specialty Tier
○	Preferred Generic	Generic	Preferred Brand	Non-Preferred Drug	Preferred Specialty Tier	Specialty Tier
○	Generic	Preferred Brand	Non-Preferred Drug	Injectable Drugs	Preferred Specialty Tier	Specialty Tier
◉	Preferred Generic	Generic	Preferred Brand	Non-Preferred Brand	Injectable Drugs	Specialty Tier
○	Preferred Generic	Generic	Preferred Brand	Non-Preferred Drug	Injectable Drugs	Specialty Tier

UPLOAD FILES

The **Formulary Resubmission - Upload Files** page allows you to upload revised Formulary, PA and ST files.

Following Bid submission, the **Formulary Resubmission - Upload Files** page will also allow you to indicate if the associated Partial Gap Coverage, Free First Fill, Home Infusion, or Value-Based Insurance Coverage files (if applicable) require or not require a change to the previous successfully-validated supplemental file.

During initial submission, you must replace full files for the Formulary, PA, ST and IBC files. After the initial submission period, your upload files will include only the changes to your Formulary, PA and ST files. Even after initial submission period, upload full files for the IBC.

Click the "Click here to view the Formulary File Upload Instructions" hyperlink (Exhibit 19), to view the detailed instructions.

The files you are uploading must be in the following formats:

- **Formulary file** - ASCII Tab delimited text file, e.g., *Formulary123*.txt
  During the initial submission period, the value of this field must be "ADD" for all records in the file. After the initial submission period, the Partial Formulary file may include a value of "ADD", "UPD", or "DEL" in the change type field.

  For more information/assistance on the Formulary file layout, see Appendices A and B in this Manual.

- **Prior Authorization File** (applicable if the Initial Submission window is open) – ASCII Tab delimited text file, e.g., *FormularyPA*.txt

  During the initial submission period, the value must be "ADD" for all records in the file. After the initial submission period, the partial PA file may include a value of "ADD", "UPD."

  For more information/assistance on the Prior Authorization File, see Appendix B.

- **Step Therapy File** (applicable if the Initial Submission window is open) – ASCII Tab delimited text file, e.g., *steptherapy123ST*.txt

  During the initial submission period, the value must be "ADD" for all records in the file. After the initial submission period, the partial ST file may include a value of "ADD", "UPD."

  For more information/assistance on the Step Therapy File, see Appendix B.

- **Indication-Based Coverage File** (applicable if the Initial Submission window is open) – ASCII Tab delimited text file, e.g., ibc*123*.txt

  Do not include change type value ("ADD") in the IBC file.

For more information/assistance on the Indication-Based Coverage File, see Appendix B.

STEP 1

On the **Formulary Resubmission - Upload Files** page (Exhibit 19); enter the full path and name of the Formulary Text File (Tab delimited .txt only) in the "Formulary file" field, e.g., c:\myFormularyfile.txt. If you are unsure of the file name or location, click the "Browse" button to locate and attach the file.

Note: If your Formulary is associated with a Partial Gap Coverage, Free First Fill, Home Infusion or Value-Based Insurance Coverage supplemental file, follow steps 2-4 unless you failed to submit your required supplemental file(s) in your prior monthly update. In this case, the options to reuse or submit a new file will not be available to you at this time. You must return to the submission module following the successful validation of your Formulary to submit your supplemental files. You may submit these files using the Submit Home Infusion File, Submit Free First Fill File, Submit Partial Gap Coverage File or Submit Value-Based Insurance Design options on the Formulary Submission Start page. Failure to upload the required supplemental files may result in a compliance action.

STEP 2A

Select the "This Formulary does not require changes to the previously uploaded copy of the Partial Gap Coverage Supplemental File" option if no changes are required to the previous uploaded Partial Gap Coverage file against the revised Formulary (if applicable). See Exhibit 19.

STEP 2B

Select the "This Formulary requires changes to the Partial Gap Coverage Supplemental File" option if changes are required to the previous uploaded Partial Gap Coverage file against the revised Formulary (if applicable). See Exhibit 19.

Note that you must upload your Partial Gap Coverage supplemental file through the HPMS Submit Partial Gap Coverage File option on the Formulary Submission Start page after your Formulary is successfully validated and sent to desk review. If a supplemental file is not applicable for your Formulary, skip to step 6.

STEP 3A

Select the "This Formulary does not require changes to the previously uploaded copy of the Free First Fill Supplemental File" option if no changes are required to the previous uploaded Free First Fill file against the revised Formulary (if applicable). See Exhibit 19.

STEP 3B

Select the "This Formulary requires changes to the Free First Fill Supplemental File" option if changes are required to the previous uploaded Free First Fill file against the revised Formulary (if applicable). See Exhibit 19.

Note that you must upload your Free First Fill supplemental file through the HPMS Submit Free First Fill File option on the Formulary Submission Start page after your Formulary is successfully validated and sent to desk review. If a supplemental file is not applicable for your Formulary, skip to step 6.

STEP 4A
Select the "This Formulary does not require changes to the previously uploaded copy of the Home Infusion Supplemental File" option if no changes are required to the previous uploaded Home Infusion file against the revised Formulary (if applicable). See Exhibit 19.

STEP 4B
Select the "This Formulary requires changes to the Home Infusion Supplemental File" option if changes are required to the previous uploaded Home Infusion file against the revised Formulary (if applicable). See Exhibit 19.

Note that you must upload your Home Infusion supplemental file through the HPMS Submit Home Infusion File option on the Formulary Submission Start page after your Formulary is successfully validated and sent to desk review. If a supplemental file is not applicable for your Formulary, skip to step 6.

STEP 5A
Select the "This Formulary does not require changes to the previously uploaded copy of the Value-Based Insurance Design Supplemental File" option if no changes are required to the previous uploaded Value-Based Insurance Design file against the revised Formulary (if applicable). See Exhibit 19.

STEP 5B
Select the "This Formulary requires changes to the Value-Based Insurance Design Supplemental File" option if changes are required to the previous uploaded Value-Based Insurance Design file against the revised Formulary (if applicable). See Exhibit 19.

Note that you must upload your Value-Based Insurance Design supplemental file through the HPMS Submit Value-Based Insurance Design File option on the Formulary Submission Start page after your Formulary is successfully validated and sent to desk review. If a supplemental file is not applicable for your Formulary, skip to step7.

STEP 6A
Select the "Formulary includes Prior Authorization Type 3 drugs only" radio button if the Formulary has PA type 3 only. If this option is selected, no file upload is required. Skip to step 8. See Exhibit 19.

STEP 6B
Select the "Use previously uploaded copy of the Prior Authorization File" if you are not making any changes to your prior authorization criteria. See Exhibit 19.

STEP 6C
Select the "Select Prior Authorization File for Upload" radio button if the Formulary has PA Type 1 or 2. Enter the full path and name of the Prior Authorization File (Tab delimited .txt file only) in the "Prior Authorization File" field or click the "Browse" button to locate and attach the file. See Exhibit 19.

Note: If you selected "No" for the prior authorization question from the Formulary Information page, this field will not be displayed.

After the initial submission period, the Partial PA file may include a value of "ADD" when a PA Group Description is added to the Formulary or "UPD" when CMS has requested a change to the PA criteria. The system will automatically delete any PA Group Descriptions from the PA file that are not in the Formulary.

STEP 7A

Select "Use previously uploaded copy of the Step Therapy File" if you are not making any changes to your step therapy criteria. See Exhibit 19.

STEP 7B

Enter the full path and name of the Step Therapy File (Tab delimited .txt file only) in the "Step Therapy File" field or click the "Browse" button to locate and attach the file (Exhibit 19).

Note: If you selected "No" for the step therapy question from the Formulary Information page, this field will not be displayed.

After the initial submission period, the Partial ST file may include a value of "ADD" when an ST Group Description is added to the Formulary or "UPD" when CMS has requested a change to the ST criteria. The system will automatically delete any ST Group Descriptions from the ST file that are not in the Formulary.

Note: You will receive an email communication from CMS when PA/ST edits are requested on the Group Descriptions that require criteria updates.

STEP 8A

Select "Use previously uploaded copy of the Indication-Based Coverage File" if you are not making any changes to your IBC file. See Exhibit 19.

STEP 8B

Enter the full path and name of the IBC File (Tab delimited .txt file only) in the "Indication-Based Coverage File" field or click the "Browse" button to locate and attach the file (Exhibit 19).

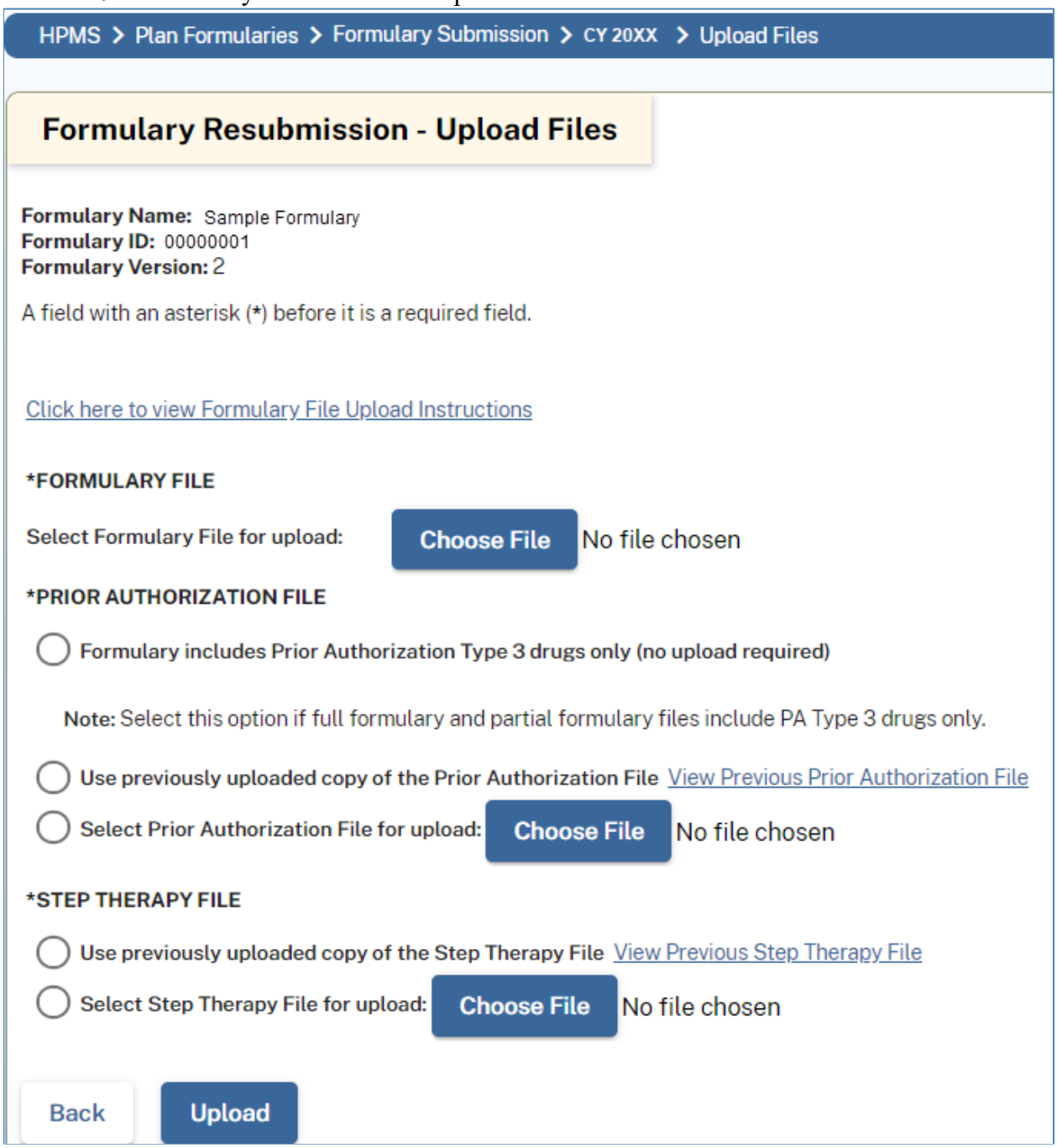
Note: If you selected "No" for the IBC question from the Formulary Information page, this field will not be displayed.

Note: You will receive an email communication from CMS when an IBC resubmission is requested that requires updates.

STEP 9

Click the "Upload" button to prepare your files for submission to HPMS and to continue to the Formulary Resubmission - Verify Resubmission page. Please wait until the file transfer is complete before attempting to navigate further.

Exhibit 19 – Formulary Resubmission - Upload Files



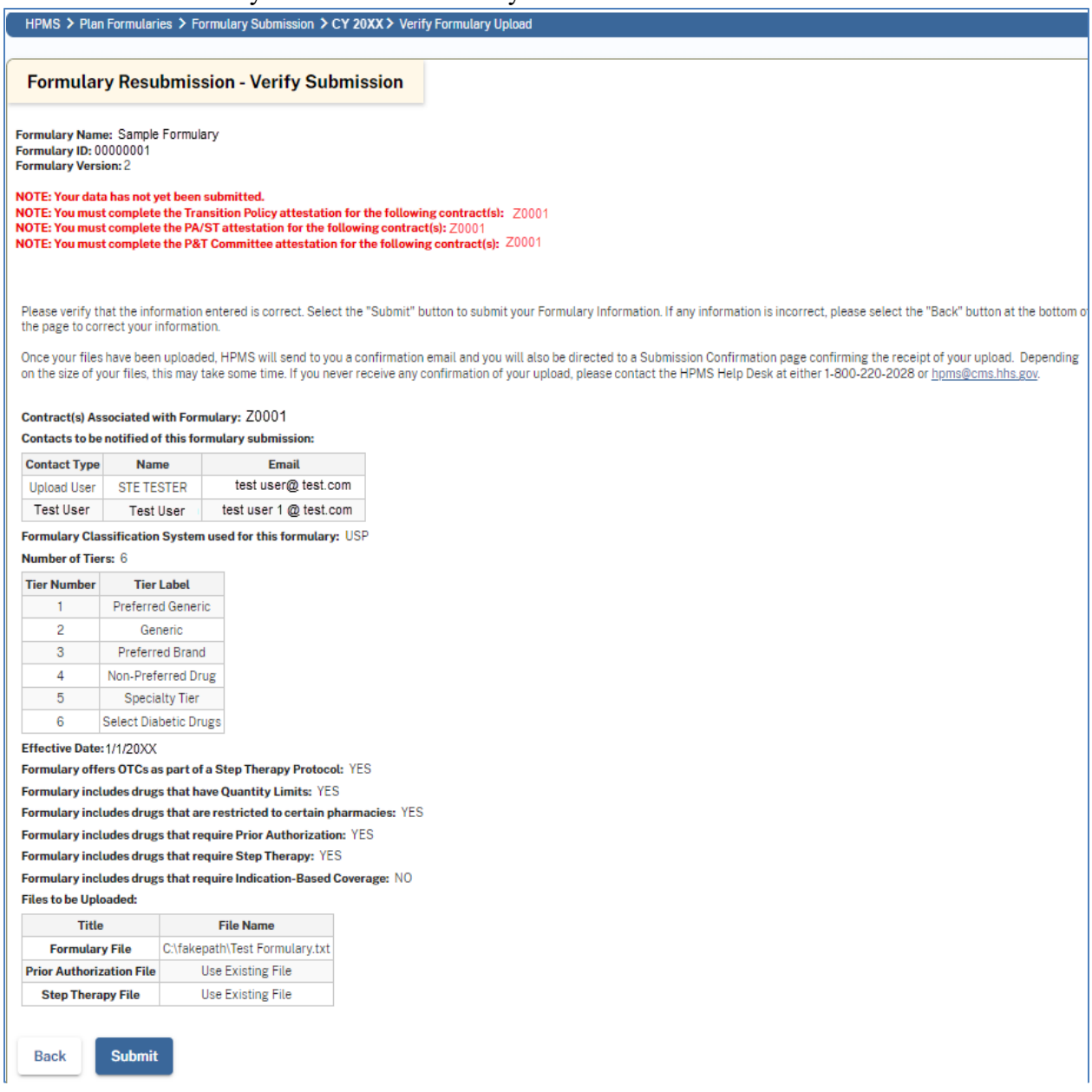
VERIFY RESUBMISSION

The **Formulary Resubmission - Verify Resubmission** page allows you to verify the information you entered during the resubmission process before you complete the upload and resubmit the information to CMS.

STEP 1

On the **Formulary Resubmission - Verify Resubmission** page (Exhibit 20), review the information for accuracy.

Exhibit 20 – Formulary Resubmission - Verify Submission



STEP 2A

If any information is incorrect, click the "Back" button to correct the information as necessary by returning to the appropriate pages.

STEP 2B

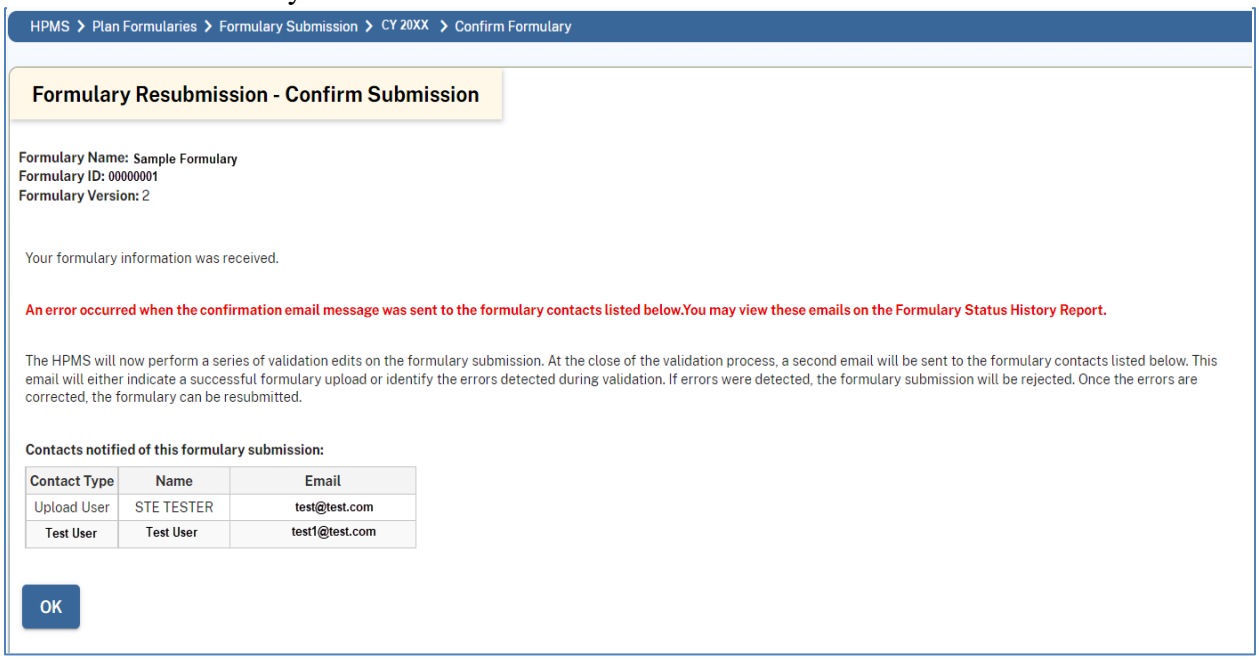
If all information is correct, click the "Submit" button to send the resubmission to CMS for review. This will take you to the Formulary Resubmission – Confirm Submission page.

CONFIRM SUBMISSION

The **Formulary Resubmission - Confirm Submission** page provides a status of the successful upload. This page will also generate an email to both the Formulary Contract and the Formulary Upload Contact identified on this page acknowledging receipt of the resubmission.

On the **Formulary Resubmission - Confirm Submission** page (Exhibit 21) review the information. Click the "OK" button to return to the Formulary Submission Start Page.

Exhibit 21 – Formulary Resubmission - Confirm Submission



At this point, you have finished resubmitting your new Formulary and need to wait for an email regarding the status of your resubmission. After receiving the uploaded Formulary file, HPMS will perform a series of validation edits. At the close of the validation process, a follow-up email will be sent to the designated Formulary contacts. This email will indicate that the Formulary was successfully validated or identify errors detected during the validation process. If errors were detected, the Formulary resubmission will be rejected.

Note: If the reused supplemental file is not sync with the new Formulary version, the supplemental file will be rejected by validation and validation errors are sent in a separate email (if applicable).

REVISE PA/ST CRITERIA ONLY

During the Formulary Review period (initial review and monthly update), if there are PA/ST file errors on your Formulary and PA/ST files you submitted previously, you will receive an ACTION REQUIRED email with the PA/ST Group Descriptions that require addition or criteria update. You will be required to upload a PA/ST file using the **Revise PA/ST Criteria** page. When you have successfully uploaded all the required changes, you will receive the Formulary successfully validated email.

Note that any PA/ST Group Descriptions that are removed from the Formulary will automatically be deleted from the PA/ST file. You will receive a confirmation of these deletions in the "Formulary – Processing Results" email.

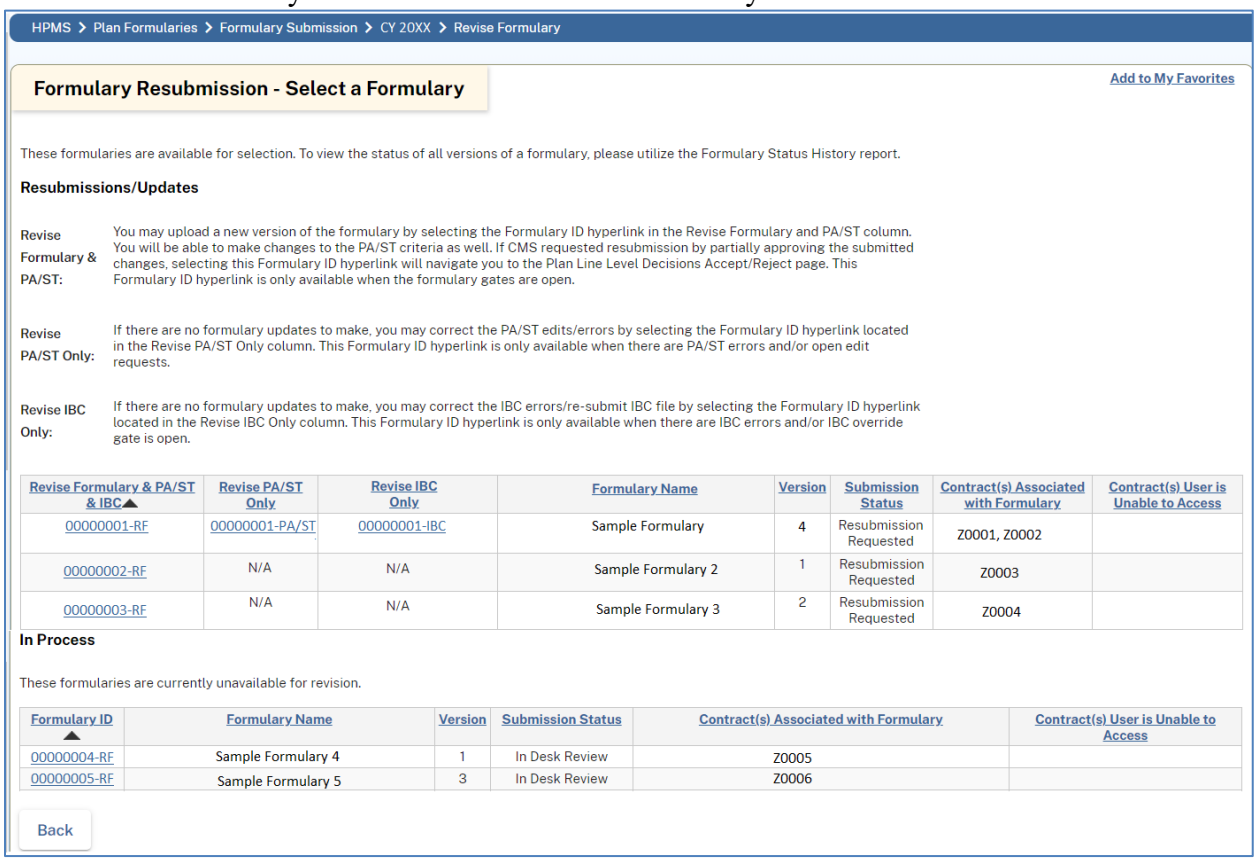
In addition to this, CMS may request revision to specific Group Descriptions. You will receive an email from CMS directing you to change your PA/ST criteria. If you are making changes to the PA/ST files only, and not the Formulary file, you may go directly to the Revise PA/ST Criteria page and upload your changes. The record format is the same as for the initial upload. You may only upload changes for the records that display on the page. The changes will be applied to the last version in desk review that is not Denied or Withdrawn. **If you are also making changes to your Formulary, you must upload the Formulary and PA/ST files together by selecting "Revise Formulary & PA/ST files" option on the Revise Formulary page.** After the files are successfully validated, the new version will be migrated to desk review.

In summary, you may go to the **Revise PA/ST Criteria** page to update PA/ST criteria and make the following changes:

- Add a PA/ST record when the PA/ST Group Description is in the Formulary file and not in the PA/ST file
- Update a PA/ST record when requested by CMS.

As shown in Exhibit **15**, click the "**Revise PA/ST Criteria Only**" hyperlink from the Formulary Resubmission – Select a Formulary page. This will take you to the Revise PA/ST Criteria – Upload page (Exhibit 23).

Exhibit 22 – Formulary Resubmission - Select a Formulary



Only the records that are displayed on the page may be submitted in the update file. The records should be in the same format as the initial PA/ST submission file. The system will only permit the action displayed on the page.

ADD: You must add a PA/ST record when you add a PA/ST Group Description to the Formulary.

UPD – You must update a PA/ST record already existing on the approved file; the system only permits the following actions:

- You must update a PA/ST record when requested by CMS.
- At least one field should be changed for the update to be successful.

Note: You should not update the PA/ST record if you are deleting the PA/ST Group Description from your Formulary. The system will automatically delete the PA/ST Group Description from the PA/ST file when it is removed from the Formulary file.

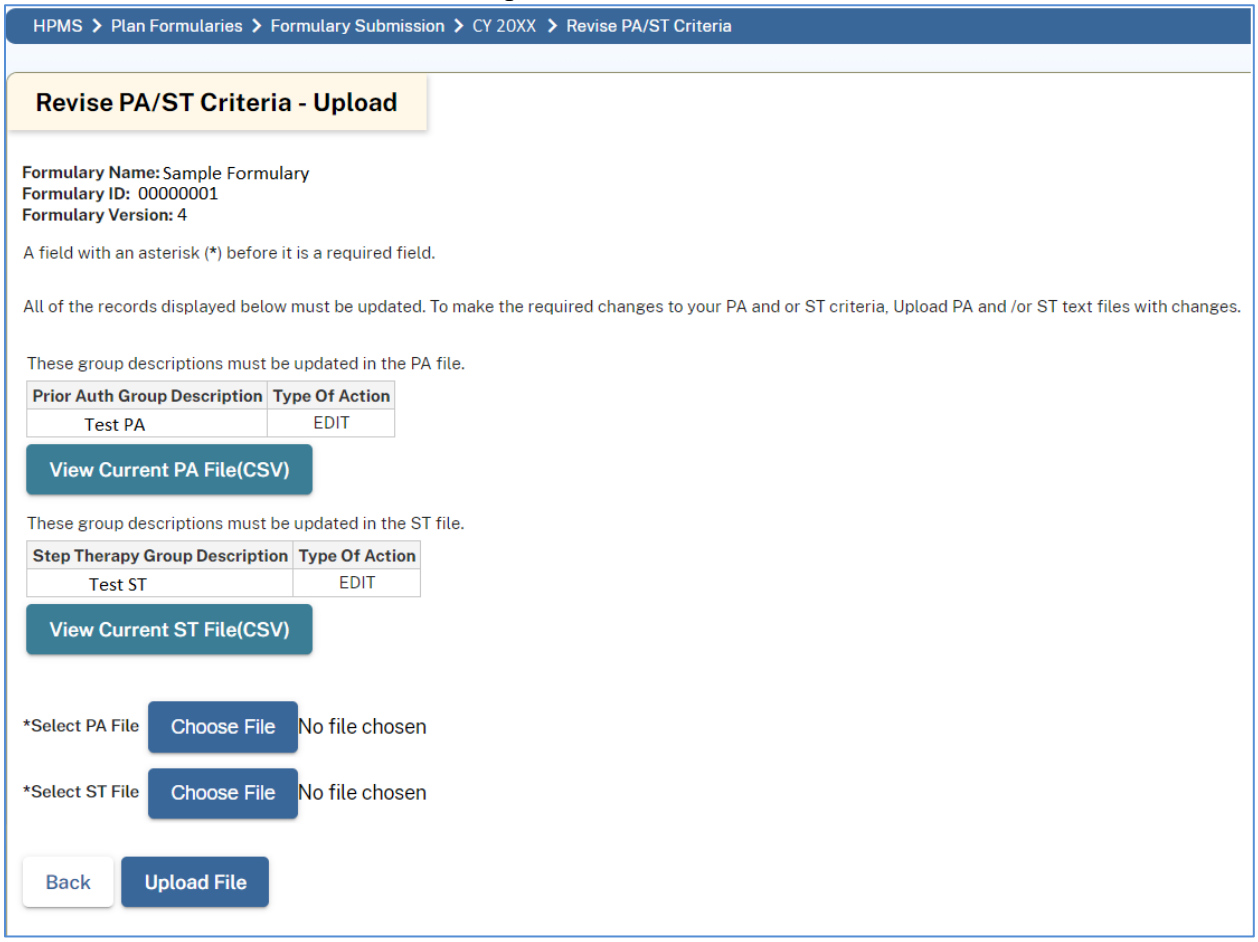
REVISE PA/ST CRITERIA – UPLOAD

The **Revise PA/ST Criteria – Upload** page allows you to specify the Prior Authorization File and Step Therapy File you want to upload. The page will pre-determine what you need to upload based on Formulary validation errors or CMS revision requests. This page displays PA and ST Group Descriptions that need to be added based on the Formulary file submission. This includes:

- PA/ST Group Descriptions that were added to your Formulary
- PA/ST Group Descriptions that were uploaded on the revise Formulary page but failed validation
- PA and ST Group Descriptions requiring revision based upon CMS review

This page also displays links to current PA/ST criteria associated with the latest version of the Formulary that is successfully sent to desk review and are not denied or withdrawn.

Exhibit 23 – Revise PA/ST Criteria - Upload



Only the records that are available on the page should be included in the partial file. Records with the Type of Action of "Edit" should have at least one field other than the Group Description updated in order to pass validation.

Both PA/ST files must be uploaded at the same time. If at least one file fails, both files will be rejected. After correcting the errors, both files must be uploaded again.

STEP 1

Enter the full path and name of the Prior Authorization File (tab delimited .txt file only) in the Step Therapy File field or click the "Browse" button to locate and attach the file (Exhibit 23).

Note: If there were no Prior Authorization file errors during Formulary revision or no pending CMS revision requests, this field will not be displayed.

STEP 2

Enter the full path and name of the Step Therapy File (tab delimited .txt file only) in the Step Therapy File field or click the "Browse" button to locate and attach the file (Exhibit 23).

Note: If there were no Step Therapy file errors during Formulary revision and no pending CMS revision requests, this field will not be displayed.

STEP 3

Click the "Upload" button to submit your files. This will take you to the Submission Confirmation page (Exhibit 24).

REVISE PA/ST ONLY -SUBMISSION CONFIRMATION

The **Revise PA/ST Criteria - Confirm Submission** page provides confirmation on validity of the files (Exhibit 24). If the files fail validation, an email with the subject "PA/ST Action Required – HPMS Formulary Upload 00000001-2 Errors" is sent to the Formulary Contacts listed on the page. If the files are successful Formulary contacts will receive "PA/ST Successful Upload – HPMS Formulary Upload 00000001-2" email.

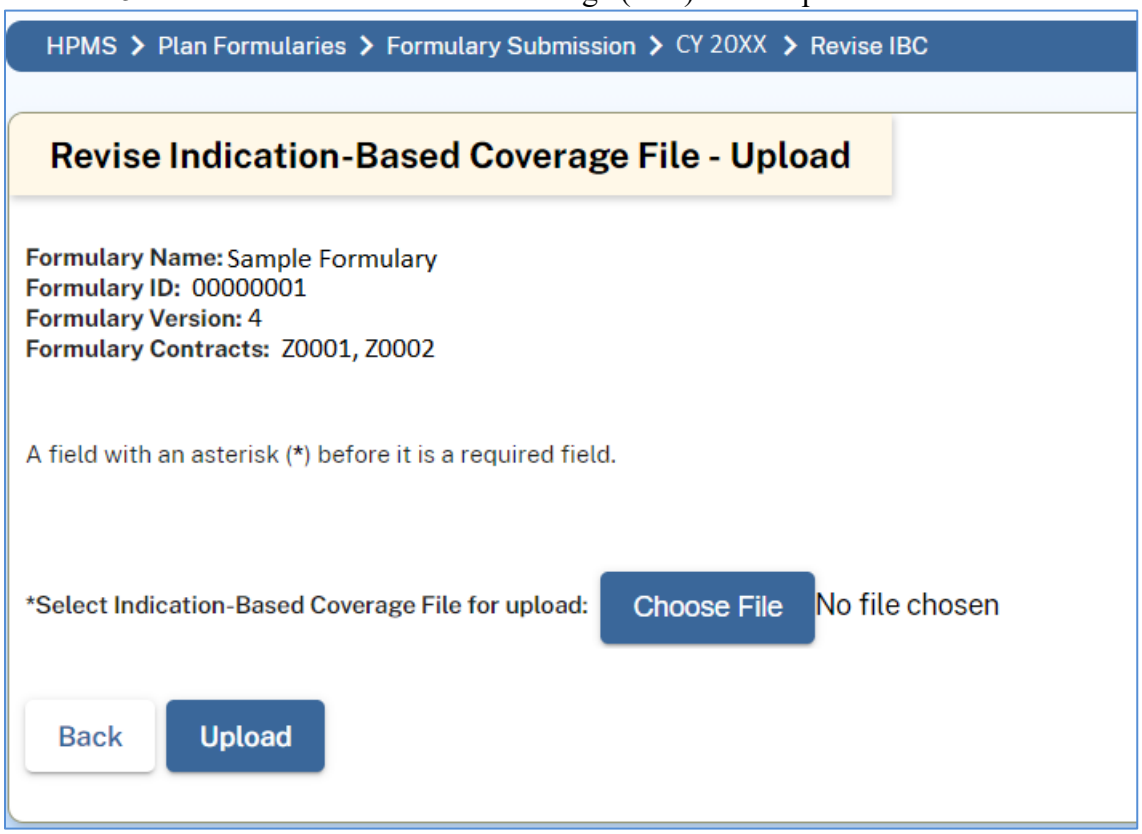
Exhibit 24 – Revise PA/ST - Confirmation

On the Revise PA/ST Criteria – Confirm Submission page (Exhibit 24), review the information.
Click the "OK" button to return to the Revise PA/ST Criteria – Select Formulary page.
At this point, you have finished resubmitting your new Formulary or PA/ST criteria revision.

REVISE INDICATION-BASED COVERAGE FILE – UPLOAD

The **Revise Indication-Based Coverage (IBC) File – Upload** page allows you to upload the Indication-Based Coverage File. The page will pre-determine what you need to upload based on Formulary validation errors or CMS revision requests.

Exhibit 25 – Revise Indication-Based Coverage (IBC) File - Upload



STEP 1

In the "Select Indication-Based Coverage File for Upload" field, select the "Choose File" button to locate and attach the file, tab delimited .txt file only (Exhibit 25).

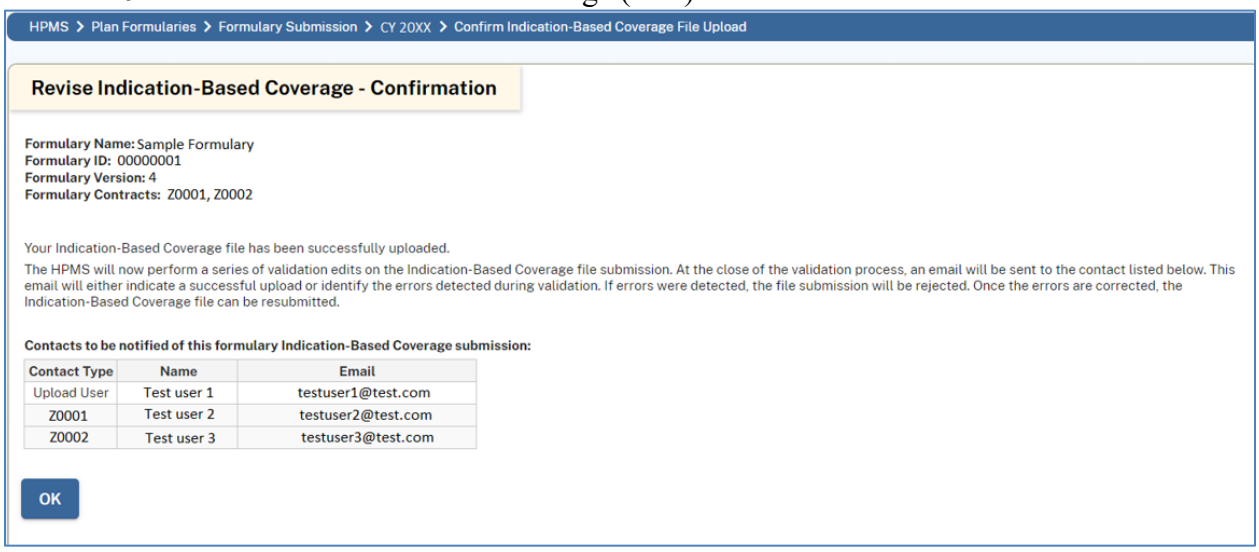
STEP 2

Click the "Upload" button to submit your files. This will take you to the Submission Confirmation page (Exhibit **26**).

REVISE IBC ONLY - SUBMISSION CONFIRMATION

The **Revise Indication-Based Covergae – Confirmation** page provides confirmation on validity of the files (Exhibit 26). If the IBC file fail validation, an email with the subject "Action Required – Indication-Based Coverage File Validation Rejected" is sent to the Formulary Contacts listed on the page. If the IBC files are successful Formulary, contacts will receive "Indication-Based Coverage File Validation Complete – 00000001-2" email.

Exhibit 26 – Revise Indication-Based Coverage (IBC) File – Confirmation



On the Revise Indication-Based Coverage – Confirmation page (Exhibit 26), review the information. Click the "OK" button to return to the Revise Formulary landing page.
At this point, you have finished resubmitting your IBC file.

IV. ACCEPT/REJECT LINE LEVEL CHANGES

CMS may find that your Formulary revision is partially acceptable. When this is the case, you will receive a resubmission request for your Formulary. When you select the Formulary from the Revise Formulary page, you will be directed to the Accept Line Level Decisions page. You may review the CMS decisions, and then confirm your acceptance. This creates a new version of the Formulary.

ACCESS TO THE LINE LEVEL DECISIONS PAGE

The system will automatically direct you to the Plan Line Level Decisions Accept/Reject page when you select a Formulary for revision.

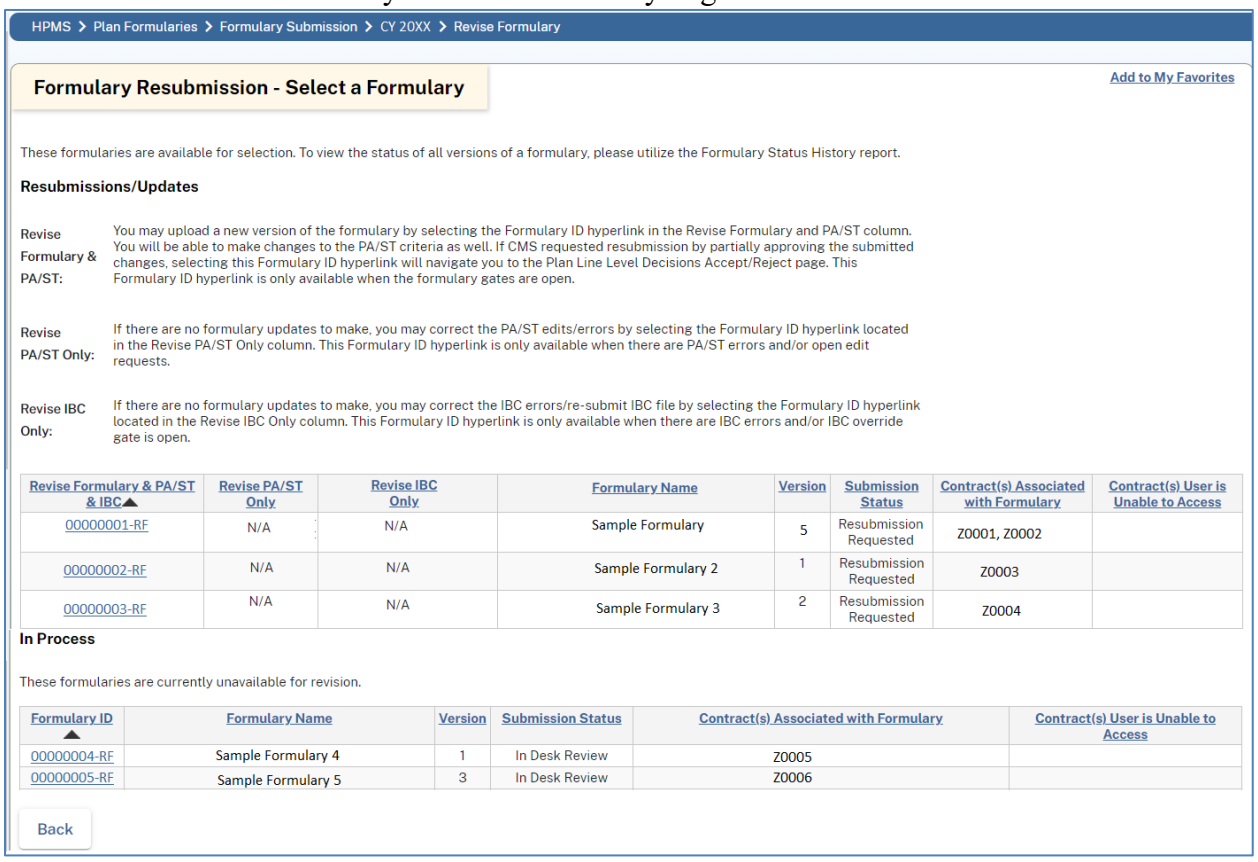
STEP 1

Select **Revise Formulary** from the Formulary Submission Start page (Exhibit 4). This will take you to the Select a Formulary page.

STEP 2

On the **Formulary Resubmission - Select a Formulary** page (Exhibit 15); click the "Revise Formulary & PA/ST & IBC" hyperlink for the Formulary to review. This will take you to the Plan Line Level Decision Accept/Reject page (Exhibit 28).

Exhibit 27 – Revise Formulary- Select a Formulary Page



HPMS > Plan Formularies > Formulary Submission > CY 20XX > Revise Formulary

Formulary Resubmission - Select a Formulary

Add to My Favorites

These formularies are available for selection. To view the status of all versions of a formulary, please utilize the Formulary Status History report.

Resubmissions/Updates

Revise Formulary & PA/ST: You may upload a new version of the formulary by selecting the Formulary ID hyperlink in the Revise Formulary and PA/ST column. You will be able to make changes to the PA/ST criteria as well. If CMS requested resubmission by partially approving the submitted changes, selecting this Formulary ID hyperlink will navigate you to the Plan Line Level Decisions Accept/Reject page. This Formulary ID hyperlink is only available when the formulary gates are open.

Revise PA/ST Only: If there are no formulary updates to make, you may correct the PA/ST edits/errors by selecting the Formulary ID hyperlink located in the Revise PA/ST Only column. This Formulary ID hyperlink is only available when there are PA/ST errors and/or open edit requests.

Revise IBC Only: If there are no formulary updates to make, you may correct the IBC errors/re-submit IBC file by selecting the Formulary ID hyperlink located in the Revise IBC Only column. This Formulary ID hyperlink is only available when there are IBC errors and/or IBC override gate is open.

Revise Formulary & PA/ST & IBC	Revise PA/ST Only	Revise IBC Only	Formulary Name	Version	Submission Status	Contract(s) Associated with Formulary	Contract(s) User is Unable to Access
00000001-RF	N/A	N/A	Sample Formulary	5	Resubmission Requested	Z0001, Z0002	
00000002-RF	N/A	N/A	Sample Formulary 2	1	Resubmission Requested	Z0003	
00000003-RF	N/A	N/A	Sample Formulary 3	2	Resubmission Requested	Z0004	

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
00000004-RF	Sample Formulary 4	1	In Desk Review	Z0005	
00000005-RF	Sample Formulary 5	3	In Desk Review	Z0006	

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PLAN LINE LEVEL DECISIONS ACCEPT/REJECT

The **Plan Line Level Decisions Accept/Reject** page displays the RxCUI, Change Type, Brand Name, SCDC, and Dose Form for each drug in your Formulary revision file, as well as the associated CMS Decision and Comment To Plan. The page also provides links to the Non-Allowable Change Report and the Update Outlier Report for the submitted version of the Formulary. When you accept the changes, the system will create a new version of the Formulary that includes only the approved changes. You will not need to upload another revision file.

Note: If your Formulary is associated with a Partial Gap Coverage, Free First Fill, Home Infusion or Value-Based Insurance Design supplemental file, follow steps 1-4 unless you failed to submit your required supplemental file(s) in your prior monthly update. In this case, the options to reuse or submit a new file will not be available to you at this time. You must return to the submission module following the successful validation of your Formulary to submit your supplemental files. You may submit these files using the Submit Home Infusion File, Submit Free First Fill File, Submit Partial Gap Coverage File or Submit Value-Based Insurance Design File options on the Formulary Submission Start page. Failure to upload the required supplemental files may result in a compliance action.

STEP 1A

Select the "This Formulary does not require changes to the previously uploaded copy of the Partial Gap Coverage Supplemental File" option if no changes are required to the previously uploaded Partial Gap Coverage file with respect to the revised Formulary (if applicable).

STEP 1B

Select the "This Formulary requires changes to the Partial Gap Coverage Supplemental File" option if changes are required to the previously uploaded Partial Gap Coverage file with respect to the revised Formulary (if applicable).

Note that you must upload your Partial Gap Coverage supplemental file using the HPMS Submit Partial Gap Coverage File option on the Formulary Submission Start page after your Formulary is successfully validated and sent to desk review. If a supplemental file is not applicable for your Formulary, skip to step 5.

STEP 2A

Select the "This Formulary does not require changes to the previously uploaded copy of the Free First Fill Supplemental File" option if no changes are required to the previously uploaded Free First Fill file with respect to the revised Formulary (if applicable).

STEP 2B

Select the "This Formulary requires changes to the Free First Fill Supplemental File" option if changes are required to the previously uploaded Free First Fill file with respect to the revised Formulary (if applicable).

Note that you must upload your Free First Fill supplemental file using the HPMS Submit Free First Fill File option on the Formulary Submission Start page after your Formulary is successfully validated and sent to desk review. If a supplemental file is not applicable for your Formulary, skip to step 5.

STEP 3A
Select the "This Formulary does not require changes to the previously uploaded copy of the Home Infusion Supplemental File" option if no changes are required to the previously uploaded Home Infusion file with respect to the revised Formulary (if applicable).

STEP 3B
Select the "This Formulary requires changes to the Home Infusion Supplemental File" option if changes are required to the previously uploaded Home Infusion file with respect to the revised Formulary (if applicable).

Note that you must upload your Home Infusion supplemental file using the HPMS Submit Home Infusion File option on the Formulary Submission Start page after your Formulary is successfully validated and sent to desk review. If a supplemental file is not applicable for your Formulary, skip to step 5.

STEP 4A
Select the "This Formulary does not require changes to the previously uploaded copy of the Value-Based Insurance Design Supplemental File" option if no changes are required to the previously uploaded Value-Based Insurance Design file with respect to the revised Formulary (if applicable).

STEP 4B
Select the "This Formulary requires changes to the Value-Based Insurance Design Supplemental File" option if changes are required to the previously uploaded Value-Based Insurance Design file with respect to the revised Formulary (if applicable).

Note that you must upload your Value-Based Insurance Design supplemental file using the HPMS Submit Value-Based Insurance Design File option on the Formulary Submission Start page after your Formulary is successfully validated and sent to desk review. If a supplemental file is not applicable for your Formulary, skip to step 5.

STEP 5A
Review CMS decisions for each record and click the "Accept" button. This will take you to the Formulary Resubmission – Confirm Submission page (Exhibit 28).

The new version of the Formulary will be validated again. You will receive an email confirmation when the Formulary is successfully validated.

Note: While "Accepting" the review decisions results in the creation of a new version of the Formulary to include only those changes that are deemed allowable, there is an exception to this process. If a protected class drug is added to the Formulary during the submission window with unacceptable attributes, such as tier or UM edits (PA, ST or QL), CMS will deny the record. By accepting the decisions through this line level process, the new Formulary that is created will not contain the protected class drug. If the protected class drug is required on formularies with the current submission, then the Formulary as a whole will be denied due to the drug's absence on the newly created file. This will result in Plan Finder suppression.

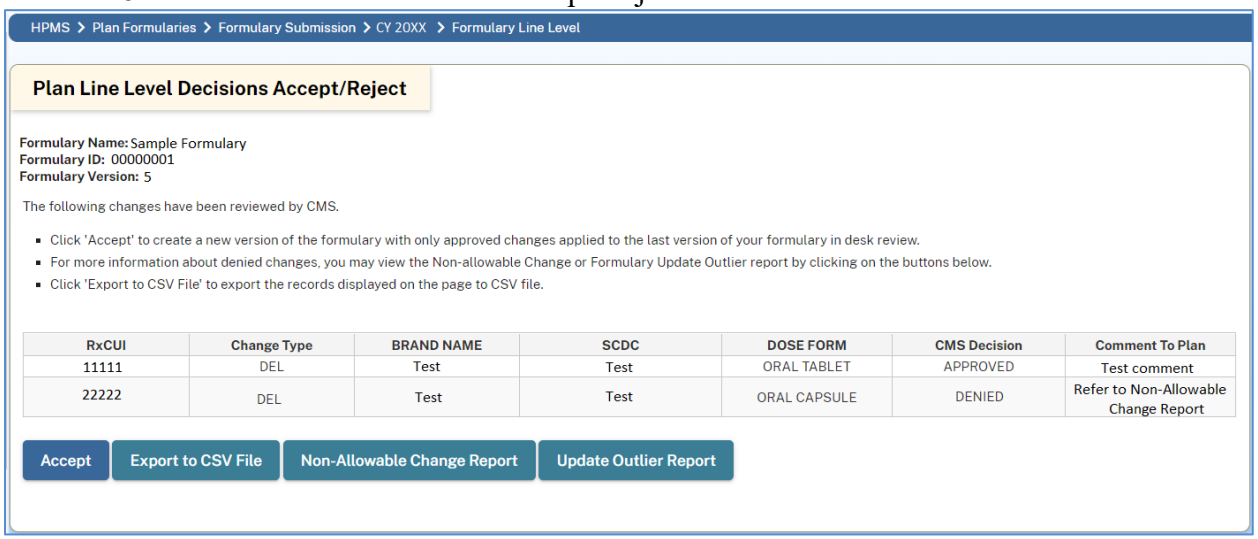
Note: You can view the contents of the new Formulary on the Formulary Status History report by clicking the Full Formulary File option.

STEP 5B

Click the "Reject" button if you do not want a new version of the Formulary to be created, applying only the approved changes. Rejecting the Line Level Decisions will automatically update the status of the Formulary to DENIED.

Note: The "Reject" button is not displayed on the Plan Line Level Decision Accept/Reject page unless there is an approved version of the Formulary.

Exhibit 28 – Plan Line Level Decision Accept/Reject

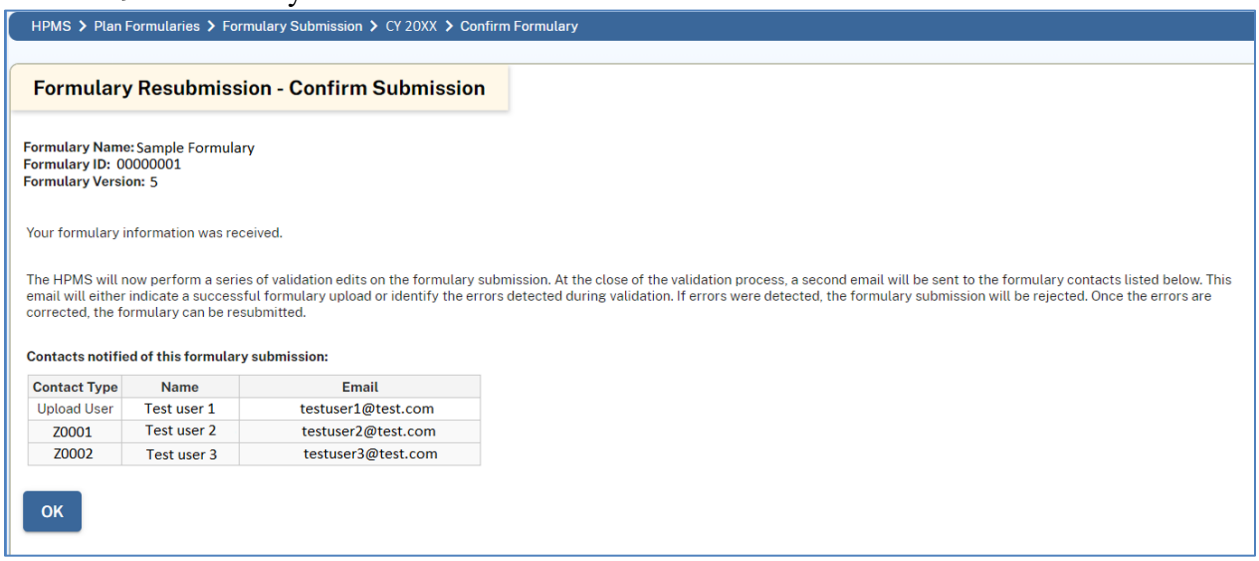


CONFIRM SUBMISSION

The **Formulary Resubmission - Confirm Submission** page provides a status of the successful upload. This page will also generate an email to both the Formulary Contact and the Formulary Upload Contact identified on this page acknowledging receipt of the resubmission.

On the **Formulary Resubmission - Confirm Submission** page (Exhibit 29) review the information. Click the "OK" button to return to the Formulary Submission Start Page.

Exhibit 29 – Formulary Resubmission - Confirm Submission



V. DELETE FORMULARY

The **Delete Formulary** page allows you to delete existing formularies that have never been approved. You should only delete a Formulary if you are certain that it is obsolete.

How to Determine Which Formularies Are Eligible For Deletion

Select **Delete Formulary** from the **Formulary Submission Start Page** (Exhibit 4). If you need help getting to the Formulary Submission Start Page, see the sub-section entitled "How to Access the HPMS Formulary submission Module" in Chapter I. This will take you to the Delete a Formulary Submission-Select a Formulary page.

The Delete Formulary - Select a Formulary page (Exhibit 30) groups formularies in two sections:

Available for deletion – This table displays the formularies that are eligible for deletion.

Unavailable for deletion – This table displays the formularies that are approved by CMS, In Desk Review or uploaded but not processed are not eligible for deletion. After the plan-to-Formulary crosswalk is locked, formularies associated with the plans are not available for deletion.

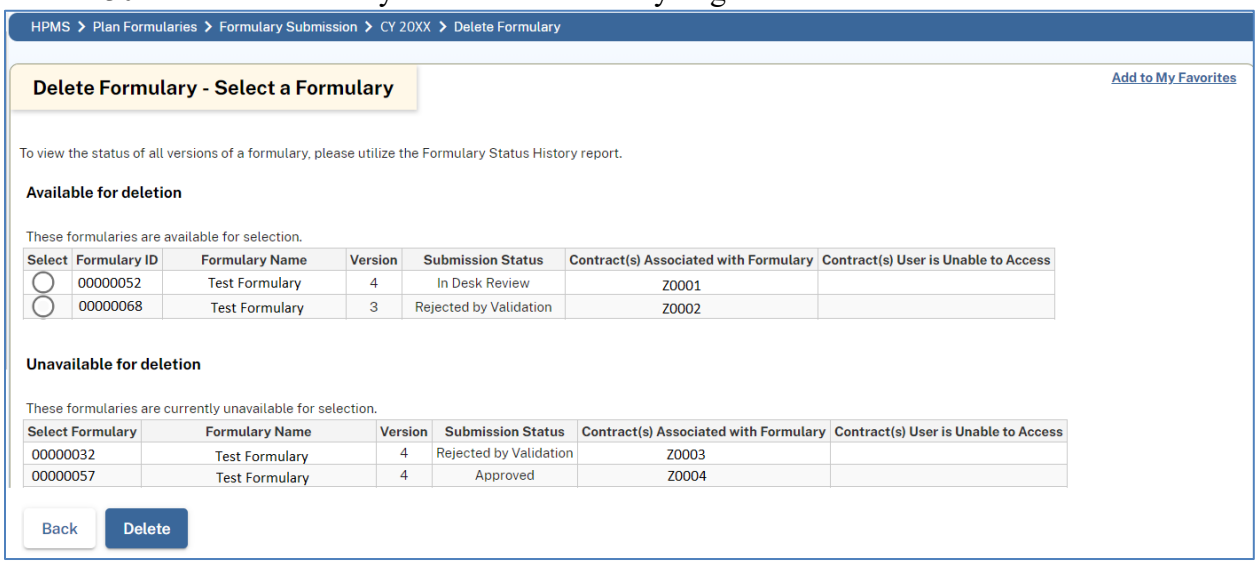
As noted above, you can only delete formularies in the "Available for Deletion" section.

Delete A Formulary

Step 1

On the **Delete Formulary - Select a Formulary** page (Exhibit 30), select the Formulary you wish to delete.

Exhibit 30 – Delete Formulary – Select a Formulary Page



Step 2

Click the "Delete" button. This will take you to the Delete a Formulary Submission - Verify Deletion page.

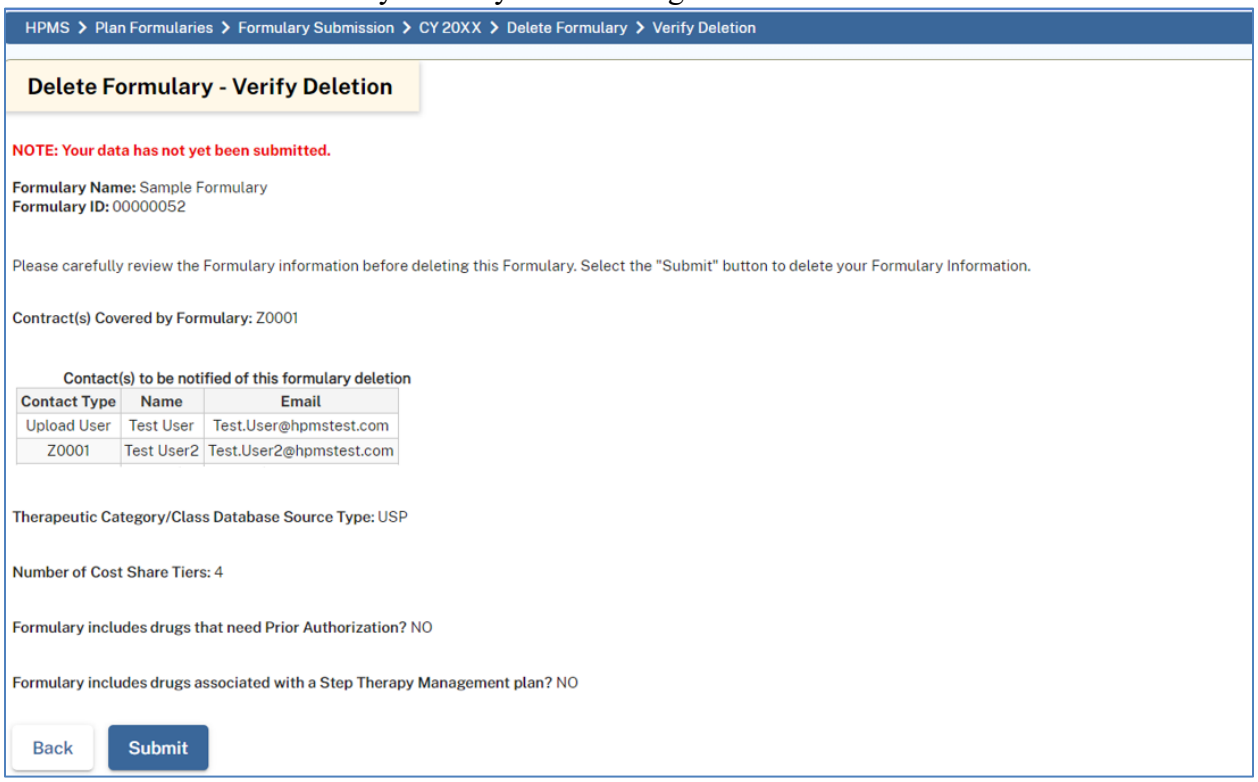
VERIFY DELETION

The Verify Deletion page allows you to verify Formulary information before you delete the Formulary.

STEP 3

On the **Delete a Formulary Submission - Verify Deletion** page (Exhibit 31), review the page carefully and select the "Submit" button to finalize the deletion. This will take you to the Delete a Formulary Submission - Deletion Confirmation page.

Exhibit 31 – Delete Formulary – Verify Deletion Page



DELETION CONFIRMATION

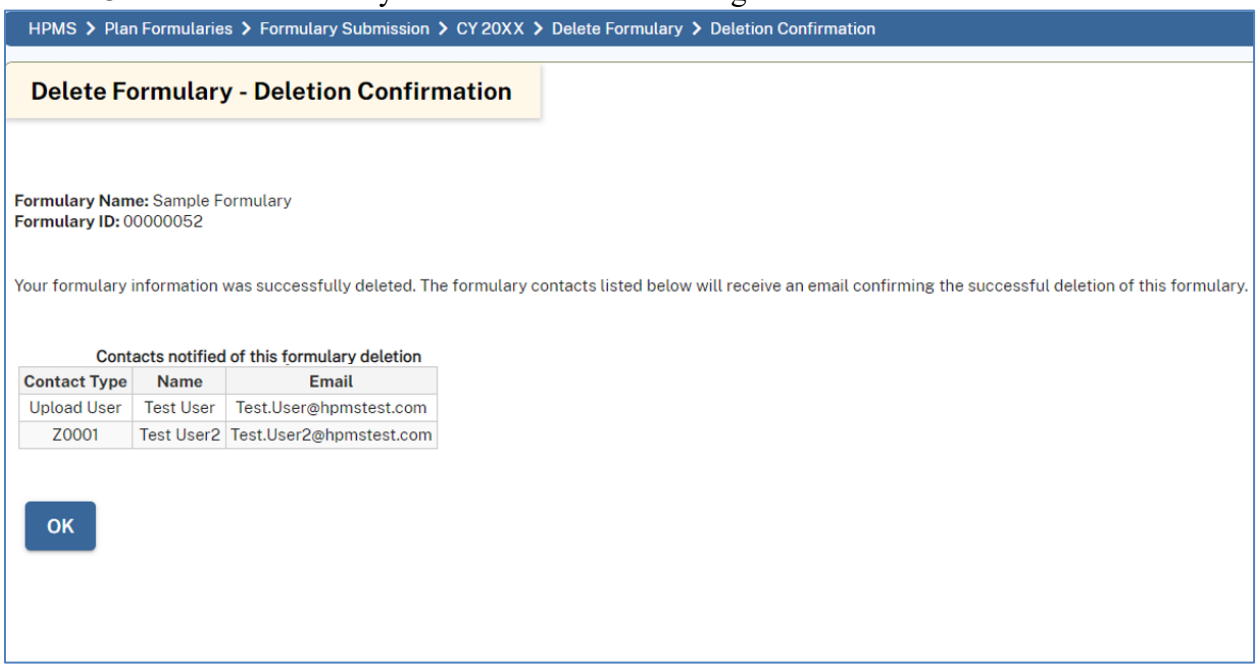
The **Submission Confirmation** page confirms successful deletion of your Formulary. This page will also generate an email to all Formulary Contacts and the Formulary Upload Contact identified on this page, confirming successful deletion of the Formulary.

STEP 4

On the **Delete a Formulary Submission - Deletion Confirmation** page (Exhibit 32), select the "OK" button to return to the Formulary Submission Start Page.

Note: You can also refer to the Formulary Status History report to verify successful deletion of the Formulary.

Exhibit 32 – Delete Formulary – Delete Confirmation Page



VI. SUBMIT FORMULARY TRANSITION POLICY ATTESTATION

All organizations must attest and upload their Transition Policy as a part of their Formulary submission. While the Formulary submission is not dependent on Formulary Transition Policy submission in HPMS, you must successfully submit the Formulary Transition Policy before CMS will renew or approve your Part D contract. A Transition Policy status is successfully submitted when the following steps are completed:

- Authorization is attested.
- All attestation questions are answered "Yes." For Employer Organizations / Plan Types, all attestation questions are answered "Yes" except attestation #14.
- Implementation Statement is contained within the submitted transition policy.
- A transition policy is uploaded.

If you need to revise a previously submitted Formulary Transition Policy, you should use the Revise Transition Policy Function (refer to Chapter VII).

STEP 1

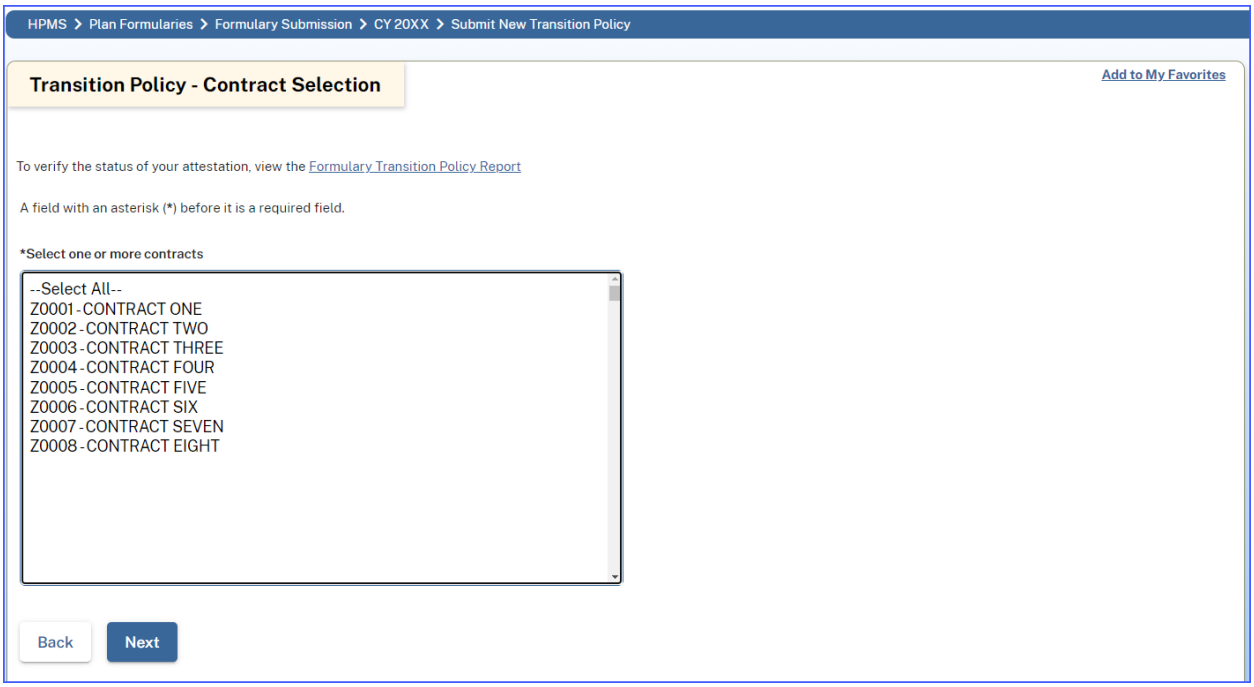
Select **Submit New Transition Policy** from the **Formulary Submission Start** page (Exhibit 4). This will take you to the Transition Submission Selection Contract page.

TRANSITION SUBMISSION - SELECT CONTRACT

STEP 2

On the **Transition Submission - Select Contract** page (Exhibit 33), select one or more of the contracts listed on the page to associate with the Formulary Transition Policy and click the "Next" button. This will take you to the Transition Submission – Attestation Questions page. If you cannot see one of your contracts, please refer to Section I – Getting Started.

Exhibit 33 – Transition Submission - Contract Selection



TRANSITION SUBMISSION – ATTESTATION QUESTIONS

STEP 3

On the **Transition Submission – Attestation Questions** page (Exhibit 34), click the attestation authorization check box to indicate that you are authorized to submit the Attestation on behalf of your organization.

Exhibit 34 – Transition Submission - Attestation Questions

HPMS > Plan Formularies > Formulary Submission > CY 20XX > Submit New Transition Policy > Attestation Questions

Transition Policy - Attestation Questions

Contract(s) Selected: Z0001

NOTE: All attestation questions must be answered "Yes", with the exception of all Pace Organizations, Employer plans, and Employer only (800 series) can answer "No" to attestation #14.

A field with an asterisk (*) before it is a required field.

ATTESTATION AUTHORIZATION

☐ *** I attest that I have authorization to complete the transition policy attestations on behalf of my organization. I agree to maintain and make available upon request reports, working documents, and other records to verify and substantiate the information provided in the below attestation.**

IMPLEMENTATION STATEMENT

☐ *** An Implementation Statement is contained within the submitted transition policy that provides a detailed explanation of how Part D sponsors process transition requests within their adjudication system; how the pharmacy is notified when transition medication is processed at the point of sale; description of edits and explanation of the process pharmacies follow to resolve transition medication edits at the point of sale.**

Sponsor must attest 'YES' to each of the following qualifications regarding a transition process for enrollees in order to be approved or renewed for a Part D contract.

Question Number	Question Text	Answer
1	Sponsor will maintain an appropriate transition process consistent with 42 CFR §423.120(b)(3) that includes a written description of how, for enrollees whose current drug therapies may not be included in their new Part D plan's formulary, it will effectuate a meaningful transition for: (1) new enrollees into prescription drug plans following the annual co-ordinated election period, (2) newly eligible Medicare beneficiaries from other coverage, (3) enrollees who switch from one<>;,. plan to another after the start of a contract year, (4) current enrollees affected by negative formulary changes across contract years, (5) enrollees residing in long-term care (LTC) facilities. test	◯ Yes ◯ No
2	Sponsor will submit a copy of its transition process policy.	◯ Yes ◯ No
3	Sponsor will ensure that its transition policy will apply to non-formulary drugs, meaning both (1) Part D drugs that are not on a plan's formulary, and (2) Part D Drugs that are on a plan's formulary but require prior authorization or step therapy, or that have an approved QL lower than the beneficiary's current dose, under a plan's utilization management rules. Sponsor will ensure that its policy addresses procedures for medical review of non-formulary drug requests, and when appropriate, a process for switching new Part D plan enrollees to therapeutically appropriate formulary alternatives failing an affirmative medical necessity determination.	◯ Yes ◯ No
4	Sponsor will have systems capabilities that allow them to provide a temporary supply of non-formulary Part D drugs in order to accommodate the immediate needs of an enrollee, as well as to allow the plan and/or the enrollee sufficient time to work with the prescriber to make an appropriate switch to a therapeutically equivalent medication or the completion of an exception request to maintain coverage of an existing drug based on medical necessity reasons.	◯ Yes ◯ No
5	Sponsor will ensure that in the retail setting, the transition policy provides for a one time temporary fill of at least a month's supply of medication (unless the enrollee presents with a prescription written for less than a month's supply in which case the Part D sponsor must allow multiple fills to provide up to a total of a month's supply of medication) anytime during the first 90 days of a beneficiary's enrollment in a plan, beginning on the enrollee's effective date of coverage.	◯ Yes ◯ No
6	Sponsor will ensure that cost-sharing for a temporary supply of drugs provided under its transition process will never exceed the statutory maximum co-payment amounts for low-income subsidy (LIS) eligible enrollees. For non-LIS enrollees, a sponsor must charge the same cost sharing for non-formulary Part D drugs provided during the transition that would apply for non-formulary drugs approved through a formulary exception in accordance with 42 CFR §423.578(b) and the same cost sharing for formulary drugs subject to utilization management edits provided during the transition that would apply if the utilization management criteria are met.	◯ Yes ◯ No
7	Sponsor will ensure that in the long-term care setting: (1) the transition policy provides for a one time temporary fill of at least a month's supply (unless the enrollee presents with a prescription written for less) which should be dispensed incrementally as applicable under 42 CFR §423.154 and with multiple fills provided if needed during the first 90 days of a beneficiary's enrollment in a plan, beginning on the enrollee's effective date of coverage (2) after the transition period has expired, the transition policy provides for a 31-day emergency supply of non-formulary Part D drugs (unless the enrollee presents with a prescription written for less than 31 days) while an exception or prior authorization is requested and (3) for enrollees being admitted to or discharged from a LTC facility, early refill edits are not used to limit appropriate and necessary access to their Part D benefit, and such enrollees are allowed to access a refill upon admission or discharge.	◯ Yes ◯ No
8	Sponsor will only apply the following utilization management edits during transition at point-of-sale: edits to determine Part A or B versus Part D coverage, edits to prevent coverage of non-Part D drugs, and edits to promote safe utilization of a Part D drug. Step therapy and prior authorization edits must be resolved at point-of-sale.	◯ Yes ◯ No
9	Sponsor will ensure that the transition policy provides refills for transition prescriptions dispensed for less than the written amount due to quantity limit safety edits or drug utilization edits that are based on approved product labeling.	◯ Yes ◯ No
10	Sponsor will ensure that it will apply all transition processes to a brand-new prescription for a non-formulary drug if it cannot make the distinction between a brand-new prescription for a non-formulary drug and an ongoing prescription for a non-formulary drug at the point-of-sale.	◯ Yes ◯ No
11	Sponsor will send written notice consistent with CMS transition requirements.	◯ Yes ◯ No
12	Sponsor will make available prior authorization or exceptions request forms upon request to both enrollees and prescribing physicians via a variety of mechanisms, including mail, fax, email, and on plan web sites.	◯ Yes ◯ No
13	Sponsor will extend its transition policy across contract years should a beneficiary enroll in a plan with an effective enrollment date of either November 1 or December 1 and need access to a transition supply.	◯ Yes ◯ No
14	Sponsor will make their transition policy available to enrollees via link from Medicare Prescription Drug Plan Finder to sponsor web site and include in pre-and post-enrollment marketing materials as directed by CMS.	◯ Yes ◯ No
15	Sponsor will make arrangements to continue to provide necessary Part D drugs to enrollees via an extension of the transition period, on a case-by-case basis, to the extent that their exception requests or appeals have not been processed by the end of the minimum transition period and until such time as a transition has been made (either through a switch to an appropriate formulary drug or a decision on an exception request).	◯ Yes ◯ No
16	For current enrollees whose drugs will be affected by negative formulary changes in the upcoming year, the Sponsor will effectuate a meaningful transition by either: (1) providing a transition process at the start of the new contract year or (2) effectuating a transition prior to the start of the new contract year.	◯ Yes ◯ No

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STEP 4
Click the Implementation Statement check box to confirm that an implementation statement is included within the Transition Policy.

STEP 5
Select the appropriate answer for all the attestation questions and click "Next." This will take you to the Transition Policy Upload page.

Note: All attestation questions must be answered "Yes." All Pace Organizations, Employer plans of organization type 13, 14, and Employer only S and H contracts (800 series) can answer "No" to attestation question # 14.

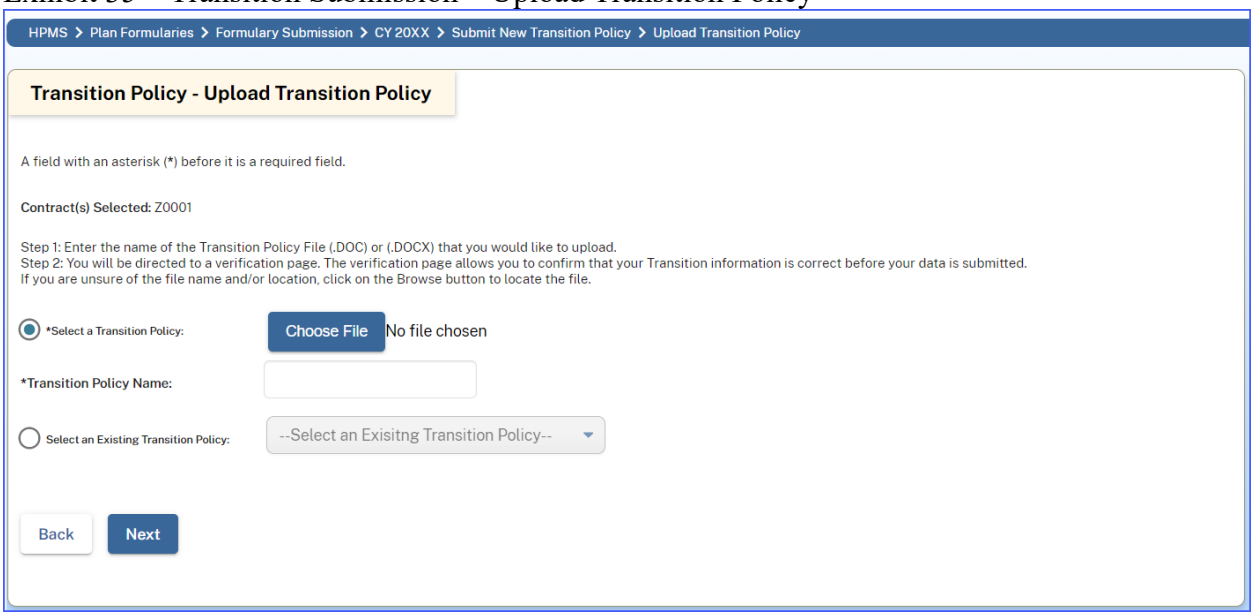
Upon successful completion of attestation questions, plans are required to upload a Formulary Transition Policy document as a Microsoft Word document (file extension .docx or .doc).

The responses to the transition attestations will not be saved if the transition policy is not uploaded.

TRANSITION SUBMISSION - UPLOAD TRANSITION POLICY

STEP 6A
On the **Transition Submission - Upload Transition Policy** page (Exhibit 35), you can select to upload a new Formulary Transition Policy from your local drive. Enter the full path and name of the Formulary Transition Policy document in the "Select a Transition Policy" field, e.g., c:\myFormularyfile.doc(x). If you are unsure of the document name or location, click the "Browse" button to locate and attach the document. Note the Transition Policy name you enter, as this will be required for resubmission. Skip to Step 8.

Exhibit 35 – Transition Submission – Upload Transition Policy



STEP 6B

If you would like to use the same transition policy that you previously uploaded for another contract, click the "Select an Existing Policy" button. You will then be able to select the transition policy name from the drop-down list.

STEP 7

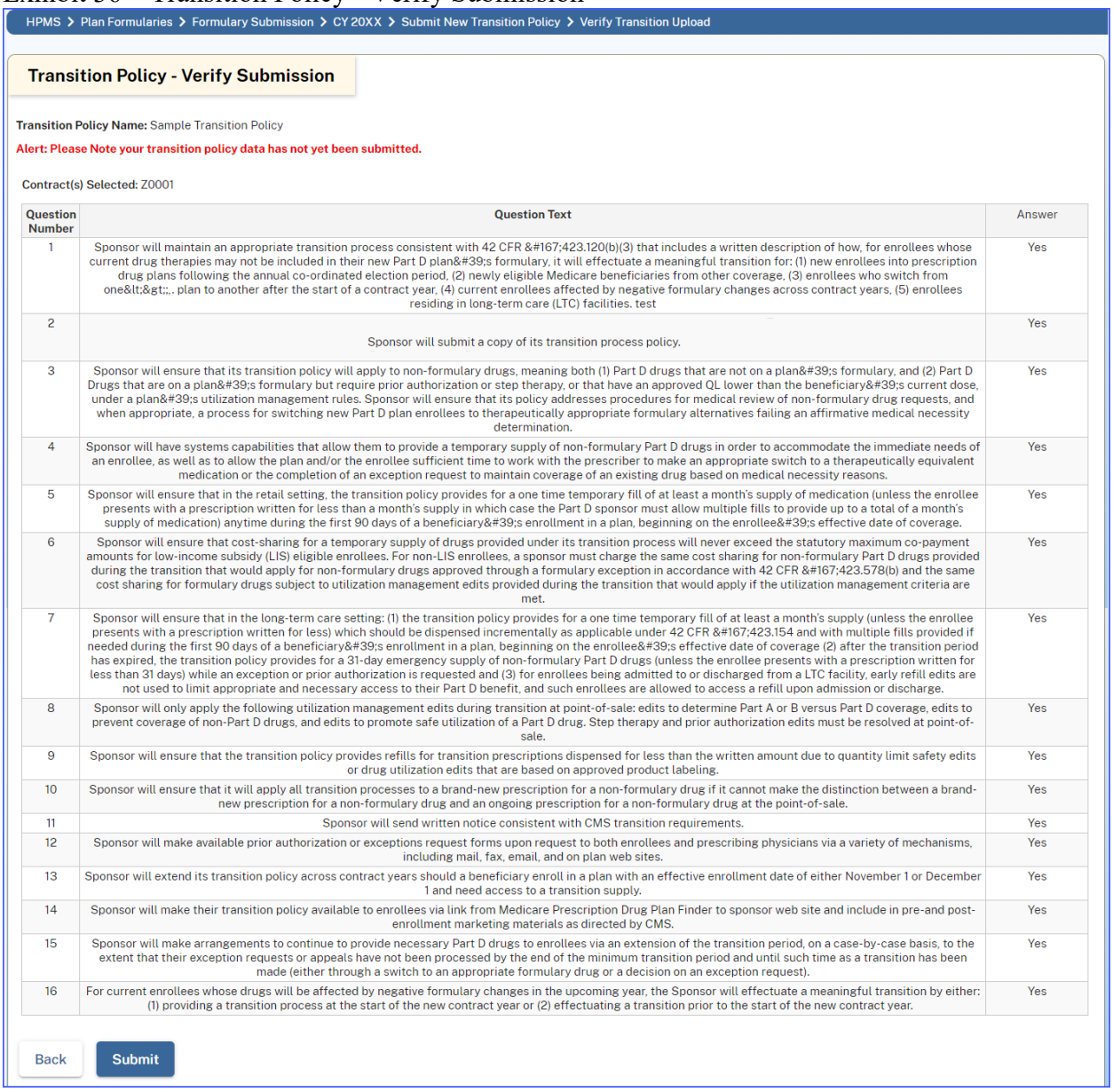
Click the "Next" button. This will take you to the Transition Submission – Verify Submission page.

TRANSITION POLICY-VERIFY SUBMISSION

STEP 8

On the **Transition Policy-Verify Submission** page (Exhibit 36), verify the responses you provided and click the "Submit" button to submit your attestation. This will take you to the Transition Submission –Submission Confirmation page (Exhibit 37).

Exhibit 36 – Transition Policy - Verify Submission



HPMS > Plan Formularies > Formulary Submission > CY 20XX > Submit New Transition Policy > Verify Transition Upload

Transition Policy - Verify Submission

Transition Policy Name: Sample Transition Policy

Alert: Please Note your transition policy data has not yet been submitted.

Contract(s) Selected: Z0001

Question Number	Question Text	Answer
1	Sponsor will maintain an appropriate transition process consistent with 42 CFR §423.120(b)(3) that includes a written description of how, for enrollees whose current drug therapies may not be included in their new Part D plan's formulary, it will effectuate a meaningful transition for: (1) new enrollees into prescription drug plans following the annual co-ordinated election period, (2) newly eligible Medicare beneficiaries from other coverage, (3) enrollees who switch from one<>;. plan to another after the start of a contract year, (4) current enrollees affected by negative formulary changes across contract years, (5) enrollees residing in long-term care (LTC) facilities. test	Yes
2	Sponsor will submit a copy of its transition process policy.	Yes
3	Sponsor will ensure that its transition policy will apply to non-formulary drugs, meaning both (1) Part D drugs that are not on a plan's formulary, and (2) Part D Drugs that are on a plan's formulary but require prior authorization or step therapy, or that have an approved QL lower than the beneficiary's current dose, under a plan's utilization management rules. Sponsor will ensure that its policy addresses procedures for medical review of non-formulary drug requests, and when appropriate, a process for switching new Part D plan enrollees to therapeutically appropriate formulary alternatives failing an affirmative medical necessity determination.	Yes
4	Sponsor will have systems capabilities that allow them to provide a temporary supply of non-formulary Part D drugs in order to accommodate the immediate needs of an enrollee, as well as to allow the plan and/or the enrollee sufficient time to work with the prescriber to make an appropriate switch to a therapeutically equivalent medication or the completion of an exception request to maintain coverage of an existing drug based on medical necessity reasons.	Yes
5	Sponsor will ensure that in the retail setting, the transition policy provides for a one time temporary fill of at least a month's supply of medication (unless the enrollee presents with a prescription written for less than a month's supply in which case the Part D sponsor must allow multiple fills to provide up to a total of a month's supply of medication) anytime during the first 90 days of a beneficiary's enrollment in a plan, beginning on the enrollee's effective date of coverage.	Yes
6	Sponsor will ensure that cost-sharing for a temporary supply of drugs provided under its transition process will never exceed the statutory maximum co-payment amounts for low-income subsidy (LIS) eligible enrollees. For non-LIS enrollees, a sponsor must charge the same cost sharing for non-formulary Part D drugs provided during the transition that would apply for non-formulary drugs approved through a formulary exception in accordance with 42 CFR §423.578(b) and the same cost sharing for formulary drugs subject to utilization management edits provided during the transition that would apply if the utilization management criteria are met.	Yes
7	Sponsor will ensure that in the long-term care setting: (1) the transition policy provides for a one time temporary fill of at least a month's supply (unless the enrollee presents with a prescription written for less) which should be dispensed incrementally as applicable under 42 CFR §423.154 and with multiple fills provided if needed during the first 90 days of a beneficiary's enrollment in a plan, beginning on the enrollee's effective date of coverage (2) after the transition period has expired, the transition policy provides for a 31-day emergency supply of non-formulary Part D drugs (unless the enrollee presents with a prescription written for less than 31 days) while an exception or prior authorization is requested and (3) for enrollees being admitted to or discharged from a LTC facility, early refill edits are not used to limit appropriate and necessary access to their Part D benefit, and such enrollees are allowed to access a refill upon admission or discharge.	Yes
8	Sponsor will only apply the following utilization management edits during transition at point-of-sale: edits to determine Part A or B versus Part D coverage, edits to prevent coverage of non-Part D drugs, and edits to promote safe utilization of a Part D drug. Step therapy and prior authorization edits must be resolved at point-of-sale.	Yes
9	Sponsor will ensure that the transition policy provides refills for transition prescriptions dispensed for less than the written amount due to quantity limit safety edits or drug utilization edits that are based on approved product labeling.	Yes
10	Sponsor will ensure that it will apply all transition processes to a brand-new prescription for a non-formulary drug if it cannot make the distinction between a brand-new prescription for a non-formulary drug and an ongoing prescription for a non-formulary drug at the point-of-sale.	Yes
11	Sponsor will send written notice consistent with CMS transition requirements.	Yes
12	Sponsor will make available prior authorization or exceptions request forms upon request to both enrollees and prescribing physicians via a variety of mechanisms, including mail, fax, email, and on plan web sites.	Yes
13	Sponsor will extend its transition policy across contract years should a beneficiary enroll in a plan with an effective enrollment date of either November 1 or December 1 and need access to a transition supply.	Yes
14	Sponsor will make their transition policy available to enrollees via link from Medicare Prescription Drug Plan Finder to sponsor web site and include in pre-and post-enrollment marketing materials as directed by CMS.	Yes
15	Sponsor will make arrangements to continue to provide necessary Part D drugs to enrollees via an extension of the transition period, on a case-by-case basis, to the extent that their exception requests or appeals have not been processed by the end of the minimum transition period and until such time as a transition has been made (either through a switch to an appropriate formulary drug or a decision on an exception request).	Yes
16	For current enrollees whose drugs will be affected by negative formulary changes in the upcoming year, the Sponsor will effectuate a meaningful transition by either: (1) providing a transition process at the start of the new contract year or (2) effectuating a transition prior to the start of the new contract year.	Yes

Back Submit

TRANSITION SUBMISSION - CONFIRMATION

STEP 9

On the **Transition Submission - Confirmation** page (Exhibit 37), a confirmation message will be displayed to notify the user that the Formulary Transition Policy and the attestation answers were successfully submitted. Click the "OK" button to go back to the Transition Submission – Select Contract page.

Exhibit 37 – Transition Policy Submission – Confirm Submission

VII. REVISE TRANSITION POLICY

The Revise Formulary Transition Policy functionality allows you to revise a Formulary Transition Policy that is already submitted. During the initial submission period, any Formulary Transition Policy with a status of "Submitted" can be revised. Once the initial submission period is closed, any Formulary Transition Policy with a status of Resubmission Requested can be revised.

STEP 1

Select **Revise Formulary Transition Policy** from the left navigation bar of the Formulary Submission Start page (Exhibit 4). This will take you to the Transition Policy Resubmission – Select a Transition Policy page.

SELECT A TRANSITION POLICY

This page displays information on the submitted Transition Policies, such as the Formulary Transition Policy ID, Formulary Transition Policy Name, Formulary Transition Policy Status, and the Contracts Associated with the Transition Policy. There will be two tables displayed on this page. One table shows the Formulary transition policies that are available for revision and the other table shows those policies that are not available for revision.

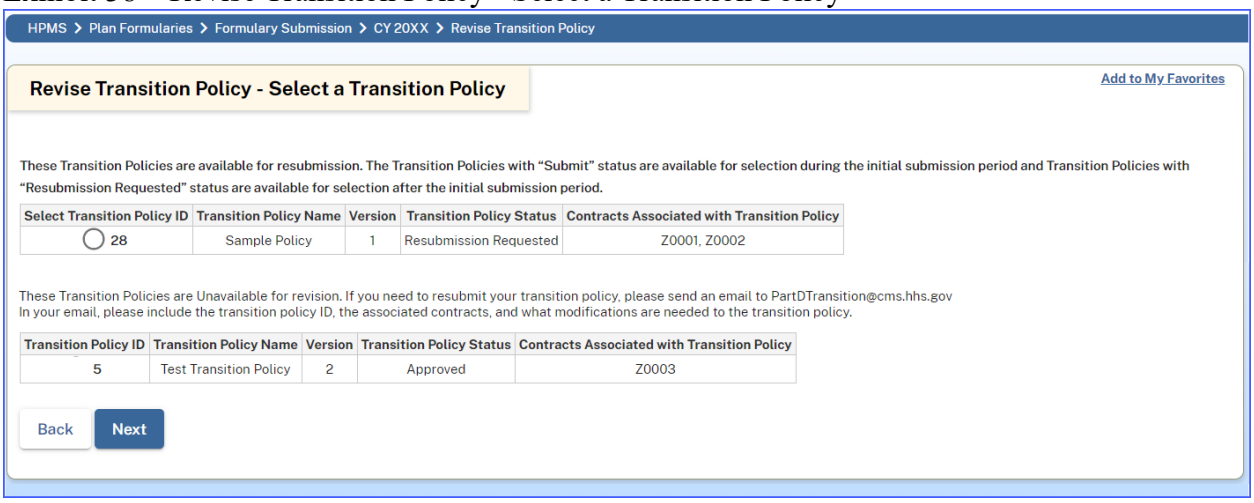
STEP 1

Select the Formulary Transition Policy ID and click the "Next" button (Exhibit 38). This will take you to the Formulary Transition Policy Resubmission – Associate Contracts to Formulary Transition Policy page.

Note: When resubmitting, the word document (.doc or.docx) should contain track changes from your most recent transition policy submission and those changes must be limited to the reasons indicated in the resubmission request."

Note: If your Transition Policy is not available for revision and you need to resubmit, please send an email to PartDTransition@cms.hhs.gov. In your email, please include the transition Policy ID, the associated contracts, and what modifications to the transition policy are necessary.

Exhibit 38 – Revise Transition Policy - Select a Transition Policy



ASSOCIATE CONTRACTS TO TRANSITION POLICY

This page allows you to upload a revised transition policy. The page displays the contracts that were previously associated with the transition policy.

STEP 1

Enter the Formulary transition policy name. Note the transition policy name you enter, as this will be required for resubmission.

Note: When resubmitting, the word document (.doc or .docx) should contain track changes from your most recent transition policy submission and those changes must be limited to the reasons indicated in the resubmission request.

STEP 2

Browse and select the revised Formulary transition policy to upload.

Note: When resubmitting, the word document (.doc or .docx) should contain track changes from your most recent transition policy submission and those changes must be limited to the reasons indicated in the resubmission request.

Enter the full path and name of the Formulary Transition Policy word document in the "Select a Transition Policy" field, e.g., c:\myFormularyfile.doc. If you are unsure of the document name or location, click the "Browse" button to locate and attach the document. You can only upload a Formulary Transition Policy as a Microsoft Word document. The acceptable file formats are .doc or .docx.

STEP 3

Indicate which of the attestation questions, implementation statement or if any other updates were made in the transition policy file to be re-submitted by selecting the respective check boxes (Exhibit 39), you may also provide additional comments to describe the updates made on the transitional policy file to be uploaded.

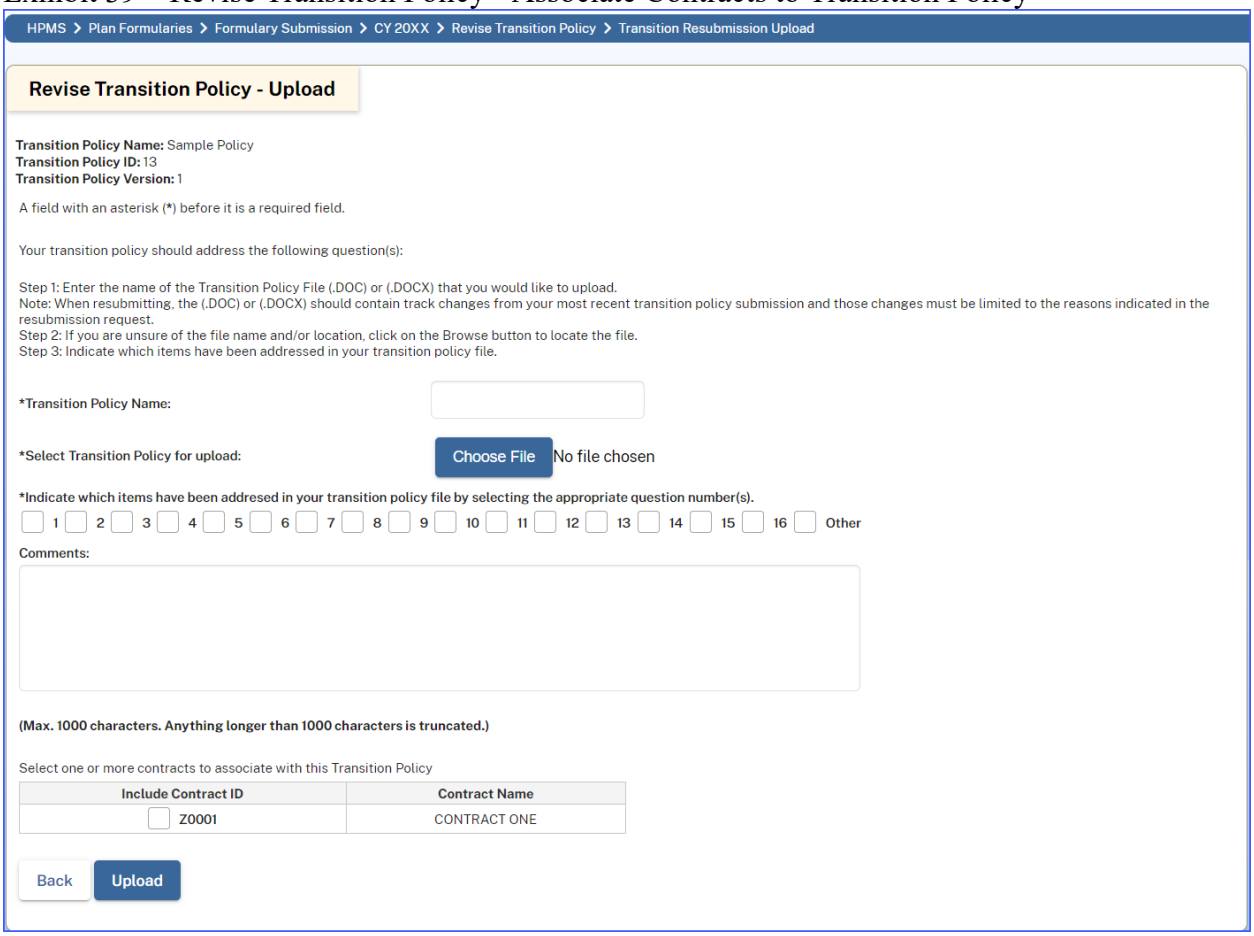
STEP 4

Review the contract associations. If any contracts are no longer valid for this transition policy, you may unselect the check box next to the contract (Exhibit 39). You can only un-select the check box next to the contracts (disassociate the contracts) during the Formulary initial submission window. After Formulary initial submission window is closed, the checkbox next to the contracts will be disabled.

STEP 5

Click the "Upload" button. This will take you to the **Revise Transition Policy –Confirmation** page (Exhibit 40).

Exhibit 39 – Revise Transition Policy - Associate Contracts to Transition Policy



TRANSITION REVISION - CONFIRMATION

STEP 1

The Revise Transition Policy – Confirmation page (Exhibit 40) displays the confirmation message that the Formulary transition policy was successfully submitted. Click the "OK" button. This will take you to the Transition Policy Resubmission Selection page (Exhibit 38).

Exhibit 40 – Transition Policy Resubmission Confirmation

VIII. SUBMIT P&T (PHARMACY AND THERAPEUTIC) ATTESTATION

All organizations must attest their Pharmacy and Therapeutic (P&T) Committee Attestations as a part of their Formulary submission. While the Formulary submission is not dependent on Formulary P&T attestation in HPMS, you must successfully submit the P&T committee attestations before CMS will renew or approve your Part D contract. A P&T committee attestation is successfully submitted when all attestation questions are answered.

If you need to re-attest previously submitted attestations, send an email to CMS at PartDTransition@cms.hhs.gov.

STEP 1

Select **P&T Committee Attestation** from the **Formulary Submission Start** page (Exhibit 4). This will take you to the P&T Committee Attestation – Select Contract page.

P&T COMMITTEE ATTESTATION – SELECT CONTRACT

STEP 2

On the P&T Committee Attestation – Select Contract page (Exhibit 41), select one or more of the contracts listed on the page and the "Next" button. This will take you to the P&T Committee Attestation – Attestation Questions page. If you cannot see one of your contracts, please refer to Section I – Getting Started.

Exhibit 41 – P&T Committee Attestation – Select Contract

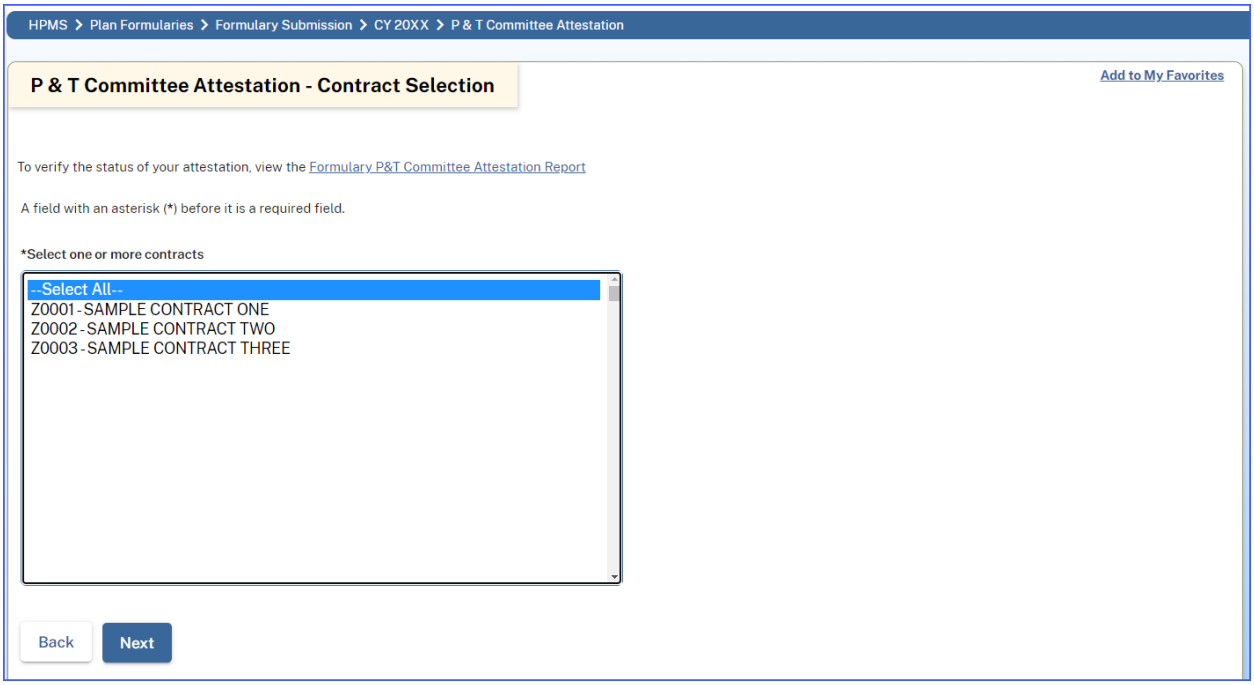
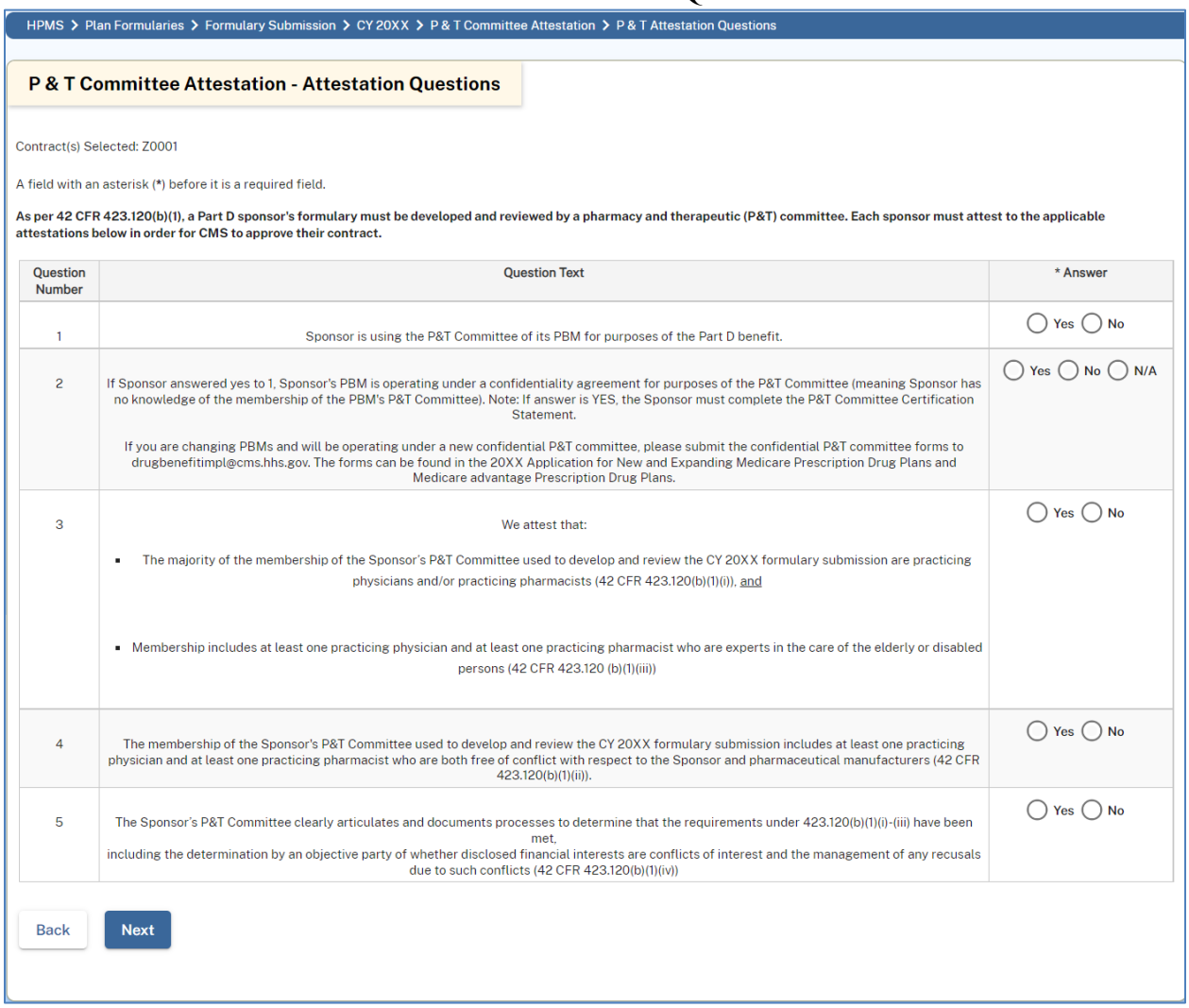


Exhibit 42 – P&T Committee Attestations – Attestation Questions



HPMS > Plan Formularies > Formulary Submission > CY 20XX > P & T Committee Attestation > P & T Attestation Questions

P & T Committee Attestation - Attestation Questions

Contract(s) Selected: Z0001

A field with an asterisk (*) before it is a required field.

As per 42 CFR 423.120(b)(1), a Part D sponsor's formulary must be developed and reviewed by a pharmacy and therapeutic (P&T) committee. Each sponsor must attest to the applicable attestations below in order for CMS to approve their contract.

Question Number	Question Text	* Answer
1	Sponsor is using the P&T Committee of its PBM for purposes of the Part D benefit.	◯ Yes ◯ No
2	If Sponsor answered yes to 1, Sponsor's PBM is operating under a confidentiality agreement for purposes of the P&T Committee (meaning Sponsor has no knowledge of the membership of the PBM's P&T Committee). Note: If answer is YES, the Sponsor must complete the P&T Committee Certification Statement. If you are changing PBMs and will be operating under a new confidential P&T committee, please submit the confidential P&T committee forms to drugbenefitimpl@cms.hhs.gov. The forms can be found in the 20XX Application for New and Expanding Medicare Prescription Drug Plans and Medicare advantage Prescription Drug Plans.	◯ Yes ◯ No ◯ N/A
3	We attest that: ▪ The majority of the membership of the Sponsor's P&T Committee used to develop and review the CY 20XX formulary submission are practicing physicians and/or practicing pharmacists (42 CFR 423.120(b)(1)(i)), and ▪ Membership includes at least one practicing physician and at least one practicing pharmacist who are experts in the care of the elderly or disabled persons (42 CFR 423.120 (b)(1)(iii))	◯ Yes ◯ No
4	The membership of the Sponsor's P&T Committee used to develop and review the CY 20XX formulary submission includes at least one practicing physician and at least one practicing pharmacist who are both free of conflict with respect to the Sponsor and pharmaceutical manufacturers (42 CFR 423.120(b)(1)(ii)).	◯ Yes ◯ No
5	The Sponsor's P&T Committee clearly articulates and documents processes to determine that the requirements under 423.120(b)(1)(i)-(iii) have been met, including the determination by an objective party of whether disclosed financial interests are conflicts of interest and the management of any recusals due to such conflicts (42 CFR 423.120(b)(1)(iv))	◯ Yes ◯ No

Back Next

STEP 3

On the P&T Committee Attestation – Attestation Questions page (Exhibit **42**), select the appropriate answer for all the attestation questions and select "Next." This will take you to the P&T Committee Attestation Upload page.

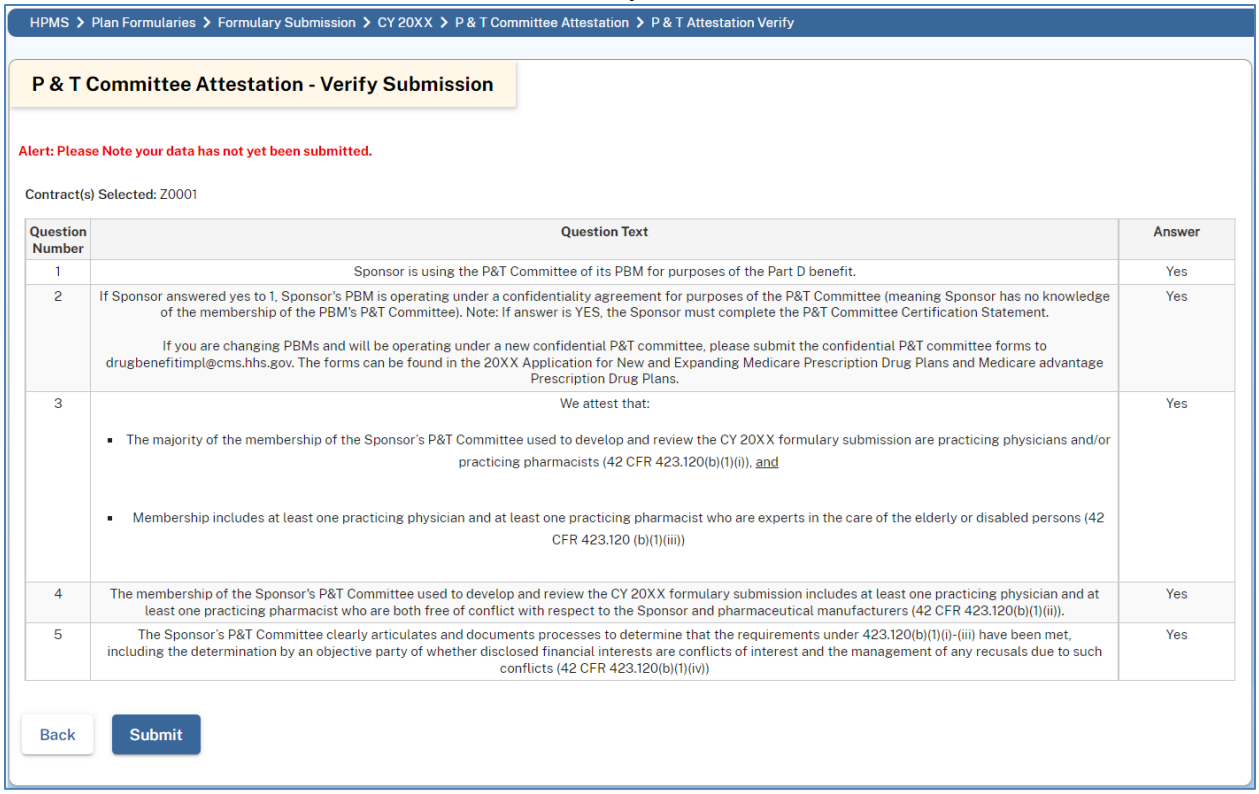
Note: Attestation questions 1,3,4,5 can be answered 'Yes' or 'No'. You may choose to answer 'NA' for attestation question # 2.

P&T Committee Attestation – Verify Submission

Step 4

On the **P&T Attestation -Verify Submission** page (Exhibit 43), verify the responses you provided and click the "Submit" button to submit your attestation. This will take you to the P&T Attestation –Submission Confirmation page (Exhibit 44).

Exhibit 43 – P&T Committee Attestation – Verify Submission



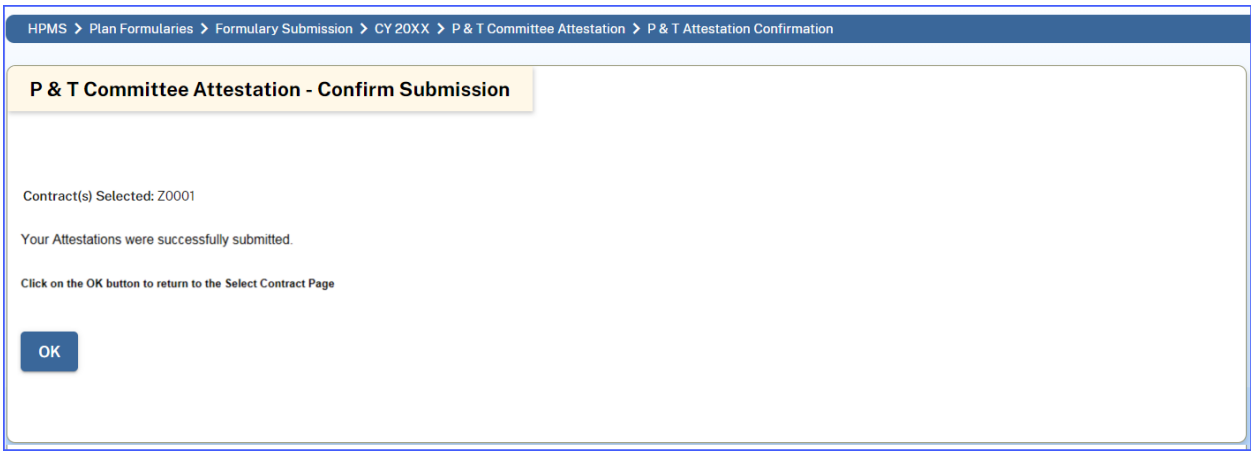
P&T Attestation – Confirmation

Step 5

On the **P&T Committee Attestation – Confirmation** page (Exhibit 44), a confirmation message will be displayed to notify the user that the attestation answers were successfully submitted.

Click the "OK" button to go back to the P&T Committee Attestation – Select Contract page.

Exhibit 44 – P&T Committee Attestation – Confirm Submission



IX. SUBMIT PRIOR AUTHORIZATION/STEP THERAPY (PA/ST) ATTESTATION

All organizations must submit Prior Authorization / Step Therapy (PA/ST) Attestations as a part of their Formulary submissions. While the Formulary submission is not dependent on PA/ST Attestations in HPMS, you must successfully submit the PA/ST attestations before CMS will renew or approve your Part D contract. This is to ensure that Part D sponsors will comply with all CMS instructions to delete or change the PA or ST criteria in their formularies.

STEP 1

Select **PA/ST Attestation** from the **Formulary Submission Start** page (Exhibit 4). This will take you to the PA/ST Attestations – Select Contract page.

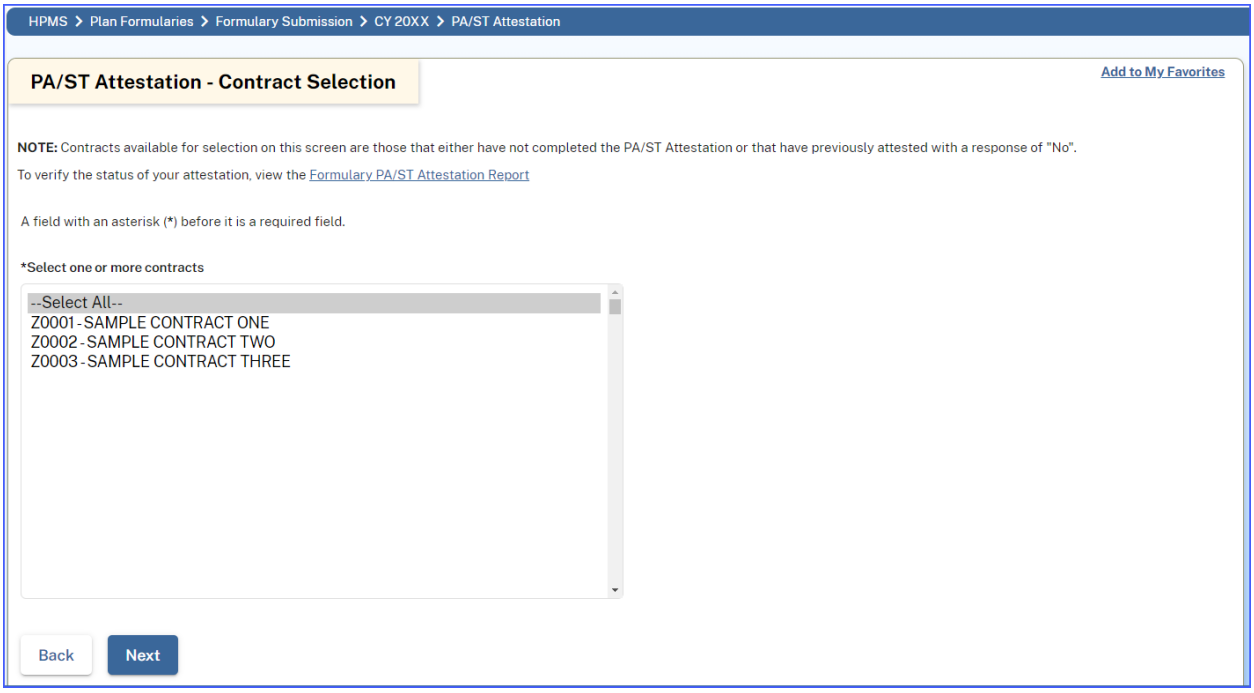
PA/ST ATTESTATION – SELECT CONTRACT

STEP 2

On the **PA/ST Attestation – Select Contract** page (Exhibit 45), select one or more of the contracts listed on the page and the "Next" button. This will take you to the PA/ST Attestation – Attestation Questions page. If you cannot see one of your contracts, please refer to Section I – Getting Started.

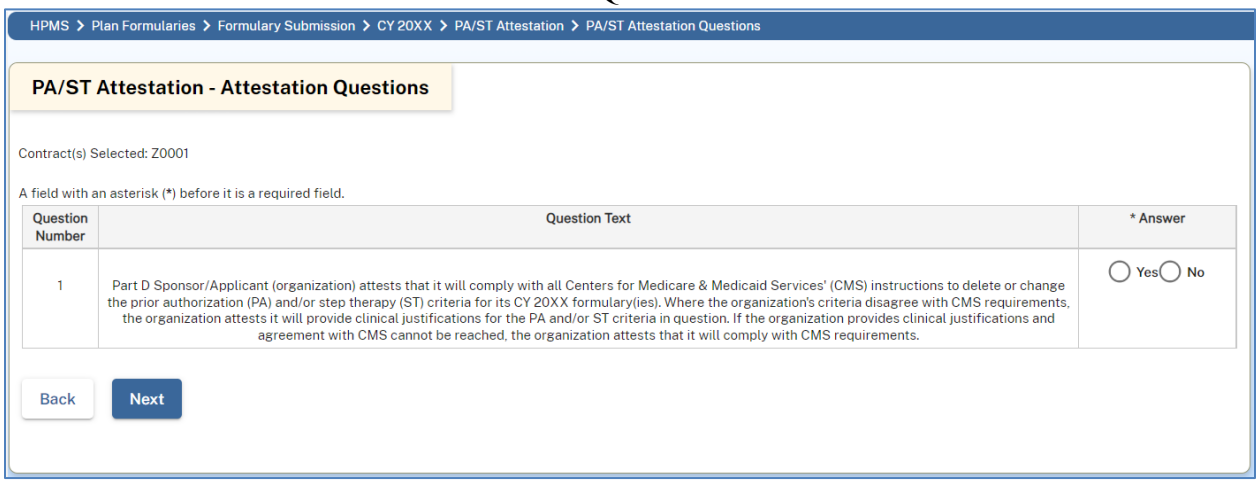
Note: You can select more than one contract to attest or "Select All" to attest to all of your associated contracts.

Exhibit 45 – PA/ST Attestation – Select Contract



PA/ST Committee Attestation – Attestation Questions

Exhibit 46 – PA/ST Attestations – Attestation Questions



Step 3

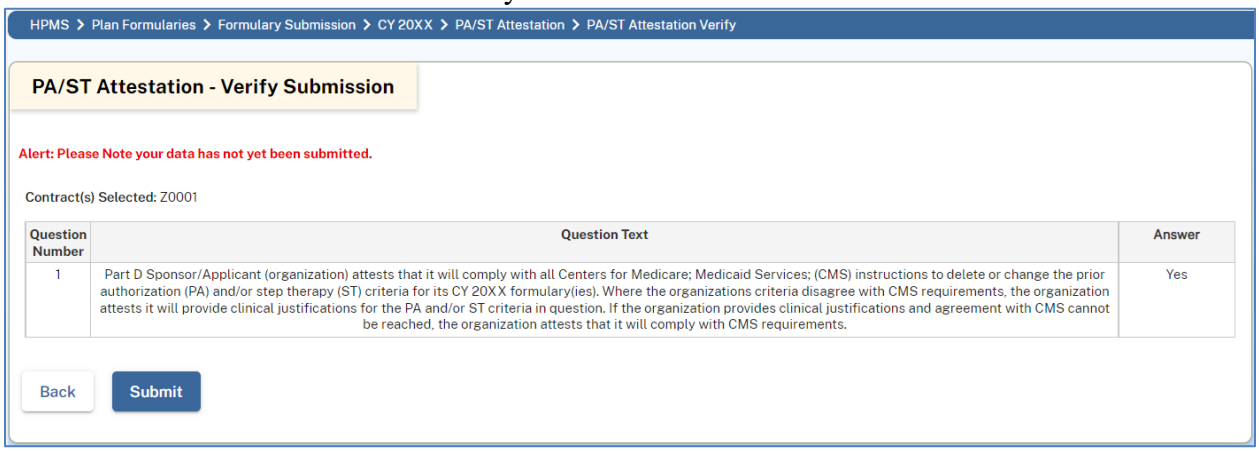
On the **PA/ST Attestation – Attestation Questions** page (Exhibit 46), select the appropriate answer for the attestation question and click "Next." This will take you to the PA/ST Verification page.

PA/ST Attestation – Verify Submission

Step 4

On the **PA/ST Attestation -Verify Submission** page (Exhibit 47), verify the response you provided and click the "Submit" button to submit your attestation. This will take you to the PA/ST Attestation –Submission Confirmation page (Exhibit 48).

Exhibit 47 – PA/ST Attestation – Verify Submission

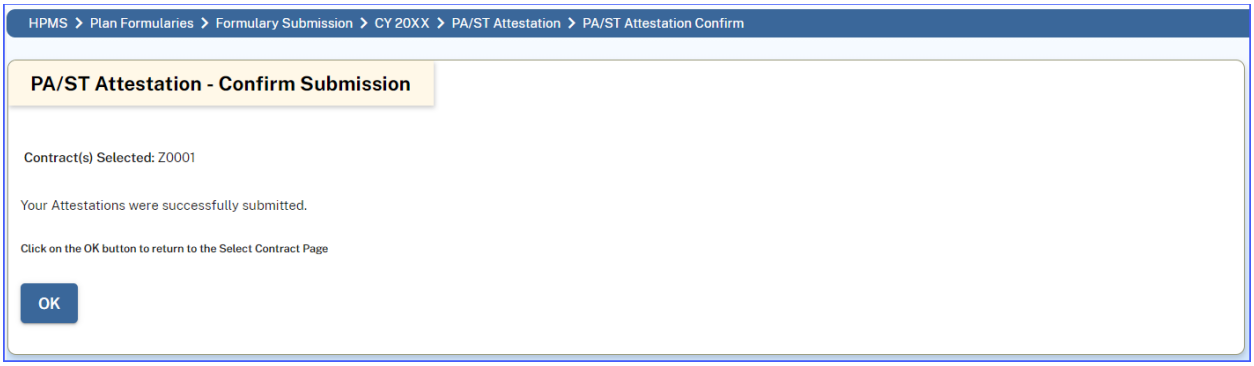


PA/ST Attestation – Confirmation

Step 5

On the **PA/ST Attestation – Confirmation** page (Exhibit 48), a confirmation message will be displayed to notify the user that the attestations were successfully submitted.
Click the "OK" button to go back to the PA/ST Attestation – Select Contract page.

Exhibit 48 – PA/ST Attestation – Confirm Submission



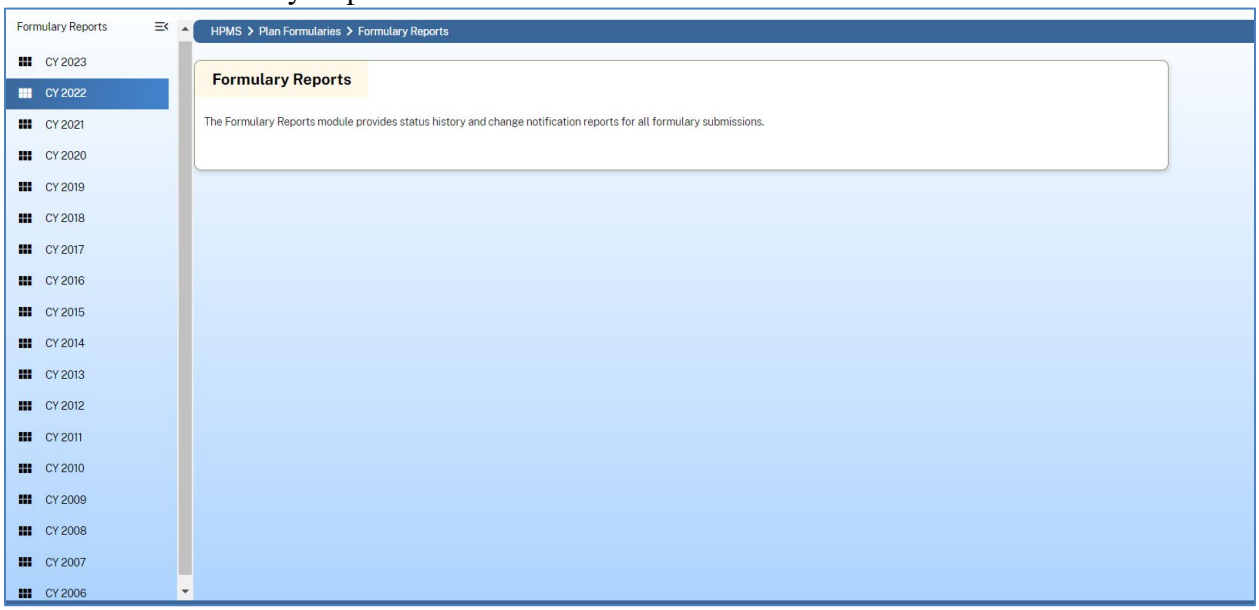
X. FORMULARY FILE REPORTS

The **Formulary Reports** functionality provides access to a variety of Formulary-related information to assist in the Formulary submission process.

STEP 1

As shown in Exhibit 49, on the HPMS Home page, select the Plan Formularies drop down from the HPMS top navigation bar. Then select the Formulary Reports menu item. This will take you to Formulary Reports Page.

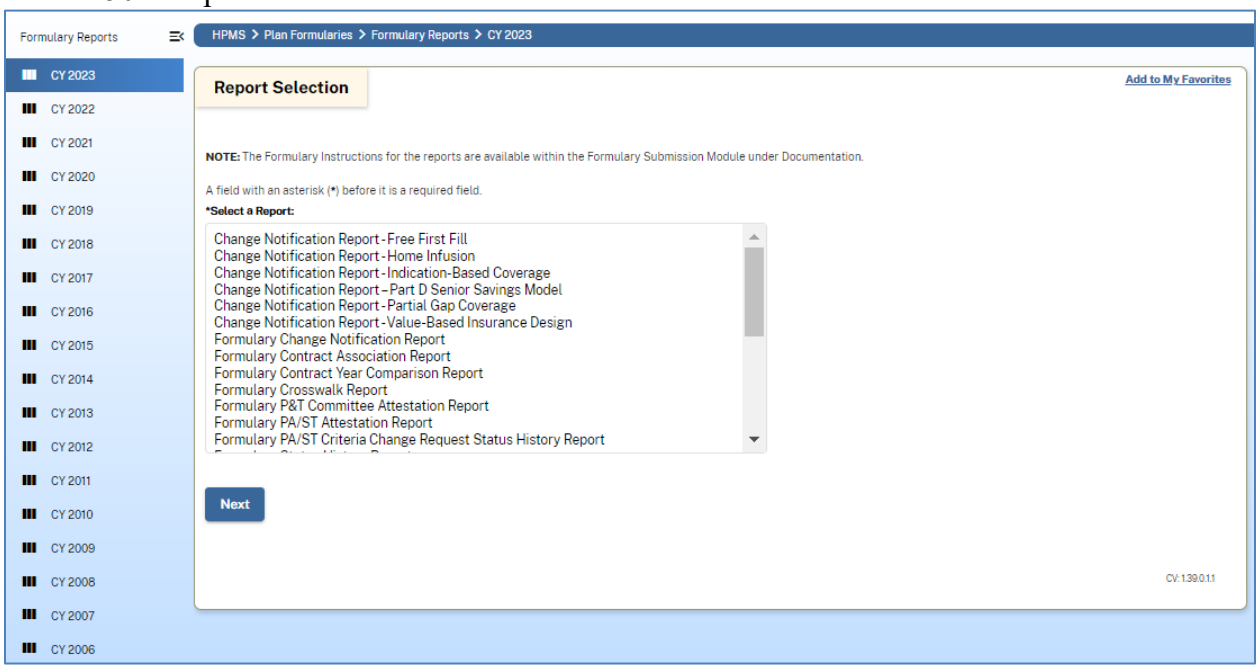
Exhibit 49 – Formulary Reports



STEP 2

On the **Formulary Reports** page, select the appropriate contract year from the collapsible navigation menu, on the left side of the page. This takes you to the Report Selection page.

Exhibit 50 – Report Contract Year Selection



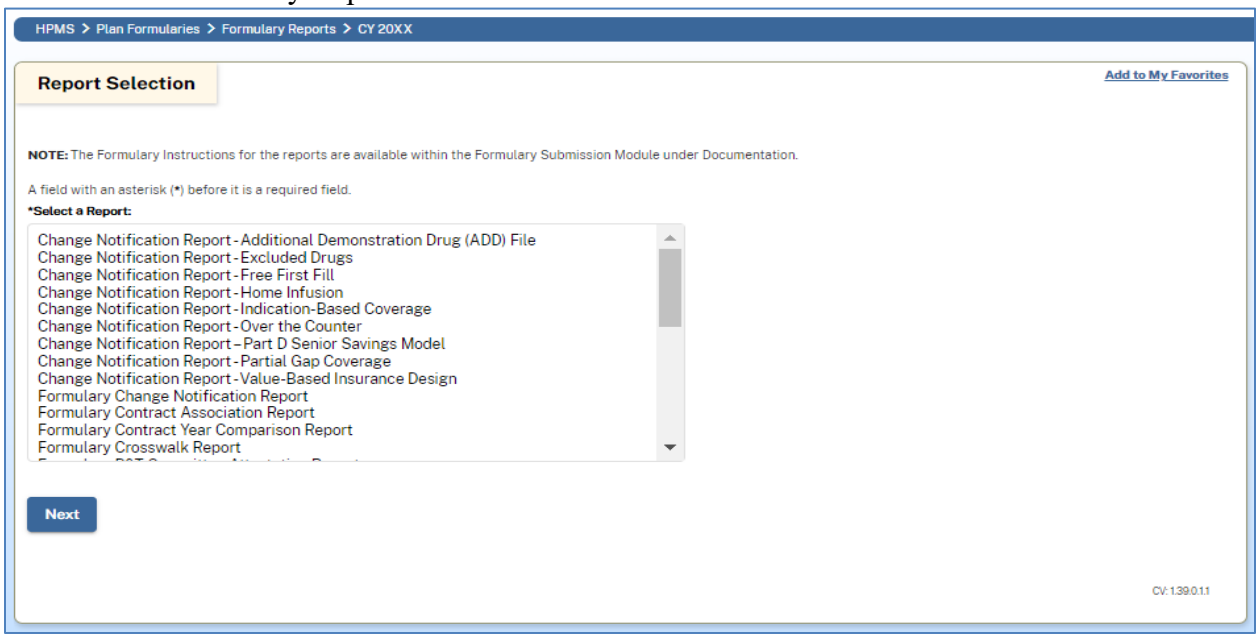
XI. FORMULARY/BID CONTACT REPORT

The **Formulary/Bid Contact Report** provides contact information at the Contract Level and Plan Level for one or more contract.

STEP 1

On the **Report Selection** page (Exhibit 51), select "Formulary/Bid Contact Report." This will take you to the Formulary Bid Report Contract Selection page.

Exhibit 51 – Formulary Report Selection



STEP 2

On the **Formulary/Bid Report - Contract Selection** page (Exhibit 52), select the desired contract numbers and click the "Next" button. This will take you to the Formulary/Bid Contact Report (Exhibit **53**). A maximum of ten contracts may be selected.

IMPORTANT NOTE:
If the information from the Formulary/Bid Contact Report is incorrect, please update the Contract Level Contact Information in the HPMS Contract Management module. Plan level contact information should be updated in the HPMS Bid Submission module.

Exhibit 52 – Formulary Bid Report Contract Selection

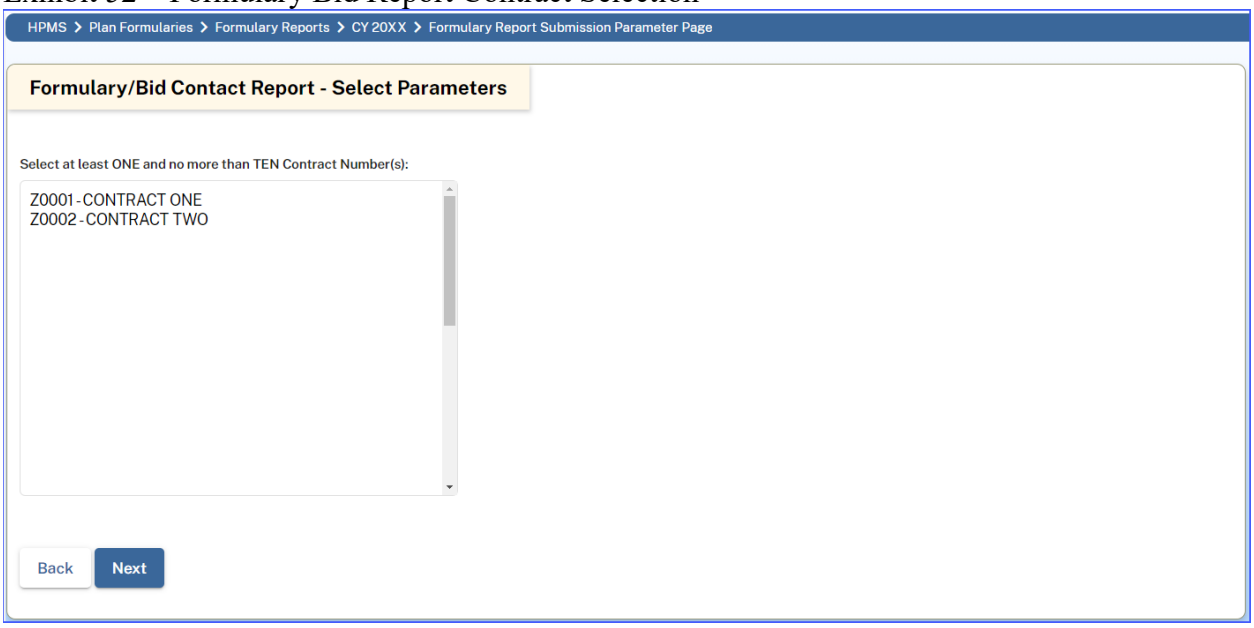
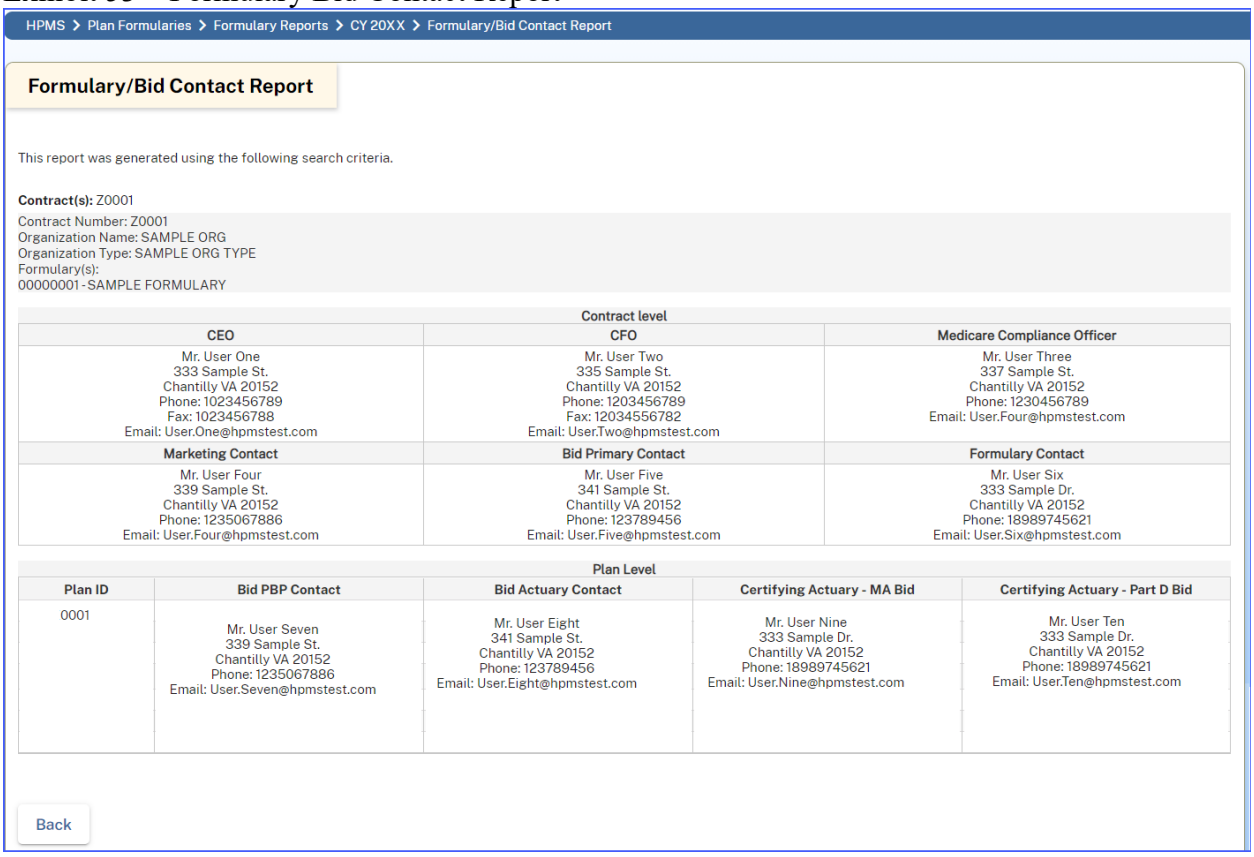


Exhibit 53 – Formulary Bid Contact Report



XII. FORMULARY CHANGE NOTIFICATION REPORT

The **Formulary Change Notification Report** provides a comparison of data between two submitted formularies. You can compare the content of two submissions from one Formulary or differences between any two different formularies.

STEP 1

On the **Formulary Reports – Select a Report** page (Exhibit 51), select "Formulary Change Notification Report." This will take you to the Formulary Change Notification Report selection criteria page.

STEP 2

On the **Formulary Change Notification Report** selection criteria page (Exhibit 54), select the desired Base Formulary ID and Version, as well as the Comparison Formulary ID and Version. (Versions will appear for selection after you select the Formulary ID and Comparison Formulary ID.) Click the "Next" button. This will take you to the Formulary Change Notification Report (Exhibit 55).

Exhibit 54 – Formulary Change Notification Report Selection Criteria

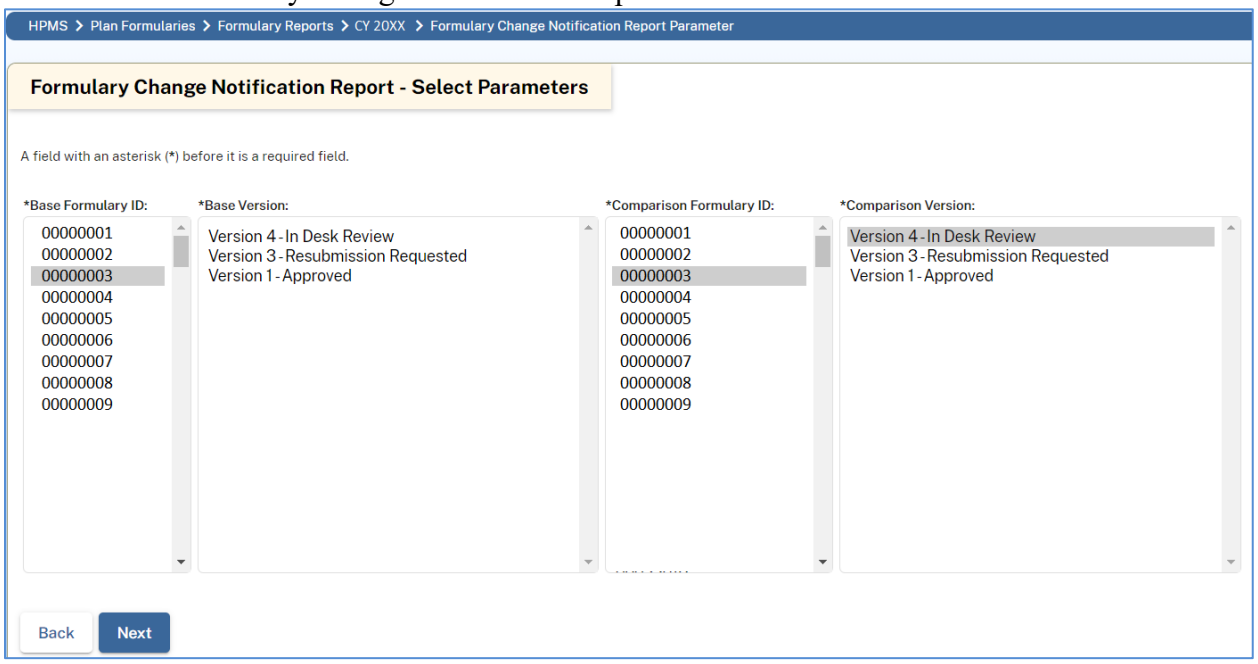


Exhibit 55 – Formulary Change Notification Report

HPMS
Health Plan Management System

Print | Close
Print Date: 3/10/2021

Formulary Change Notification Report

Search Criteria: This report was generated using the following search criteria.

Formulary IDs: 00000003 To 00000003
Compare: Version 3 To Version 1

The report compares detailed formulary data for the selected base formulary ID and the selected comparison formulary ID. The user may export the Formulary Differences section to a CSV file. In the Export Formulary Differences to CSV file, a cell will contain "NC" if the value did not change from the Base formulary.

FORMULARY COMPARISON

Formulary Information	Formulary ID-Version: 00000003-3	Formulary ID-Version: 00000003-1
Formulary Name	Test	Test
Review Status	*In Desk Review*	Approved
Formulary Type	*Update*	Original
Contract(s)	Z0001	Z0001
Database Source	USP	USP
Number of Cost Share Tiers	6	6
Tier Label	Preferred Generic, Generic , Preferred Brand, Non-Preferred Drug, Specialty Tier, Select Diabetic Drugs	Preferred Generic, Generic , Preferred Brand, Non-Preferred Drug, Specialty Tier, Select Diabetic Drugs
Limited Access (Y/N)	Yes	Yes
Prior Authorization (0-3)	Prior Authorization Applies	Prior Authorization Applies
Prior Authorization File	Prior Authorization File[CSV]	Prior Authorization File[CSV]
Quantity Limit (Y/N)	Yes	Yes
Step Therapy (0-2)	Step Therapy Applies	Step Therapy Applies
Step Therapy File	Step Therapy File[CSV]	Step Therapy File[CSV]
Formulary Submission Date	*2/3/2021*	1/15/2021

Jump To: In Comparison Formulary
Jump To: Formulary Differences

In Base Formulary

Formulary ID: 00000003
Version: Version 3

Formulary ID	Version	RxCUI	Related BN	Related SCDC	Related DF	Cost Share Tier Level Value	Unique Quantity Limit Type	Unique Quantity Limit Amount	Unique Quantity Limit Days	Prior Authorization (0-3)	Therapeutic Category	Therapeutic Class	Step Therapy (0-2)	Number Of Step Therapy Groups
00000003	2	11111	BN1	SCDC1	ORAL CAPSULE	5	1	21	28	2	Category1	Class1	0	

Jump To: Top
Jump To: In Base Formulary
Jump To: Formulary Differences

In Comparison Formulary

Formulary ID: 00000003
Version: Version 1

In Comparison Formulary

Formulary ID: 00022181
Version: Version 1

Formulary ID	Version	RxCUI	Related BN	Related SCDC	Related DF	Cost Share Tier Level Value	Unique Quantity Limit Type	Unique Quantity Limit Amount	Unique Quantity Limit Days	Prior Authorization (0-3)	Therapeutic Category	Therapeutic Class	Step Therapy (0-2)	Number Of Step Therapy Groups
00000003	2	22222	BN2	SCDC2	ORAL CAPSULE	5	1	21	28	2	Category2	Class2	0	

Jump To: Top
Jump To: In Base Formulary
Jump To: In Comparison Formulary

FORMULARY DIFFERENCES

Formulary IDs: 00000003 To 00000003
Compare: Version 3 To Version 1
NOTE: The values that highlight the differences shall be displayed in red text and cells with no differences will be blank.

Formulary ID	Version	RxCUI	Related BN	Related SCDC	Related DF	Cost Share Tier Level Value	Unique Quantity Limit Type	Unique Quantity Limit Amount	Unique Quantity Limit Days	Prior Authorization (0-3)	Therapeutic Category	Therapeutic Class	Limited Access (Y/N)	Step Therapy (0-2)	Number Of Step Therapy Groups
00000003	3	33333	BN3	SCDC3	ORAL CAPSULE	5	1	120	25	2	Category3	Class3	0	0	
00000003	1								30						

Export Formulary differences to File [CSV] Export All to Excel

XIII. FORMULARY CONTRACT ASSOCIATION REPORT

The **Formulary Contract Association Report** provides a listing of which formularies are associated with a given Part D contract (if any).

STEP 1

On the **Formulary Reports – Select a Report** page (Exhibit 51), select Formulary Contract Association Report. This will take you to the Formulary Contract Association Report selection criteria page.

STEP 2

On the **Formulary Contract Association Report** selection criteria page (Exhibit 56), select the desired contract, and then click the "Next" button. This will take you to the **Formulary Contract Association Report** page.

Exhibit 56 – Formulary Contract Association Report Selection Criteria

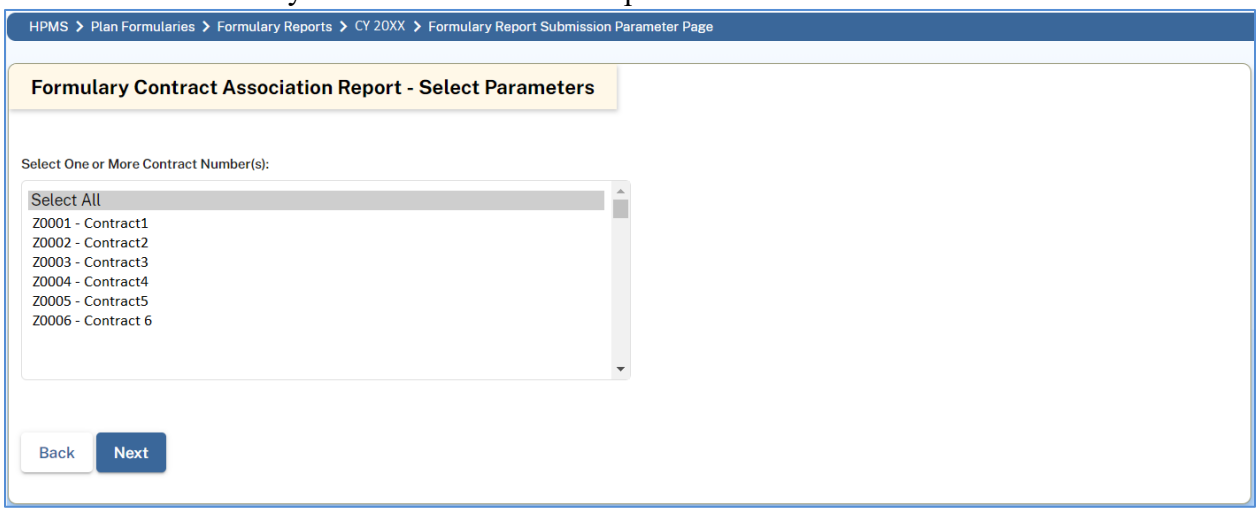
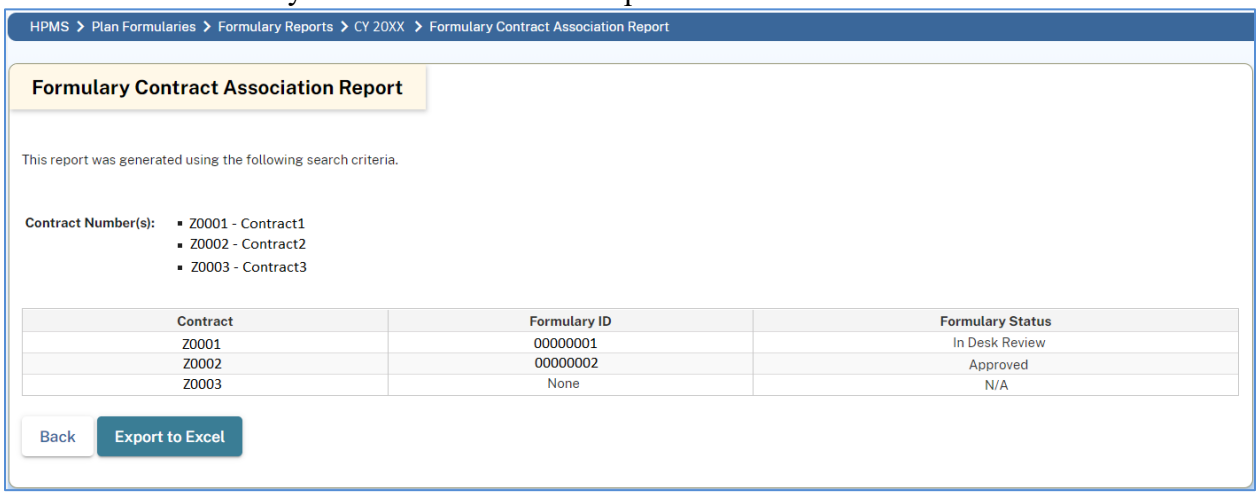


Exhibit 57 – Formulary Contract Association Report



XIV. FORMULARY CROSSWALK REPORT

The **Formulary Crosswalk Report** identifies the Formulary ID associated with each Part D plan and the status of the Formulary. All formularies must be associated with at least one plan.

STEP 1

On the **Formulary Reports – Select a Report** page (Exhibit 51), select "Formulary Crosswalk Report." This will take you to the Formulary Crosswalk Reports – Select a Contract page.

STEP 2

On the **Formulary Crosswalk Reports – Select a Contract** page (Exhibit 58), select the desired contracts and then click the "Next" button. This will take you to the Formulary Crosswalk Report (Exhibit 4).

Exhibit 58 – Formulary Crosswalk Report Select a Contract

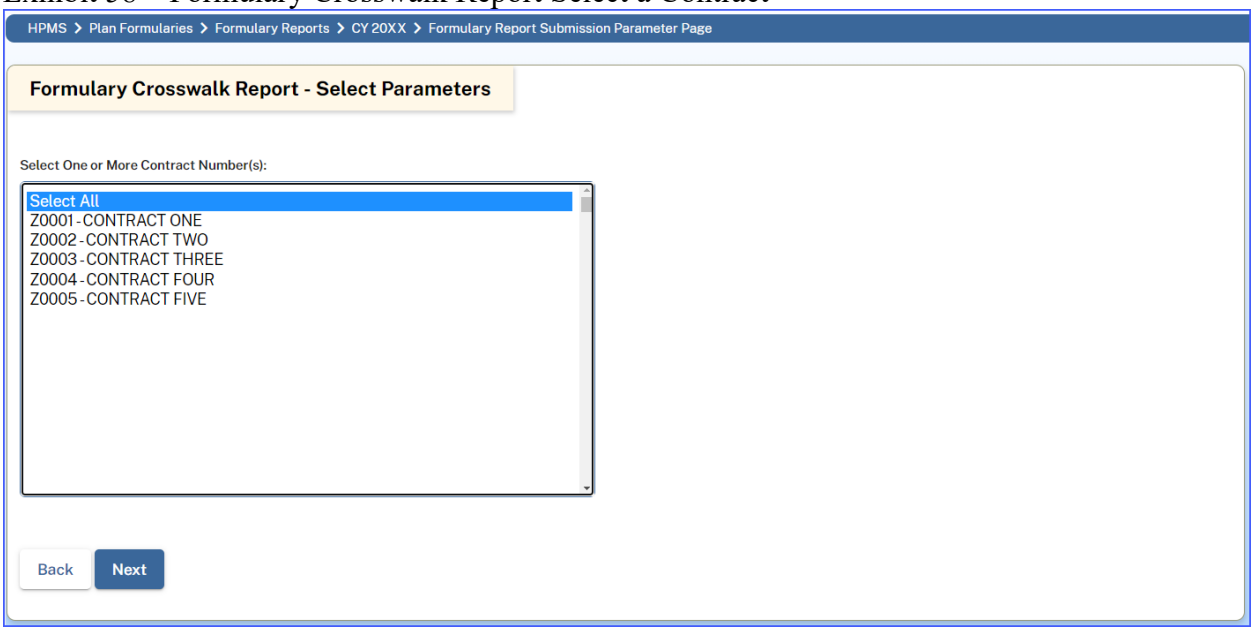
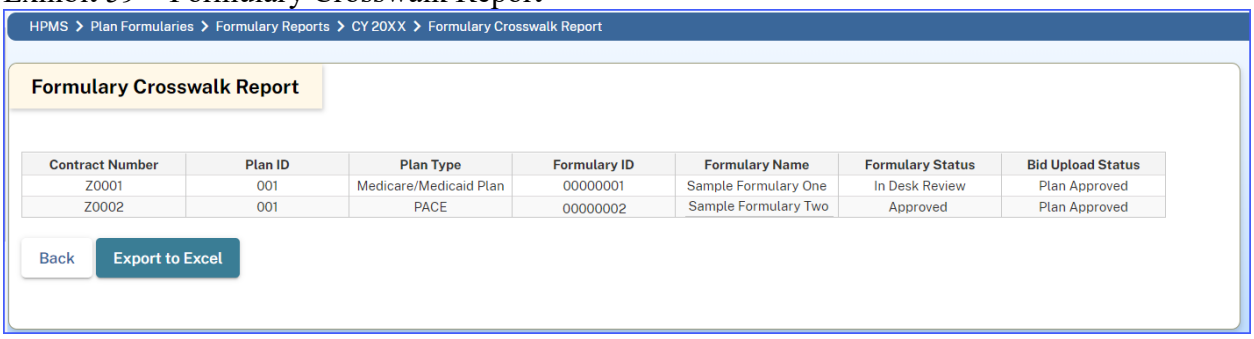


Exhibit 59 – Formulary Crosswalk Report



XV. FORMULARY STATUS HISTORY REPORT

The **Formulary Status History Report** provides detailed status information about all versions for a given Formulary ID.

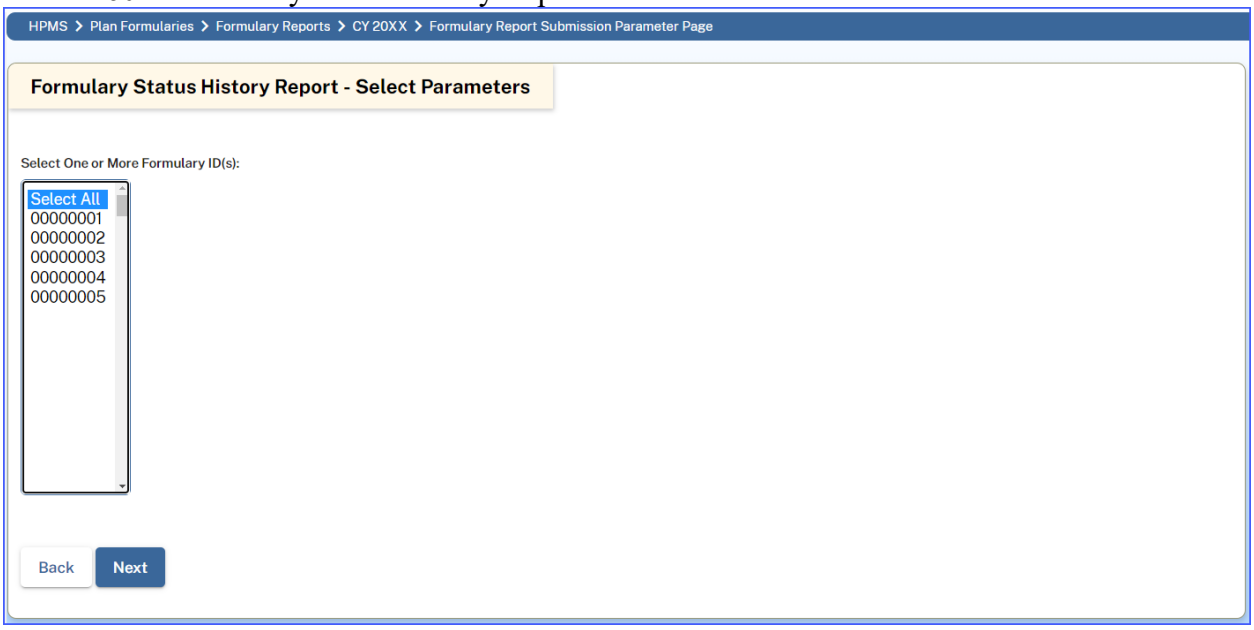
STEP 1

On the **Formulary Reports – Select a Report** page (Exhibit 51), select **Formulary Status History Report**. This will take you to the Formulary Status History Report selection criteria page.

STEP 2

On the **Formulary Status History Report selection criteria** page (Exhibit 60), select the desired formularies, and then click the "Next" button. This will take you to the Formulary Status History Report.

Exhibit 60 – Formulary Status History Report Selection



STEP 3

On the Formulary Status History Report (Exhibit 61), there are several actions you can take to view more details or get background information:

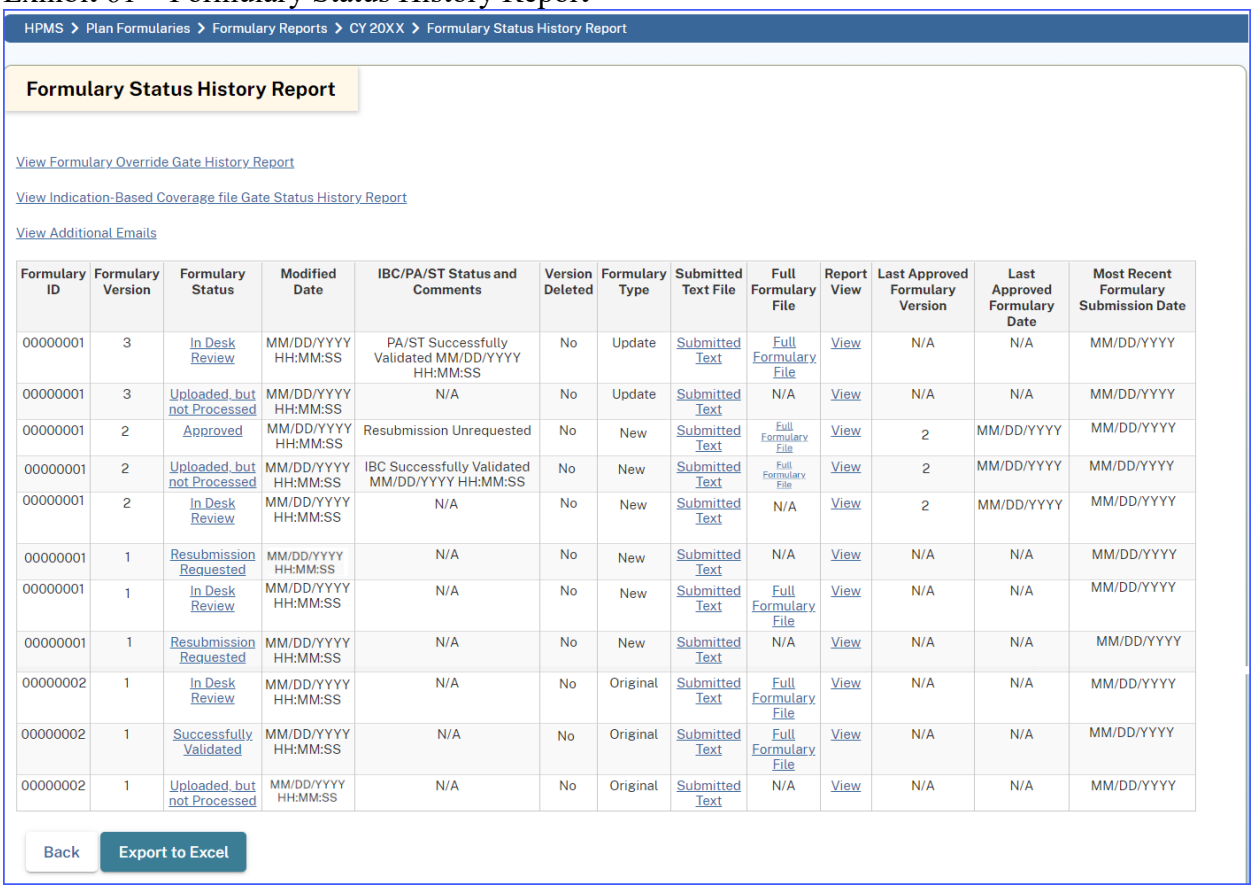
- To view the email sent regarding the Formulary, PA, ST and IBC file upload, click the link provided under the Formulary status link. A pop-up window will appear. When you have finished reviewing the information, click the "Close" button at the bottom of the window.
- To view the email sent, after the PA/ST files are successfully uploaded from Revise PA/ST Criteria – Upload Page, click the link provided under the Formulary Status column for the row where the PA/ST status is displayed, in the "IBC/PA/ST Status Comments" column. A pop-up window will appear. When you have finished reviewing the information, click the "Close" button at the bottom of the window.
- To view the email sent after IBC files are successfully uploaded from Revise IBC – Upload Page, click the link provided under the Formulary Status column for the row

where the IBC status is displayed in the "IBC/PA/ST Status Comments" column. A pop-up window will appear. When you have finished reviewing the information, click the "Close" button at the bottom of the window.

- To view the text file previously submitted, click the "Submitted Text" hyperlink (Exhibit 62). A pop-up window will appear. If the version is created after accepting line level decision, "Submitted Text" link will display CMS line level decisions (Exhibit 67). When you have finished reviewing the information, click the "Close" button at the bottom of the window.
- To view the full Formulary file that includes the successfully validated changes as well as the existing Formulary records, click the "Full Formulary File" hyperlink (Exhibit 63). A pop-up window will appear. This file is only available for versions of the Formulary in successfully validated in desk review or Approved status. When you have finished reviewing the information, click the "Close" button at the bottom of the window.
  Note: To save full Formulary file as text file (.txt), in the full Formulary file popup command bar, select "save as" to create a text file.
- To view the RxCUI report (Exhibit 65) for the Formulary, click the "View" button and then click the "View contents of the Formulary Submission [CSV] link. A CSV file will be displayed. When you have finished reviewing the information, click the "Close" button at the bottom of the window.
- To view the submitted PA/ST files, click the "View" button and then click the Submitted Prior Authorization File and Submitted Step Therapy File links (Exhibit 65). A pop-up window will appear. This file only contains the latest submitted changes. When you have finished reviewing the information, click the "Close" button at the bottom of the window.
- To view the submitted IBC files, click the "View" button and then click the "Submitted Indication-Based Coverage File" links (Exhibit 65). A pop-up window will appear. When you have finished reviewing the information, click the "Close" button at the bottom of the window.
- To view the approved formularies gate open/close history outside of the scheduled update windows, click the link "View Formulary Override Gate History Report" (Exhibit 61). A pop-up window will appear. The following details will be displayed in the Formulary Override Gate History Report pop-up window: Formulary ID, Formulary Version, Gate Status (Open Gate/Close Gate), Gate Open/Close Date, Gate Auto-Close Date (Exhibit 66). Note that the gate status of 'Open Gate' will be a hyperlink to the Email sent to users from Formulary Desk Review. When you have finished reviewing the information, click the "Close" button at the bottom of the window.
- To view the full PA/ST files that include the successfully validated changes as well as the existing criteria associated with the Formulary, click the "View" button and then click the full Prior Authorization File and full Step Therapy File links (Exhibit 65). A .csv file opens, which lists all the Group Descriptions associated to the latest version of the Formulary that is sent to desk review in excel format. When you have finished reviewing the information, close the .csv file.
- To view the full PA/ST files that include the successfully validated changes as well as the existing criteria associated with the Formulary, click the "View" button and then click the full Prior Authorization File and full Step Therapy File links (Exhibit 65). A .csv file opens, which lists all the Group Descriptions associated to the latest version of the Formulary that is sent to desk review in excel format. When you have finished reviewing the information, close the .csv file.

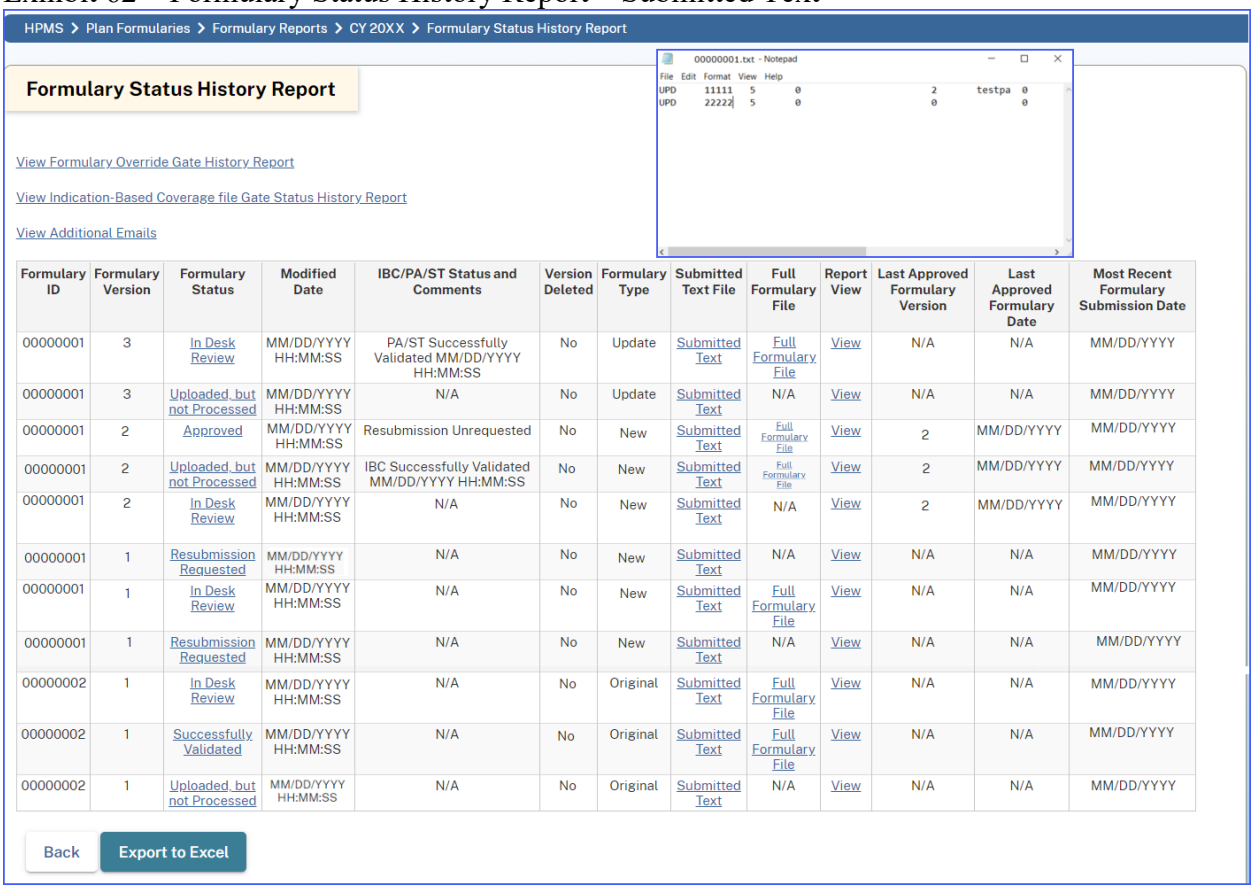
- To view the full IBC files that include the successfully validated changes and excludes the RxCUIs that are auto-deleted from IBC file as they are deleted from Formulary file, click the "View" button and then click the "Full Indication-Based Coverage File" link (Exhibit 65). A .csv file opens, which lists all the RxCUIs associated to the latest version of the Formulary that is sent to desk review in excel format. When you have finished reviewing the information, close the .csv file.
- To export the Formulary Status History Report to Excel, click the "Export to Excel" button.
- To view the Indication-Based Coverage gate open/close history outside of the scheduled Formulary windows, click the link "View Indication-Based Coverage file Gate Status History Report" (Exhibit 61). A pop-up window will appear. The following details will be displayed in the Indication-Based Coverage Gate History Report pop-up window: Formulary ID, Gate Status, Gate Date and Gate Auto-Close Date (Exhibit 68). Note that the gate status of 'Open Gate' will be a hyperlink to the Email sent to users by CMS. When you have finished reviewing the information, click the "Close" button at the bottom of the window.
- To view the Additional Emails for the formularies sent by the CMS to the Plans, click the link "View Additional Emails" (Exhibit 61). A pop-up window will appear. The following details will be displayed in the Additional Emails Report pop-up window: Formulary ID, Formulary Version, Additional Email and Email Date (Exhibit 69). Note that the 'Additional Email' hyperlink will display the Email sent to users by CMS. When you have finished reviewing the information, click the "Close" button at the bottom of the window.

Exhibit 61 – Formulary Status History Report



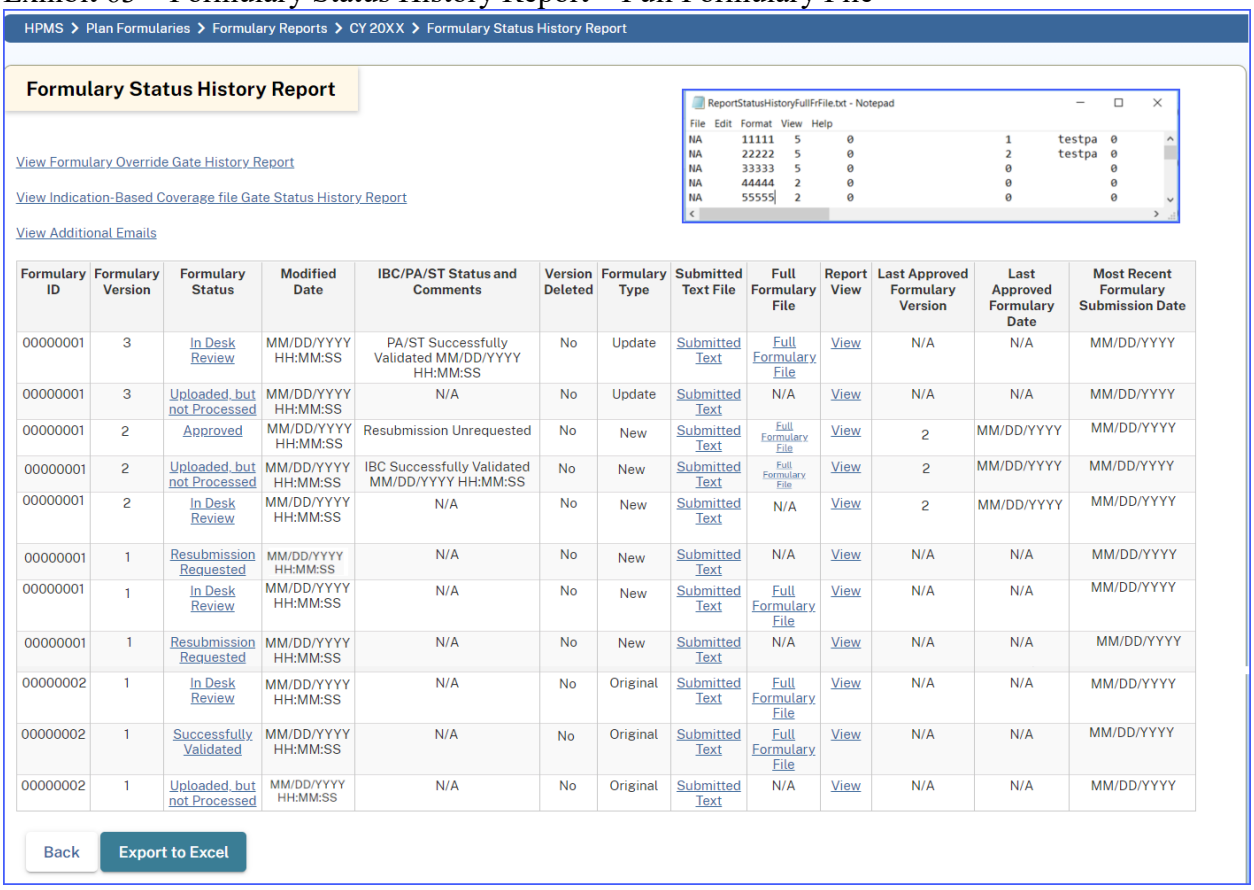
Formulary ID	Formulary Version	Formulary Status	Modified Date	IBC/PA/ST Status and Comments	Version Deleted	Formulary Type	Submitted Text File	Full Formulary File	Report View	Last Approved Formulary Version	Last Approved Formulary Date	Most Recent Formulary Submission Date
00000001	3	In Desk Review	MM/DD/YYYY HH:MM:SS	PA/ST Successfully Validated MM/DD/YYYY HH:MM:SS	No	Update	Submitted Text	Full Formulary File	View	N/A	N/A	MM/DD/YYYY
00000001	3	Uploaded, but not Processed	MM/DD/YYYY HH:MM:SS	N/A	No	Update	Submitted Text	N/A	View	N/A	N/A	MM/DD/YYYY
00000001	2	Approved	MM/DD/YYYY HH:MM:SS	Resubmission Unrequested	No	New	Submitted Text	Full Formulary File	View	2	MM/DD/YYYY	MM/DD/YYYY
00000001	2	Uploaded, but not Processed	MM/DD/YYYY HH:MM:SS	IBC Successfully Validated MM/DD/YYYY HH:MM:SS	No	New	Submitted Text	Full Formulary File	View	2	MM/DD/YYYY	MM/DD/YYYY
00000001	2	In Desk Review	MM/DD/YYYY HH:MM:SS	N/A	No	New	Submitted Text	N/A	View	2	MM/DD/YYYY	MM/DD/YYYY
00000001	1	Resubmission Requested	MM/DD/YYYY HH:MM:SS	N/A	No	New	Submitted Text	N/A	View	N/A	N/A	MM/DD/YYYY
00000001	1	In Desk Review	MM/DD/YYYY HH:MM:SS	N/A	No	New	Submitted Text	Full Formulary File	View	N/A	N/A	MM/DD/YYYY
00000001	1	Resubmission Requested	MM/DD/YYYY HH:MM:SS	N/A	No	New	Submitted Text	N/A	View	N/A	N/A	MM/DD/YYYY
00000002	1	In Desk Review	MM/DD/YYYY HH:MM:SS	N/A	No	Original	Submitted Text	Full Formulary File	View	N/A	N/A	MM/DD/YYYY
00000002	1	Successfully Validated	MM/DD/YYYY HH:MM:SS	N/A	No	Original	Submitted Text	Full Formulary File	View	N/A	N/A	MM/DD/YYYY
00000002	1	Uploaded, but not Processed	MM/DD/YYYY HH:MM:SS	N/A	No	Original	Submitted Text	N/A	View	N/A	N/A	MM/DD/YYYY

Exhibit 62 – Formulary Status History Report – Submitted Text



Formulary ID	Formulary Version	Formulary Status	Modified Date	IBC/PA/ST Status and Comments	Version Deleted	Formulary Type	Submitted Text File	Full Formulary File	Report View	Last Approved Formulary Version	Last Approved Formulary Date	Most Recent Formulary Submission Date
00000001	3	In Desk Review	MM/DD/YYYY HH:MM:SS	PA/ST Successfully Validated MM/DD/YYYY HH:MM:SS	No	Update	Submitted Text	Full Formulary File	View	N/A	N/A	MM/DD/YYYY
00000001	3	Uploaded, but not Processed	MM/DD/YYYY HH:MM:SS	N/A	No	Update	Submitted Text	N/A	View	N/A	N/A	MM/DD/YYYY
00000001	2	Approved	MM/DD/YYYY HH:MM:SS	Resubmission Unrequested	No	New	Submitted Text	Full Formulary File	View	2	MM/DD/YYYY	MM/DD/YYYY
00000001	2	Uploaded, but not Processed	MM/DD/YYYY HH:MM:SS	IBC Successfully Validated MM/DD/YYYY HH:MM:SS	No	New	Submitted Text	Full Formulary File	View	2	MM/DD/YYYY	MM/DD/YYYY
00000001	2	In Desk Review	MM/DD/YYYY HH:MM:SS	N/A	No	New	Submitted Text	N/A	View	2	MM/DD/YYYY	MM/DD/YYYY
00000001	1	Resubmission Requested	MM/DD/YYYY HH:MM:SS	N/A	No	New	Submitted Text	N/A	View	N/A	N/A	MM/DD/YYYY
00000001	1	In Desk Review	MM/DD/YYYY HH:MM:SS	N/A	No	New	Submitted Text	Full Formulary File	View	N/A	N/A	MM/DD/YYYY
00000001	1	Resubmission Requested	MM/DD/YYYY HH:MM:SS	N/A	No	New	Submitted Text	N/A	View	N/A	N/A	MM/DD/YYYY
00000002	1	In Desk Review	MM/DD/YYYY HH:MM:SS	N/A	No	Original	Submitted Text	Full Formulary File	View	N/A	N/A	MM/DD/YYYY
00000002	1	Successfully Validated	MM/DD/YYYY HH:MM:SS	N/A	No	Original	Submitted Text	Full Formulary File	View	N/A	N/A	MM/DD/YYYY
00000002	1	Uploaded, but not Processed	MM/DD/YYYY HH:MM:SS	N/A	No	Original	Submitted Text	N/A	View	N/A	N/A	MM/DD/YYYY

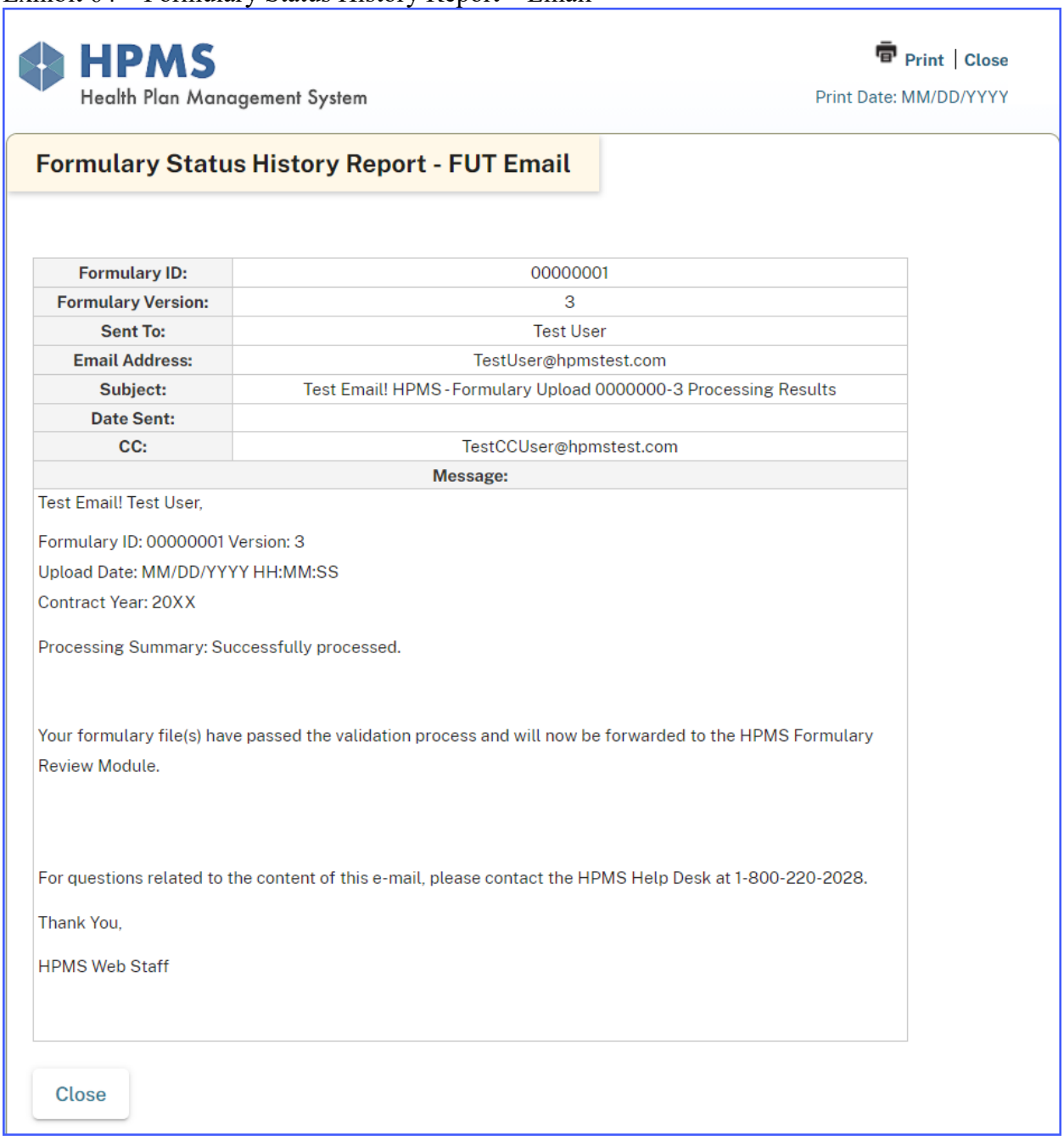
Exhibit 63 – Formulary Status History Report – Full Formulary File



Formulary ID	Formulary Version	Formulary Status	Modified Date	IBC/PA/ST Status and Comments	Version Deleted	Formulary Type	Submitted Text File	Full Formulary File	Report View	Last Approved Formulary Version	Last Approved Formulary Date	Most Recent Formulary Submission Date
00000001	3	In Desk Review	MM/DD/YYYY HH:MM:SS	PA/ST Successfully Validated MM/DD/YYYY HH:MM:SS	No	Update	Submitted Text	Full Formulary File	View	N/A	N/A	MM/DD/YYYY
00000001	3	Uploaded, but not Processed	MM/DD/YYYY HH:MM:SS	N/A	No	Update	Submitted Text	N/A	View	N/A	N/A	MM/DD/YYYY
00000001	2	Approved	MM/DD/YYYY HH:MM:SS	Resubmission Unrequested	No	New	Submitted Text	Full Formulary File	View	2	MM/DD/YYYY	MM/DD/YYYY
00000001	2	Uploaded, but not Processed	MM/DD/YYYY HH:MM:SS	IBC Successfully Validated MM/DD/YYYY HH:MM:SS	No	New	Submitted Text	Full Formulary File	View	2	MM/DD/YYYY	MM/DD/YYYY
00000001	2	In Desk Review	MM/DD/YYYY HH:MM:SS	N/A	No	New	Submitted Text	N/A	View	2	MM/DD/YYYY	MM/DD/YYYY
00000001	1	Resubmission Requested	MM/DD/YYYY HH:MM:SS	N/A	No	New	Submitted Text	N/A	View	N/A	N/A	MM/DD/YYYY
00000001	1	In Desk Review	MM/DD/YYYY HH:MM:SS	N/A	No	New	Submitted Text	Full Formulary File	View	N/A	N/A	MM/DD/YYYY
00000001	1	Resubmission Requested	MM/DD/YYYY HH:MM:SS	N/A	No	New	Submitted Text	N/A	View	N/A	N/A	MM/DD/YYYY
00000002	1	In Desk Review	MM/DD/YYYY HH:MM:SS	N/A	No	Original	Submitted Text	Full Formulary File	View	N/A	N/A	MM/DD/YYYY
00000002	1	Successfully Validated	MM/DD/YYYY HH:MM:SS	N/A	No	Original	Submitted Text	Full Formulary File	View	N/A	N/A	MM/DD/YYYY
00000002	1	Uploaded, but not Processed	MM/DD/YYYY HH:MM:SS	N/A	No	Original	Submitted Text	N/A	View	N/A	N/A	MM/DD/YYYY

Back | Export to Excel

Exhibit 64 – Formulary Status History Report – Email



HPMS
Health Plan Management System

Print | Close
Print Date: MM/DD/YYYY

Formulary Status History Report - FUT Email

Formulary ID:	00000001
Formulary Version:	3
Sent To:	Test User
Email Address:	TestUser@hpmstest.com
Subject:	Test Email! HPMS - Formulary Upload 0000000-3 Processing Results
Date Sent:	
CC:	TestCCUser@hpmstest.com

Message:

Test Email! Test User,

Formulary ID: 00000001 Version: 3
Upload Date: MM/DD/YYYY HH:MM:SS
Contract Year: 20XX

Processing Summary: Successfully processed.

Your formulary file(s) have passed the validation process and will now be forwarded to the HPMS Formulary Review Module.

For questions related to the content of this e-mail, please contact the HPMS Help Desk at 1-800-220-2028.

Thank You,

HPMS Web Staff

Close

Exhibit 65 – Formulary Status History RxCUI Report

HPMS
Health Plan Management System

Print | Close
Print Date: MM/DD/YYYY

Formulary Status History Report - Formulary RxCUI Report

Formulary ID:	00000001
Formulary Name:	Sample Formulary
Formulary Version:	4
Number of Tiers:	5
Effective Date:	MM/DD/YYYY
Quantity Limit:	1
Formulary Classification:	USP
Limited Access:	Yes
Prior Authorization:	Yes
Step Therapy Management:	Yes
Formulary Status:	In Desk Review
Expedited Substitution:	Yes
Indication-Based Coverage:	Yes
Formulary Type:	U
Contracts:	Z0001 - contract one
Formulary Data:	Contents of the formulary submission are not available.
Formulary Attachments:	Full Prior Authorization File [CSV] Submitted Prior Authorization File [TXT] Full Step Therapy File [CSV] Submitted Step Therapy File [TXT]

Tier Level	Tier Label
1	Preferred Generic
2	Generic
3	Preferred Brand
4	Non-Preferred Drug
5	Specialty Tier
6	Select Diabetic Drugs

Close

Exhibit 66 – Formulary Override Gate History Report

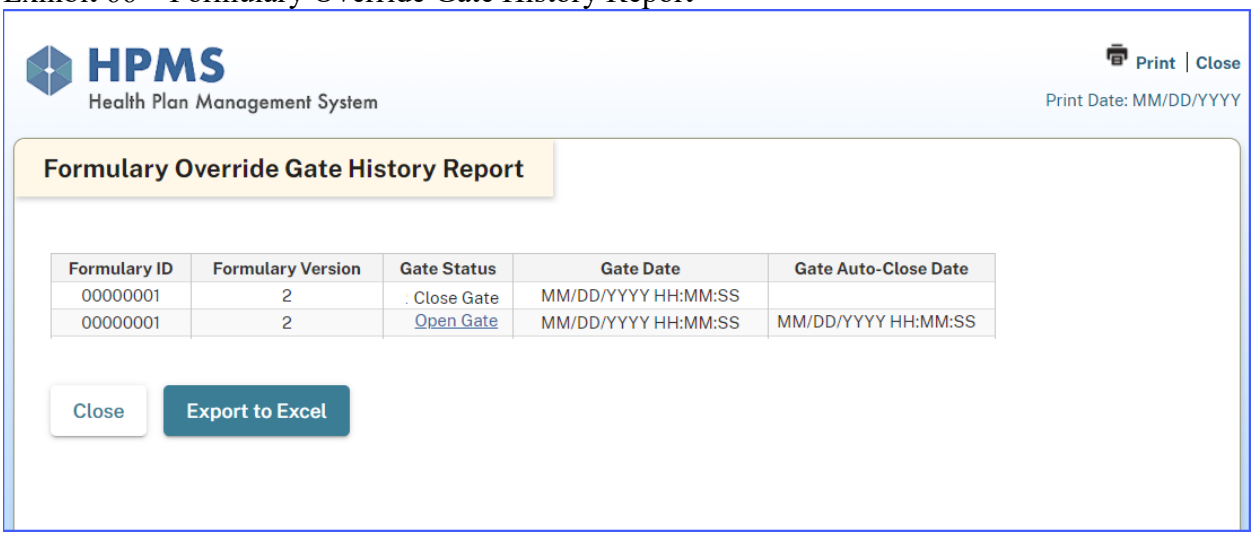


Exhibit 67 – Formulary Status History Report – Accepted Line Level Decisions Report

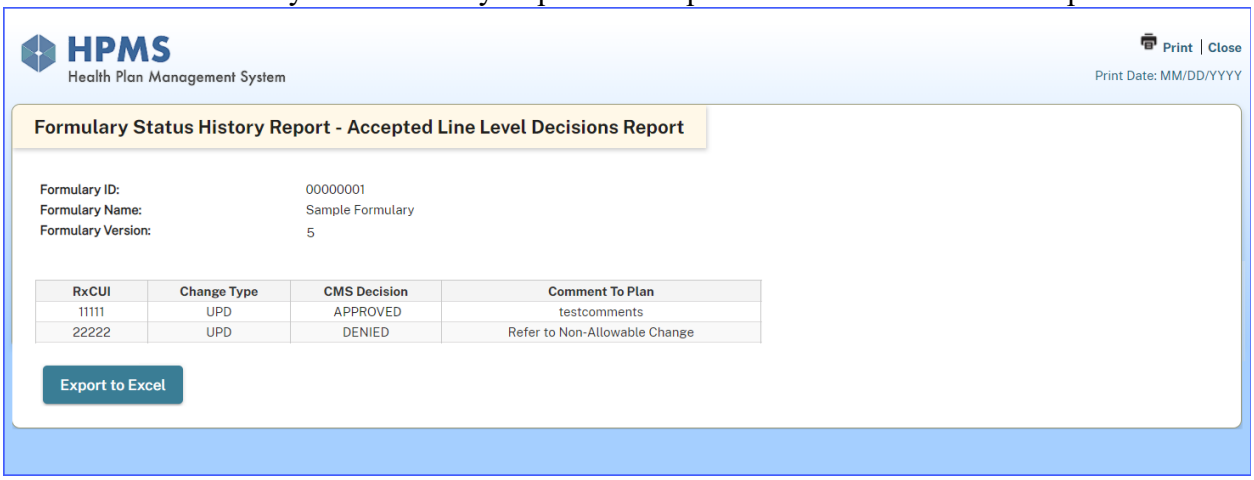


Exhibit 68 – Indication-Based Coverage Gate History Report

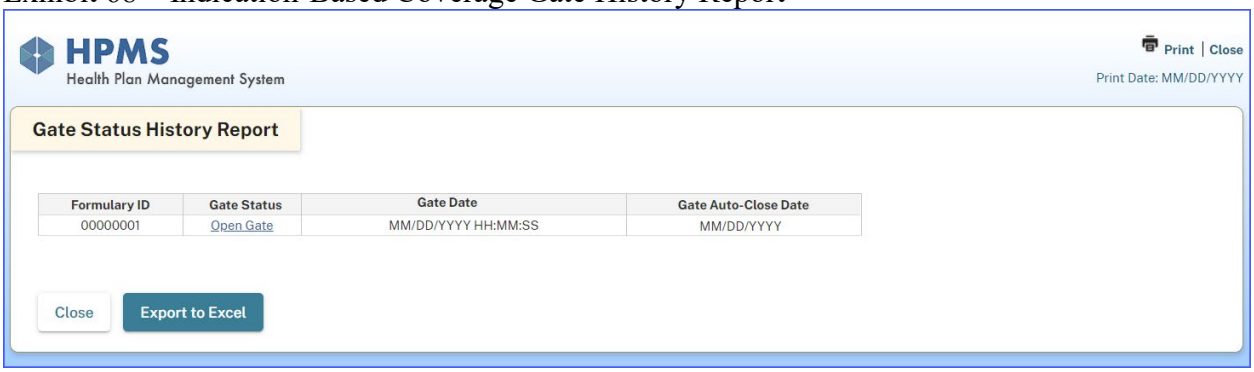
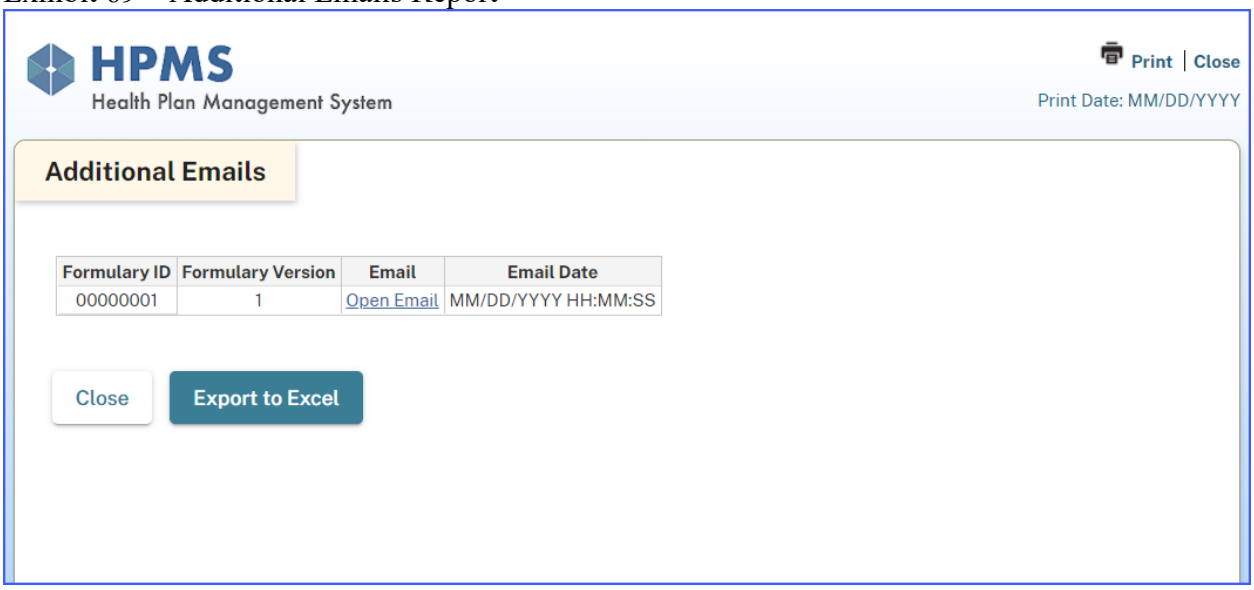


Exhibit 69 – Additional Emails Report



XVI. INDICATION-BASED COVERAGE FILE – CHANGE NOTIFICATION REPORT

The Indication-Based Coverage File Change Notification Report allows you to compare two versions of IBC files that are associated with a Formulary**.**

STEP 1

As shown in Exhibit 2 on the **HPMS Home** page, select the **Plan Formularies** link in the left navigation bar. On the fly out menu, select the **Formulary Reports** link, This takes you to the Formulary Reports Contract Year Selection page.

STEP 2

On the **Formulary Reports Contract Year Selection** page (Exhibit 50), select the appropriate Contract Year link. This takes you to the Formulary Reports – Select a Report page.

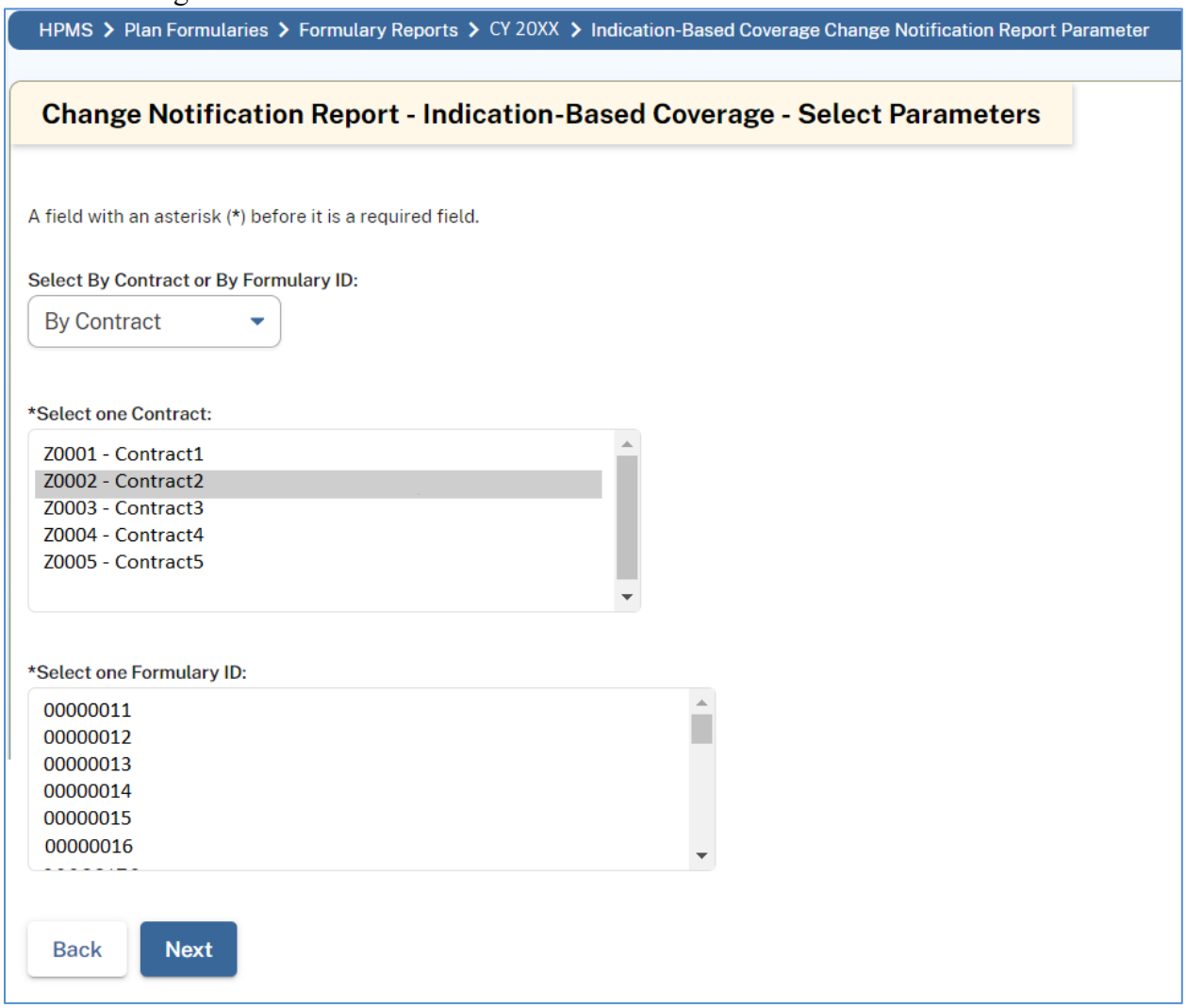
STEP 3

On the **Select a Report** page (Exhibit 51), select "Change Notification Report – Indication-Based Coverage." This takes you to the Select By Contract or By Formulary ID Selection page.

STEP 4

On the **Select By Contract or By Formulary ID** page (Exhibit 70), select a contract ID or Formulary ID you want to view in the report and click "Next." This takes you to the Submission Comparison Selection page.

Exhibit 70 – Change Notification Report (CNR) - Indication-Based Coverage File - Select Parameters Page



STEP 5

On the **Submission Comparison Selection page** (Exhibit 71), select two Formulary versions to view in the report and click "Next." This takes you to the Change Notification Report – Indication-Based Coverage Report page (Exhibit 72).

Exhibit 71 – Change Notification Report – Indication-Based Coverage - Submission Comparison Selection

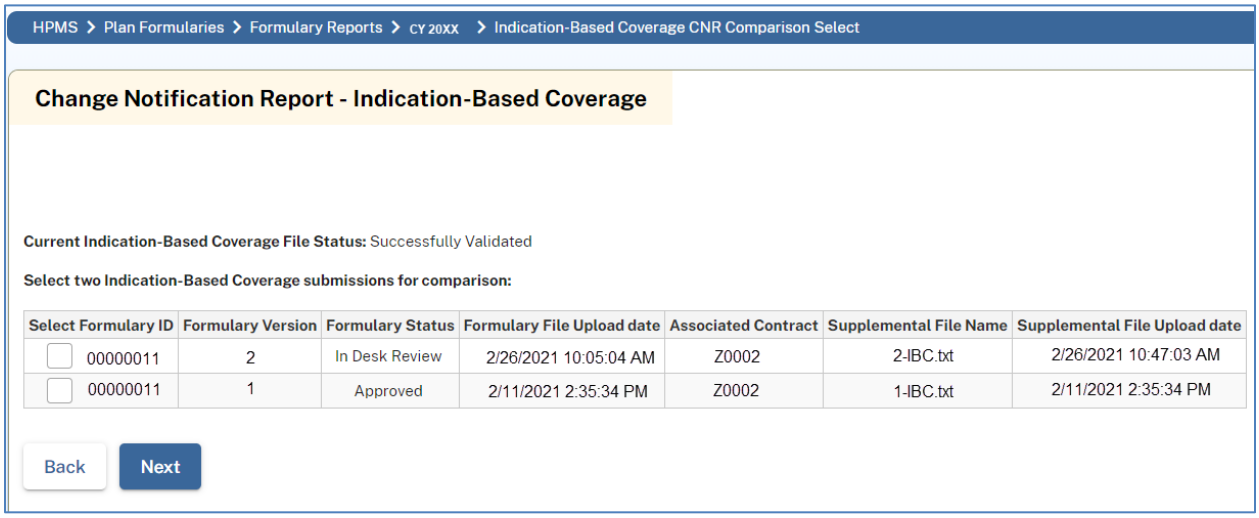
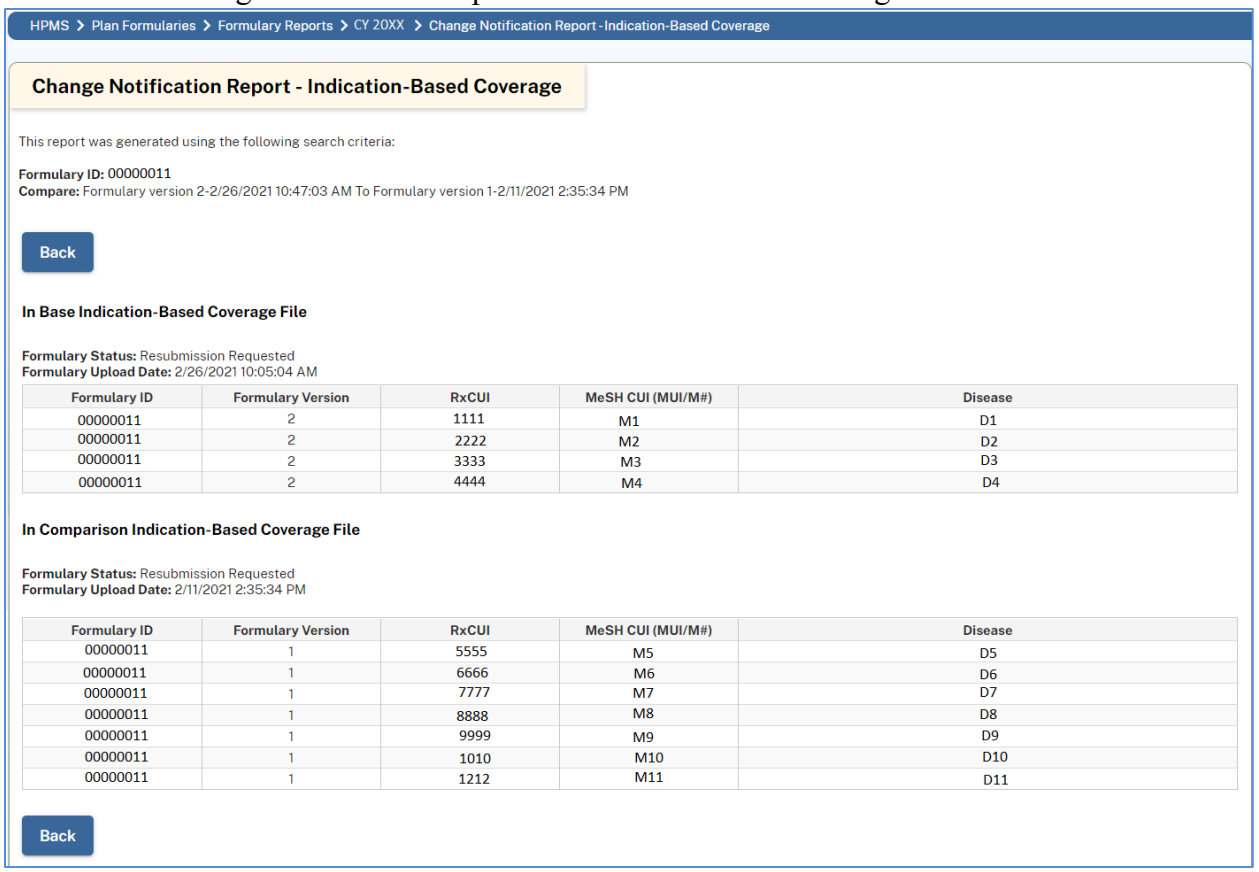


Exhibit 72 – Change Notification Report – Indication-Based Coverage



XVII. FORMULARY P&T COMMITTEE ATTESTATION REPORT

The **Formulary P&T Committee Attestation Report** provides attestation status for a given Contract(s).

STEP 1

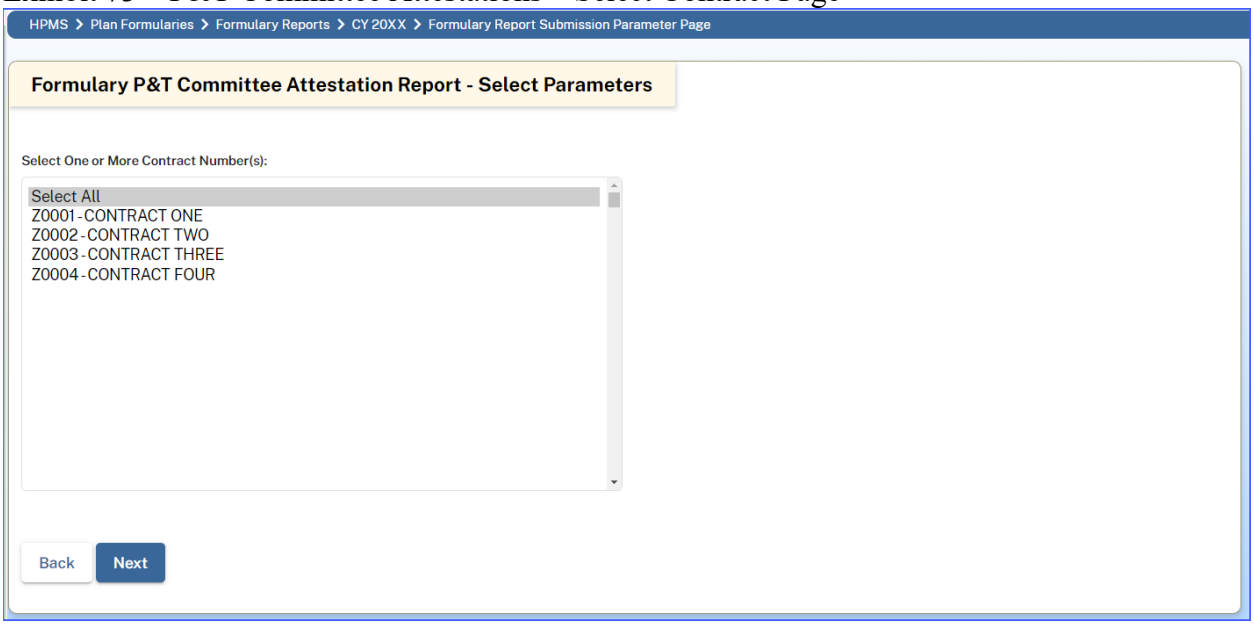
On the **Formulary Reports – Select a Report page (**Exhibit 51**),** select Formulary P&T Committee Attestation Report. This will take you to the Formulary P&T Committee Attestation Report selection criteria page.

STEP 2

On the **Formulary P&T Committee Attestation Report** selection criteria page (Exhibit 73), select the desired contracts, and then click the "Next" button. This will take you to the Formulary P&T Committee Attestation Report page (Exhibit 74).

Note that only contracts that have submitted P&T Committee attestations are displayed on the selection criteria page.

Exhibit 73 – P&T Committee Attestations – Select Contract Page

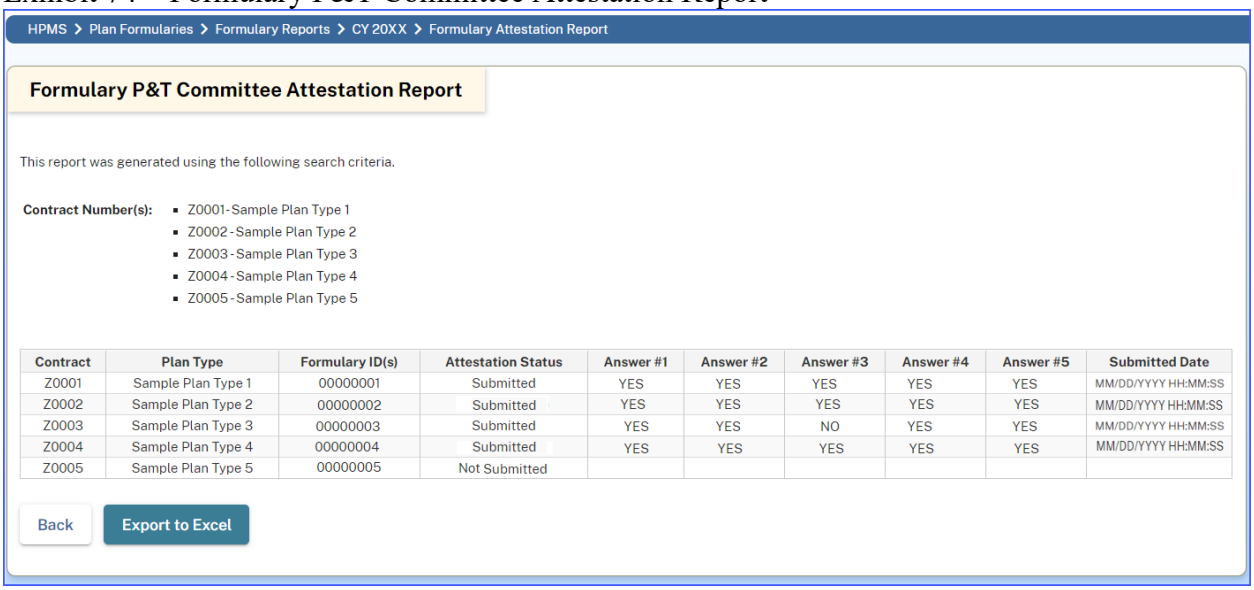


STEP 3

The **Formulary P&T Committee Attestation Report** displays the Contract, Plan Type, Formulary ID(s), Attestation Status and Answer # <#> (Yes or No or N/A) for the selected contracts.

- To export the **Formulary P&T Committee Attestation Report** to Excel, click the "Export to Excel" button.

Exhibit 74 – Formulary P&T Committee Attestation Report



Contract	Plan Type	Formulary ID(s)	Attestation Status	Answer #1	Answer #2	Answer #3	Answer #4	Answer #5	Submitted Date
Z0001	Sample Plan Type 1	00000001	Submitted	YES	YES	YES	YES	YES	MM/DD/YYYY HH:MM:SS
Z0002	Sample Plan Type 2	00000002	Submitted	YES	YES	YES	YES	YES	MM/DD/YYYY HH:MM:SS
Z0003	Sample Plan Type 3	00000003	Submitted	YES	YES	NO	YES	YES	MM/DD/YYYY HH:MM:SS
Z0004	Sample Plan Type 4	00000004	Submitted	YES	YES	YES	YES	YES	MM/DD/YYYY HH:MM:SS
Z0005	Sample Plan Type 5	00000005	Not Submitted						

XVIII. FORMULARY PA/ST ATTESTATION REPORT

The **Formulary PA/ST Attestation Report** provides attestation information for a given Contract(s).

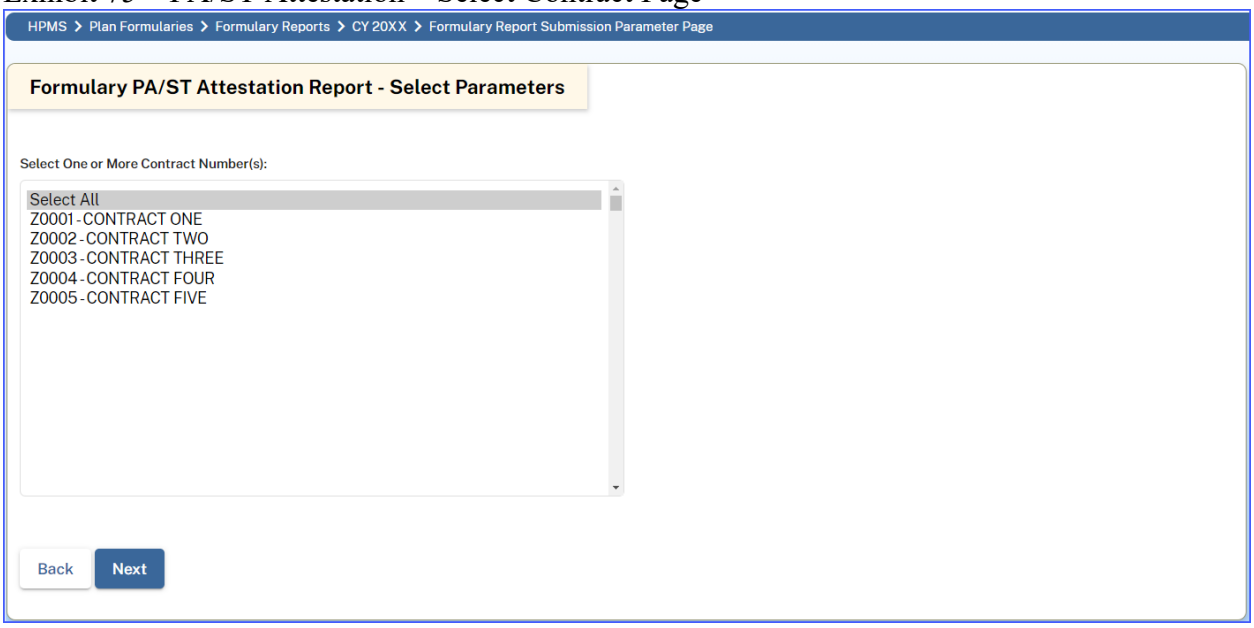
STEP 1

On the **Formulary Reports – Select a Report** page (Exhibit 51), select **Formulary PA/ST Attestation Report**. This will take you to the Formulary PA/ST Attestation Report selection criteria page.

STEP 2

On the **Formulary PA/ST Attestation Report** selection criteria page (Exhibit 75), select the desired contracts, and then click the "Next" button. This will take you to the **Formulary PA/ST Attestation Report**.

Exhibit 75 – PA/ST Attestation – Select Contract Page

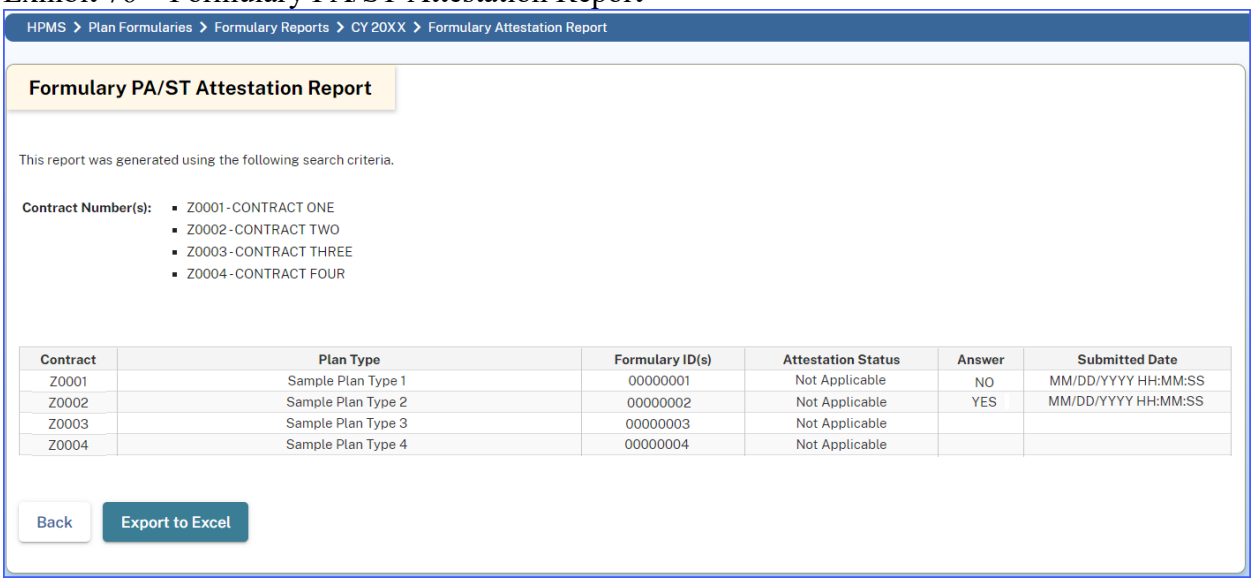


STEP 3

The **Formulary PA/ST Attestation Report** displays the Contract, Plan Type, Formulary ID(s), Attestation Status and Answer (Yes or No) for the selected contracts.

To export the **Formulary PA/ST Attestation Report** to Excel, click the "Export to Excel" button.

Exhibit 76 – Formulary PA/ST Attestation Report



XIX. FORMULARY TRANSITION POLICY REPORT

The **Formulary Transition Policy Report** provides detailed transition attestation and policy status for a given Contract.

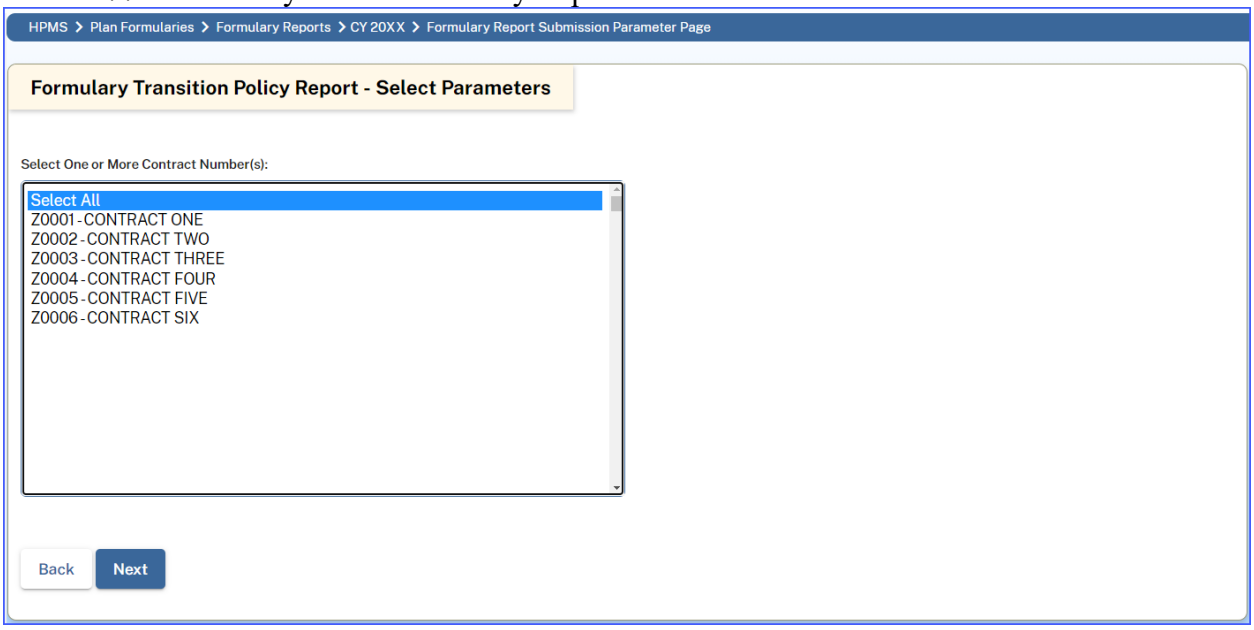
STEP 1

On the **Formulary Reports – Select a Report** page (Exhibit 51), select **Formulary Transition Policy Report**. This will take you to the Formulary Transition Policy Report - selection criteria page.

STEP 2

On the **Formulary Transition Policy Report selection criteria** page (Exhibit 77), select the desired contracts, and then click the "Next" button. This will take you to the **Formulary Transition Policy Report**.

Exhibit 77 - Formulary Transition Policy Report - Select Parameters



STEP 3

On the **Formulary Transition Policy Report** page (Exhibit 78):

- Click the Transition Policy Status link for the contract to view the attestation questions and responses submitted. A pop-up window will appear (Exhibit 79).
- To export the Attestation Questions and Reponses to Excel, click the "Export to Excel" button. When you have finished viewing the information, click the "Close" button at the bottom of the pop-up window.

Note: The Transition Policy Status column displays 'NA' when there is no Formulary associated with the contract.

Exhibit 78 - Formulary Transition Policy Report

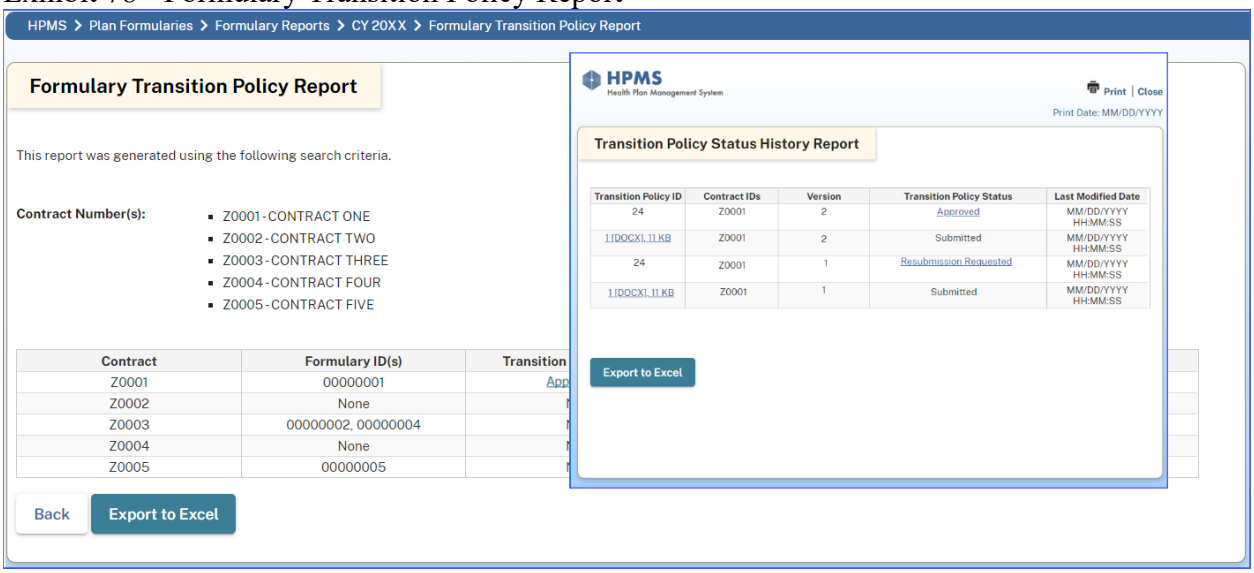
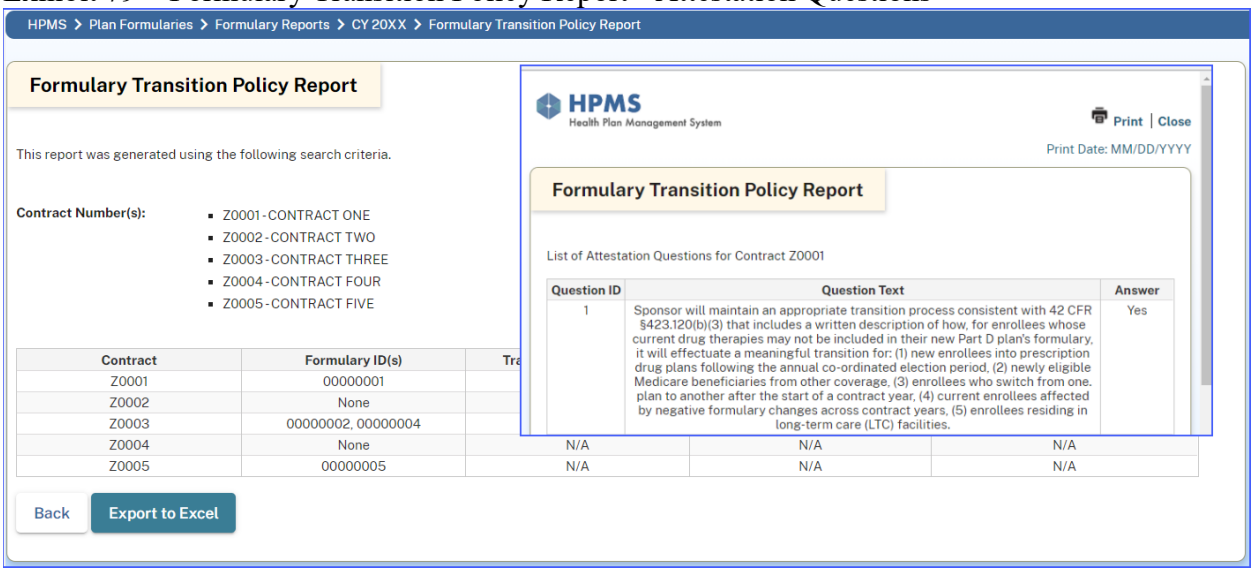


Exhibit 79 – Formulary Transition Policy Report - Attestation Questions



- Click the Transition Policy ID link for the contract to view the submitted policy document. A pop-up window will appear. When you have finished viewing the information, click the "Close" button at the bottom of the pop-up window.
- Click the View Status History link for the contract to view the transition policy status history including transition policy resubmission request and approval emails. A pop-up window will appear (Exhibit 80). Select the Transition Policy Status link to view the email sent (Exhibit 81). Select the Transition Policy ID link to view the policy document (Exhibit 82). When you have finished viewing the information, click the "Close" button at the bottom of the pop-up window.

Exhibit 80 - Transition Policy Status History Report - View Status History

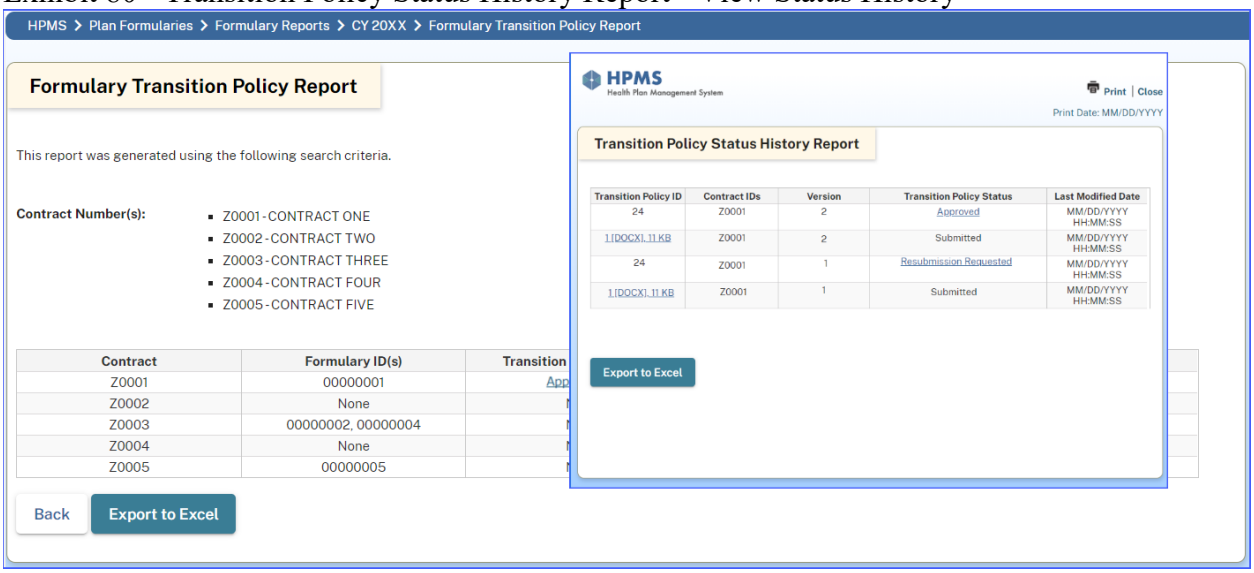


Exhibit 81 - Transition Policy Status History Report – E-mail

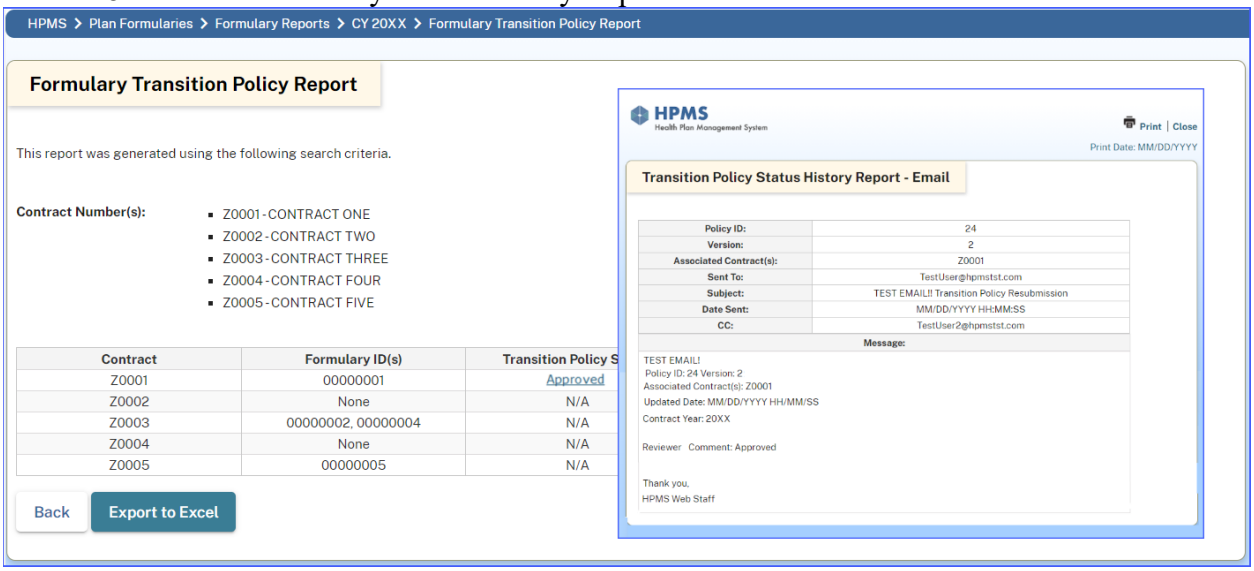
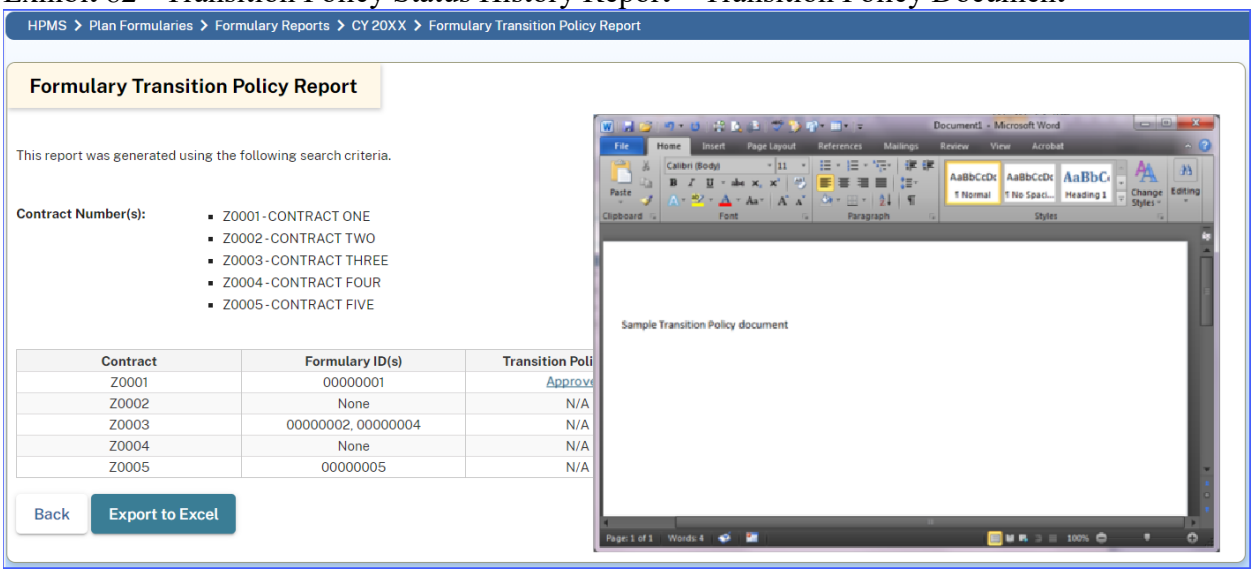


Exhibit 82 - Transition Policy Status History Report – Transition Policy Document



XX. TWO DRUG REVIEW REPORT

The **Two Drug Review Report** displays the plan defined therapeutic categories and therapeutic classes that do not appear to include RxCUIs for at least two distinct drugs. Please note that the Two Drug Review report is available to Plan sponsors only during the initial Formulary submission period.

STEP 1

On the **Formulary Reports – Select a Report** page (Exhibit 51), select **Two Drug Review Report**. This will take you to the Two Drug Review Report selection page.

STEP 2

On the Two Drug Review Report Selection page (Exhibit 83), select the desired formularies, and then select the "Export to Excel" button. This will open the Two Drug Review Report [CSV] (Exhibit 84).

Exhibit 83 – Two Drug Review Report Selection

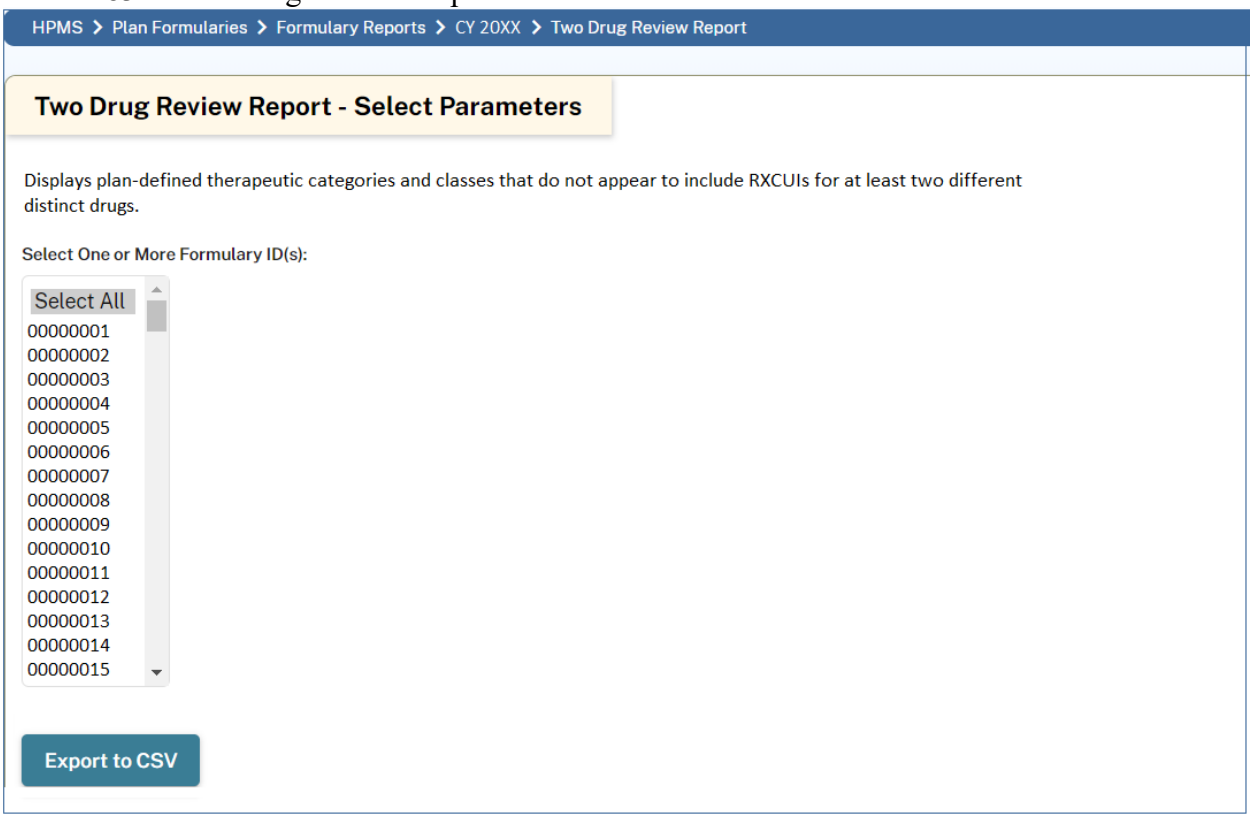


Exhibit 84 – Two Drug Review Report [CSV]

	A	B	C	D	E	F
1	Formulary ID	Formulary Version	Therapeutic Category	Therapeutic Class	Two Drug Grouping	Contract ID
2	00000001	1	Test Category 1	Test Class 1	Test Grouping 1	Z0001
3	00000001	1	Test Category 2	Test Class 2	Test Grouping 2	Z0001
4	00000001	1	Test Category 3	Test Class 3	Test Grouping 3	Z0001
5	00000001	1	Test Category 4	Test Class 4	Test Grouping 4	Z0001
6	00000001	1	Test Category 5	Test Class 5	Test Grouping 5	Z0001
7	00000002	1	Test Category 6	Test Class 6	Test Grouping 6	Z0002, Z0003
8	00000002	1	Test Category 7	Test Class 7	Test Grouping 7	Z0002, Z0003
9	00000002	1	Test Category 8	Test Class 8	Test Grouping 8	Z0002, Z0003
10	00000003	2	Test Category 9	Test Class 9	Test Grouping 9	Z0004
11	00000003	2	Test Category 10	Test Class 10	Test Grouping 10	Z0004

The following table contains a description of each field on the Two Drug Review Report.

Table 1: Two Drug Review Report Field Descriptions

Field Name	Field Type
FORMULARY ID	The unique identifier for the Formulary.
FORMULARY VERSION	The Version Number corresponding to the most recently submitted Formulary version.
THERAPEUTIC CATEGORY	Plan defined therapeutic category for an RxCUI.
THERAPEUTIC CLASS	Plan defined pharmacologic class for an RxCUI.
TD GROUPING	RxCUIs' Two Drug Grouping Name from the Formulary Reference Data.
Contract ID	The Contract ID(s) associated to a Formulary.

XXI. HOW TO SUBMIT SUPPLEMENTAL FILES

As part of the Formulary submission process, you are required to submit certain supplemental files depending on what is included in your bid. Organizations must submit this supplemental information for all the plans offering this coverage. The supplemental files cannot be loaded until the organization has successfully submitted its related bids, and the bid has migrated to "desk review" in the HPMS system. The required supplemental file gates will automatically open once your bid is in desk review. This section provides detailed information on how to submit the following supplemental files:

- Partial Gap Coverage (PGC)
- Free First Fill (FFF)
- Home Infusion (HI)
- Over-the-Counter (OTC)
- Excluded Drug (ExD)

When a plan is required to submit certain supplemental files, only one of each file type may be uploaded for all of the plans associated with a specific Formulary ID. Therefore, while multiple plans may still share a single Formulary ID, only one version of each supplemental file type may be used across all plans associated to that Formulary. This means that the content of supplemental files shared by plans with the same Formulary ID must be identical. For example, it is not possible for one plan to cover some drugs on a particular supplemental file while another plan only covers a subset of those drugs if they are sharing a Formulary ID. Additional restrictions for the different file types are included in the list of files below.

Alternatively, it is not required that all plans associated with a specific Formulary offer the same supplemental coverage. For example, there may be four plans associated with a single Formulary ID and only two of the plans offer partial gap coverage. As long as the plans that offer additional gap coverage for partial tier(s) will offer the exact same partial tier coverage (drug content and tiers) and are able to share the same partial gap coverage supplemental file, then all four of these plans can be associated with the same Formulary ID. For the remaining two plans which are not offering additional gap coverage for a partial tier, the partial gap coverage file that is submitted will not apply to them. In other words, sharing a Formulary ID requires an all-or-nothing approach to supplemental file content. Plans can only share a Formulary ID if all plans offer identical supplemental coverage for a particular file or if some associated plans will not use that supplemental file at all.

If your organization has additional questions regarding whether certain supplemental files can be shared across the same Formulary ID, please email PartDBenefits@cms.hhs.gov before creating additional Formulary IDs.

You begin the supplemental file upload process on the Formulary Submission Start page (Exhibit 4). If you need help accessing the Formulary Submission Start Page, see the sub-section entitled "How to Access the HPMS Formulary Submission Module" in Chapter I.

The Submit Partial Gap Coverage (PGC) File, Free First Fill (FFF) File, Home Infusion (HI) File, Over-the-Counter (OTC) File and Excluded Drug (ExD) File pages become available to you once your bid is written off to desk review.

- Partial Gap Coverage (PGC):
  Enhanced alternative (EA) plans (except MMPs) may offer additional gap coverage through a Part D supplemental benefit. This additional gap coverage would be above and beyond the standard benefit for generic and brand drugs and in addition to the Coverage Gap Discount Program for brand drugs. If your bid submission for an EA plan indicated that additional coverage is offered for a subset of drugs on a tier or tiers in the gap, then you must submit this partial tier gap coverage information via a supplemental PGC file, before CMS will fully review the bid.

  Note: plans that will require distinct PGC files based on the PBP submissions are not permitted to be associated with the same Formulary ID. For example, two plans requiring a PGC file could not share a supplemental file if one offered partial gap coverage on two tiers but the other only offered partial gap coverage on one tier. Therefore, the two plans in this example could not be associated with the same Formulary ID.

- Free First Fill (FFF):
  Basic alternative (BA) or enhanced alternative (EA) plans may offer a free first fill benefit. If your bid submission indicated that a plan offers FFF, you must submit the FFF file before CMS will fully review the bid.

  Note: plans that will require distinct FFF files because they intend to offer this benefit for a differing list of drugs are not permitted to be associated with the same Formulary ID.

- Home Infusion (HI):
  If your bid submission indicated that a plan offers Part D HI drugs as a supplemental benefit under Part C, you must submit the HI file before CMS will fully review the bid.

  Note: plans that will require distinct HI files because they intend to offer this benefit for a differing list of drugs are not permitted to be associated with the same Formulary ID.

- Over-the-Counter (OTC):
  If your bid submission indicated that you offer OTC drugs, you must submit the OTC file before CMS will fully review the bid.

  Note: plans that will require distinct OTC files because they intend to offer this benefit for a differing list of drugs are not permitted to be associated with the same Formulary ID. In addition, this file includes fields to provide details on the utilization management type and step therapy criteria for each drug. All of the information in these fields must be identical in order for plans to share an OTC file.

- Excluded Drug (ExD):
  Enhanced alternative (EA) plans (except MMPs) may offer excluded drug coverage through a Part D supplemental benefit. If your bid submission for an EA plan indicated that ExD coverage is offered, then you must submit the ExD file before CMS will fully review the bid.

  Note: plans that will require distinct ExD files because they intend to offer this benefit for a differing list of drugs are not permitted to be associated with the same Formulary

ID. In addition, this file includes fields to designate the tier, quantity limit, capped benefit, prior authorization, step therapy, and gap coverage for each drug. All of the information included in these fields must be identical in order for a plan to share an ExD file. For example, if a plan intended to cover a particular excluded drug with gap coverage for one plan but without gap coverage for another, those plans could not share a supplemental file, and would not be permitted to be associated with the same Formulary ID.

While the following instructions demonstrate how to submit the Free First Fill file, you can also use these instructions to upload the Partial Gap Coverage, Home Infusion, Value-Based Insurance Design, Excluded Drug and OTC files. The steps taken to upload files are the same for each supplemental file type.

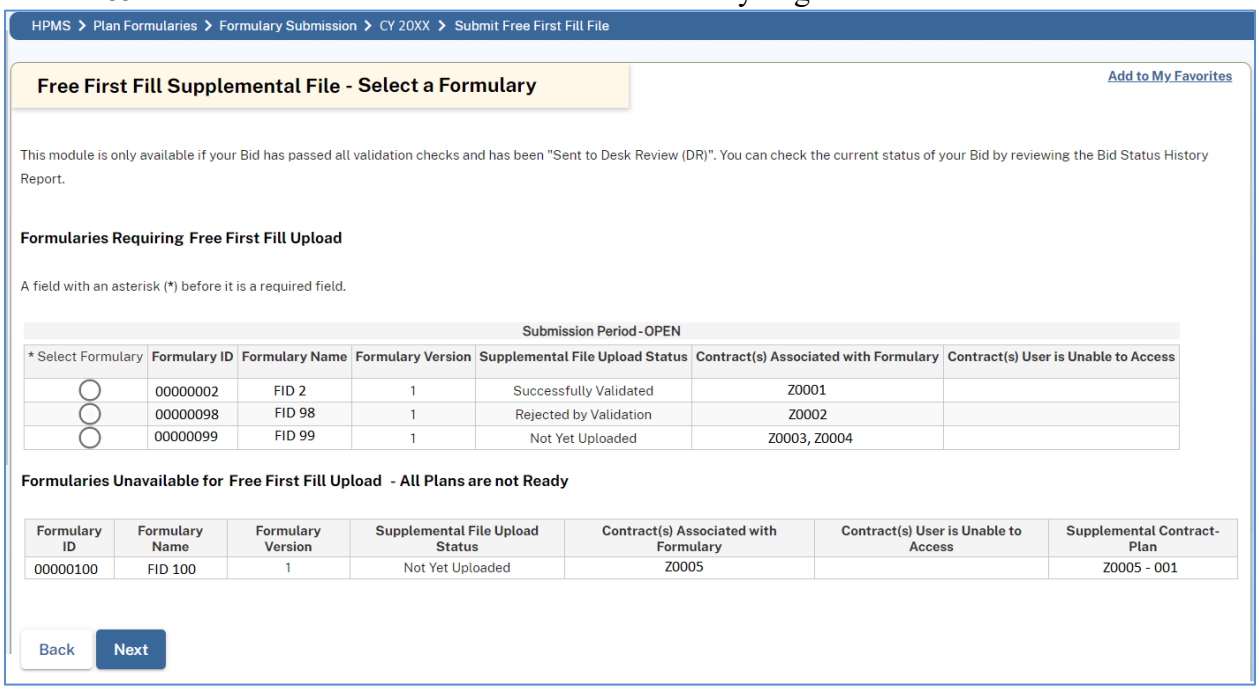
STEP 1

As shown in Exhibit 4, select Submit Free First Fill File from the **Formulary Submission Start Page.** This takes you to the Free First Fill Supplemental Files-Select a Formulary page (Exhibit 85).

STEP 2

The **Free First Fill Supplemental File-Select a Formulary** page (Exhibit 85) contains a table of all formularies that require a Free First Fill file. Note that only one Formulary can be selected at a time. Select the Formulary for which to upload a Free First Fill file and click "Next." This takes you to the Free First Fill Supplemental Files-Upload Supplemental File page.
Please note that only those plans with bid submissions that offer this benefit will be displayed. Plans that are linked to this Formulary, but that do not offer this benefit will not be displayed, as the supplemental file submission is not applicable to them.

Exhibit 85 – Submit Free First Fill File Select a Formulary Page

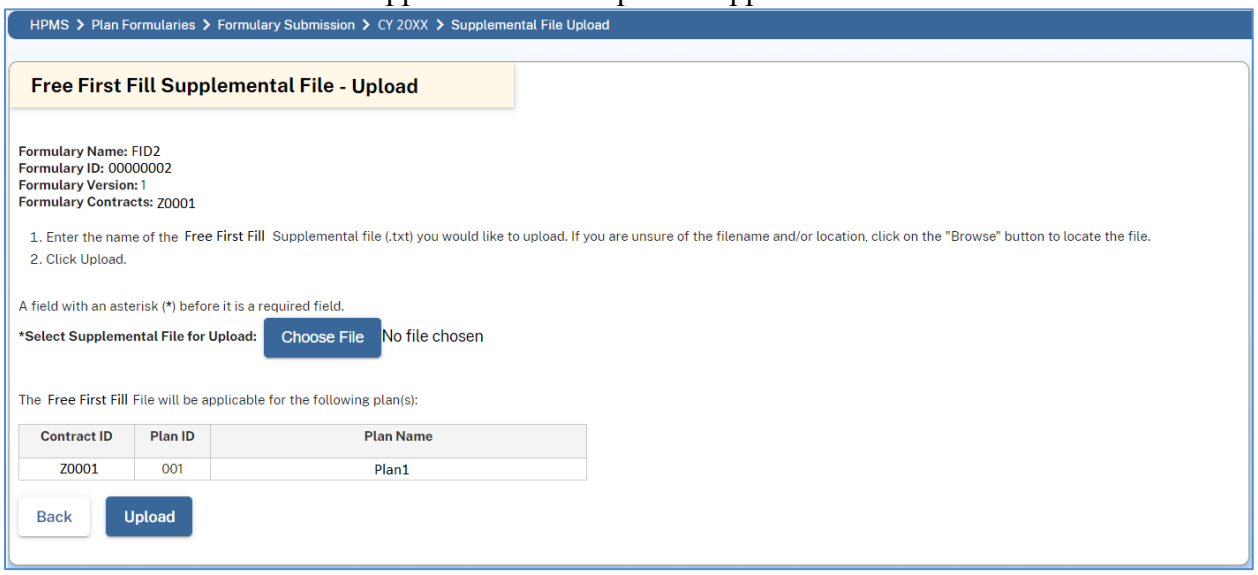


STEP 3

On the **Free First Fill Supplemental File– upload Supplemental File** page (Exhibit 86), enter the name of the Free First Fill Supplemental file (.txt) you wish to upload. If you are unsure of the filename or location, click the "Browse" button to locate the file.

Select the "Upload" button to continue with the Free First Fill File submission process. This takes you to the Free First Fill Supplemental File-Verify Supplemental File Upload page.

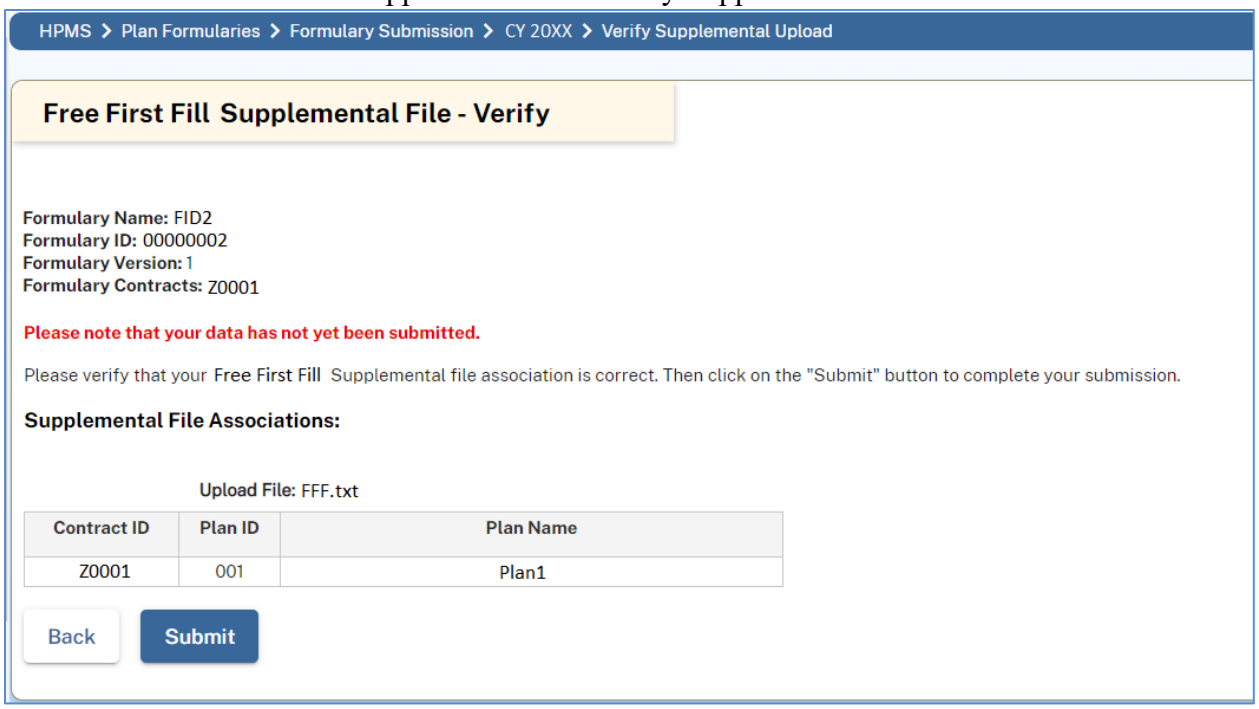
Exhibit 86 – Free First Fill Supplemental File Upload Supplemental File



STEP 4

On the **Free First Fill Supplemental File-Verify Supplemental File Upload** page (Exhibit 87), click the "Submit" button. This takes you to the Free First Fill Supplemental File-Submission Confirmation page.

Exhibit 87 – Free First Fill Supplemental File Verify Supplemental File



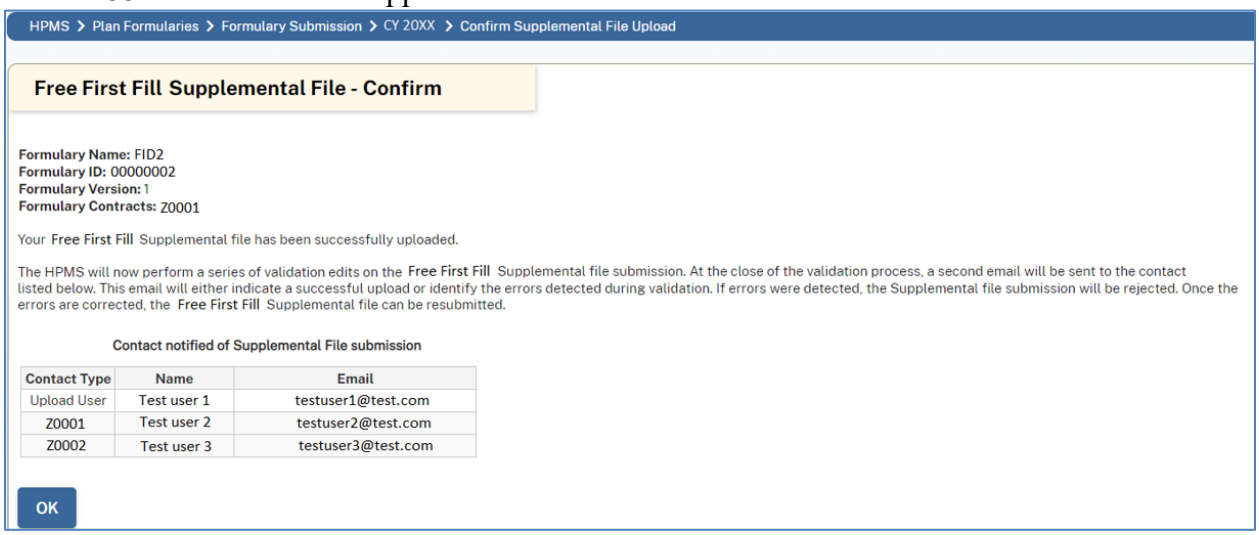
STEP 5

On the **Free First Fill Supplemental File-Submission Confirmation** page (Exhibit 88), review the information and click the "OK" button to complete the submission and return to the Free First Fill Supplemental File-Select a Formulary page.

The Submission Confirmation page provides a status of the successful upload. The system sends an email to the contact identified on this page.

After receiving the uploaded Free First Fill file, the HPMS performs a series of validation checks. At the close of the validation process, a second email is sent to the designated contact listed on this page. If errors were detected, the supplemental file submission is rejected. You must correct the Free First Fill file and resubmit the file using the Submit Free First Fill File function.

Exhibit 88 – Free First Fill Supplemental Files Submission Confirmation



XXII. SUPPLEMENTAL FILE REPORTS

The **Formulary Supplemental File** reports provide access to a variety of Formulary-related information to assist you in the Formulary supplemental submission process. The following Supplemental File reports are available:

- Status History Reports:
  - Partial Gap Coverage
  - Free First Fill
  - Home Infusion
  - Excluded Drug
  - Over-the-Counter

- Change Notification Reports:
  - Partial Gap Coverage
  - Free First Fill
  - Home Infusion

SUPPLEMENTAL FILE STATUS HISTORY REPORTS

Note: While the following instructions demonstrate how to access and view the Status History Report – Free First Fill, you can also use these instructions for all of the Supplemental File Status History reports. The steps to access and view reports are the same for each report.

STEP 1

As shown in Exhibit 49 , on the **HPMS Home** page, select the **Plan Formularies** drop down from the HPMS top navigation bar. Then select the Formulary Reports menu item. This will take you to Formulary Reports Page.

STEP 2

On the **Formulary Reports** page, select the appropriate contract year from the collapsible navigation menu, on the left side of the page (Exhibit 50). This takes you to the Report Selection page.

STEP 3

On the **Select a Report** page (Exhibit 51), select Status History Report – Free First Fill. This takes you to the select by Contract or by Formulary ID Selection page.

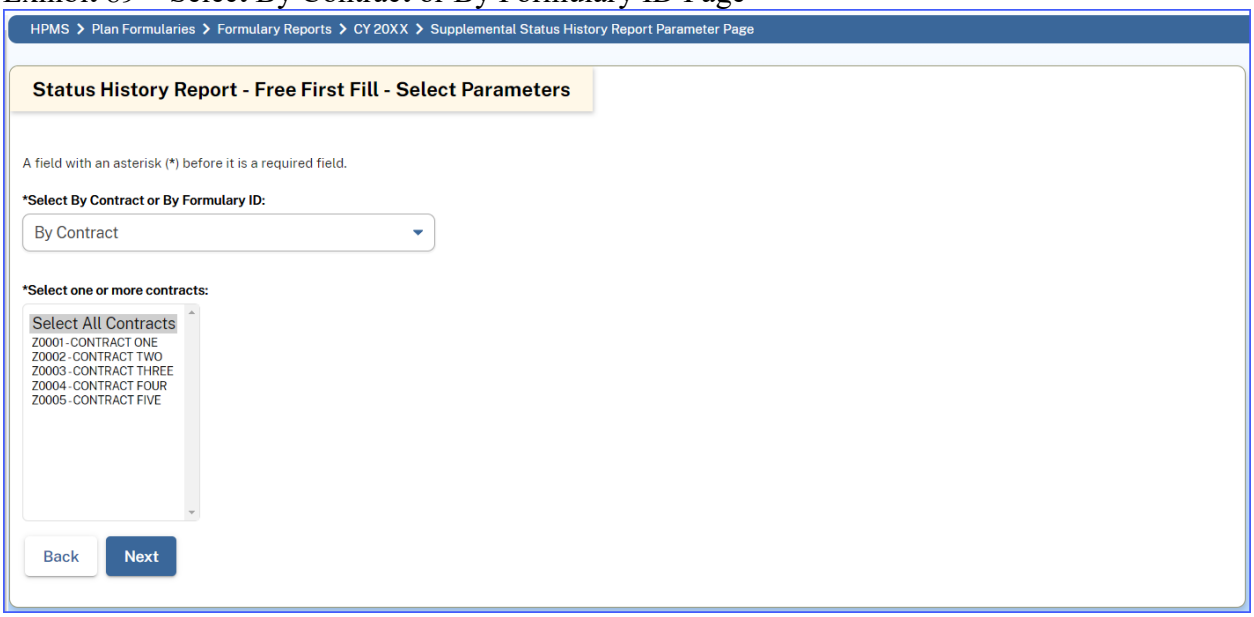
STEP 4

On the **Select By Contract or By Formulary ID** page (Exhibit 89), you have three options to select the contracts or formularies to view:

- Click Select All Contracts or Select All Formularies
- Click a single contract or Formulary ID
- Press the CTRL key and click multiple contracts or formularies

After selecting the appropriate contract or Formulary IDs, click the "Next" button. This takes you to the Status History Report – Free First Fill Report page.

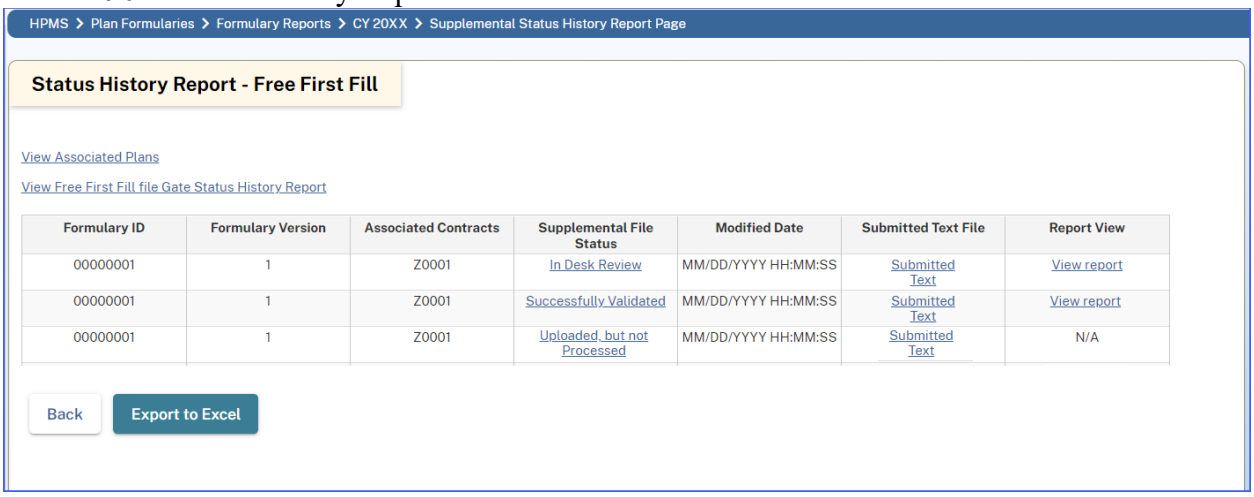
Exhibit 89 – Select By Contract or By Formulary ID Page



STEP 5

On the Status History Report – Free First Fill page (Exhibit 90), you can review information about the supplemental file status, review the submitted text file, and view report details. You can also view Formulary to plan ID details by clicking the **View Associated Plans** link.

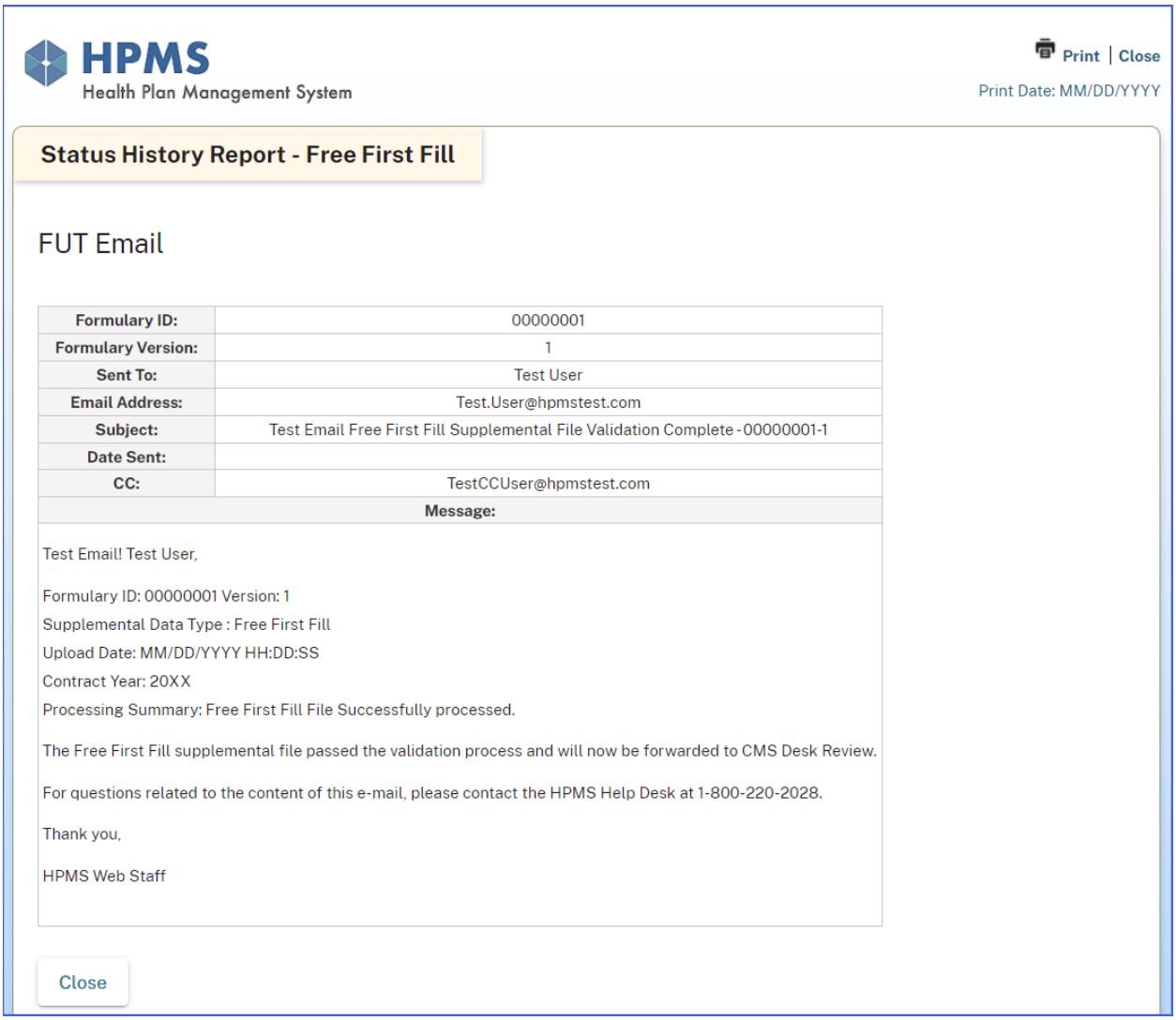
Exhibit 90 – Status History Report – Free First Fill



STEP 5A – REVIEW INFORMATION ABOUT SUPPLEMENTAL FILE STATUS

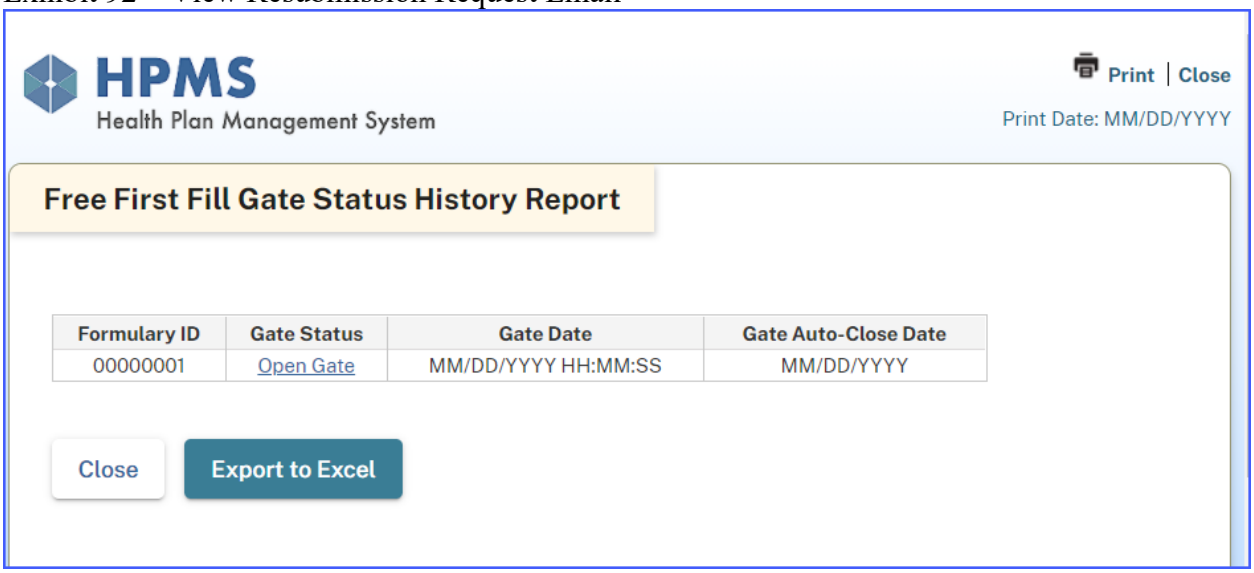
In the Supplemental File Status column, you may have a Formulary ID assigned the status "Successfully Validated" or "Rejected by Validation." If this is the case, the status is displayed as a link. Click the hyperlink to view the email that was sent to you in a pop-up window (Exhibit 91). When you have finished reviewing the information, click the "Close" button at the bottom of the window.

Exhibit 91 – View Submission Email



To view the supplemental file gate open/close history, click the link "View Supplemental File Gate Status History Report" (Exhibit 90). A pop-up window will appear (Exhibit 92). The following details will be displayed in the Supplemental File Gate History Report pop-up window: Formulary ID, Gate Status (Open Gate/Close Gate), Gate Open/Close Date, Gate Auto-Close Date. Note that the gate status of 'Open Gate' will be a hyperlink to the resubmission request email sent when the gate is open. When you have finished reviewing the information, click the "Close" button at the bottom of the window.

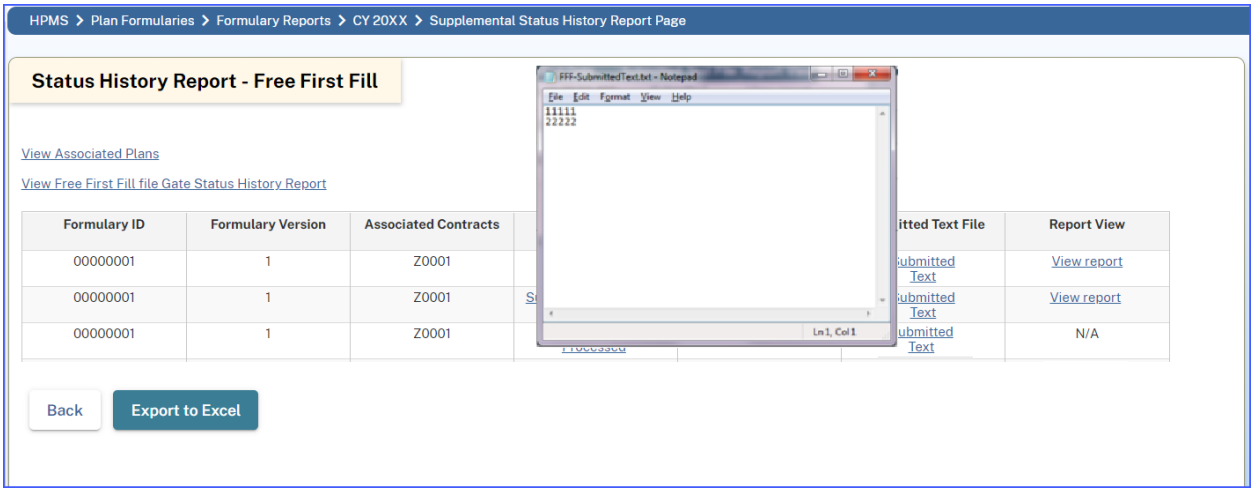
Exhibit 92 – View Resubmission Request Email



STEP 5B – REVIEW THE SUBMITTED TEXT FILE

To view the text file previously submitted, click the Submitted Text link. A pop-up window appears (Exhibit 93). When you have finished reviewing the information, you may close the browser window for the Submitted Text.

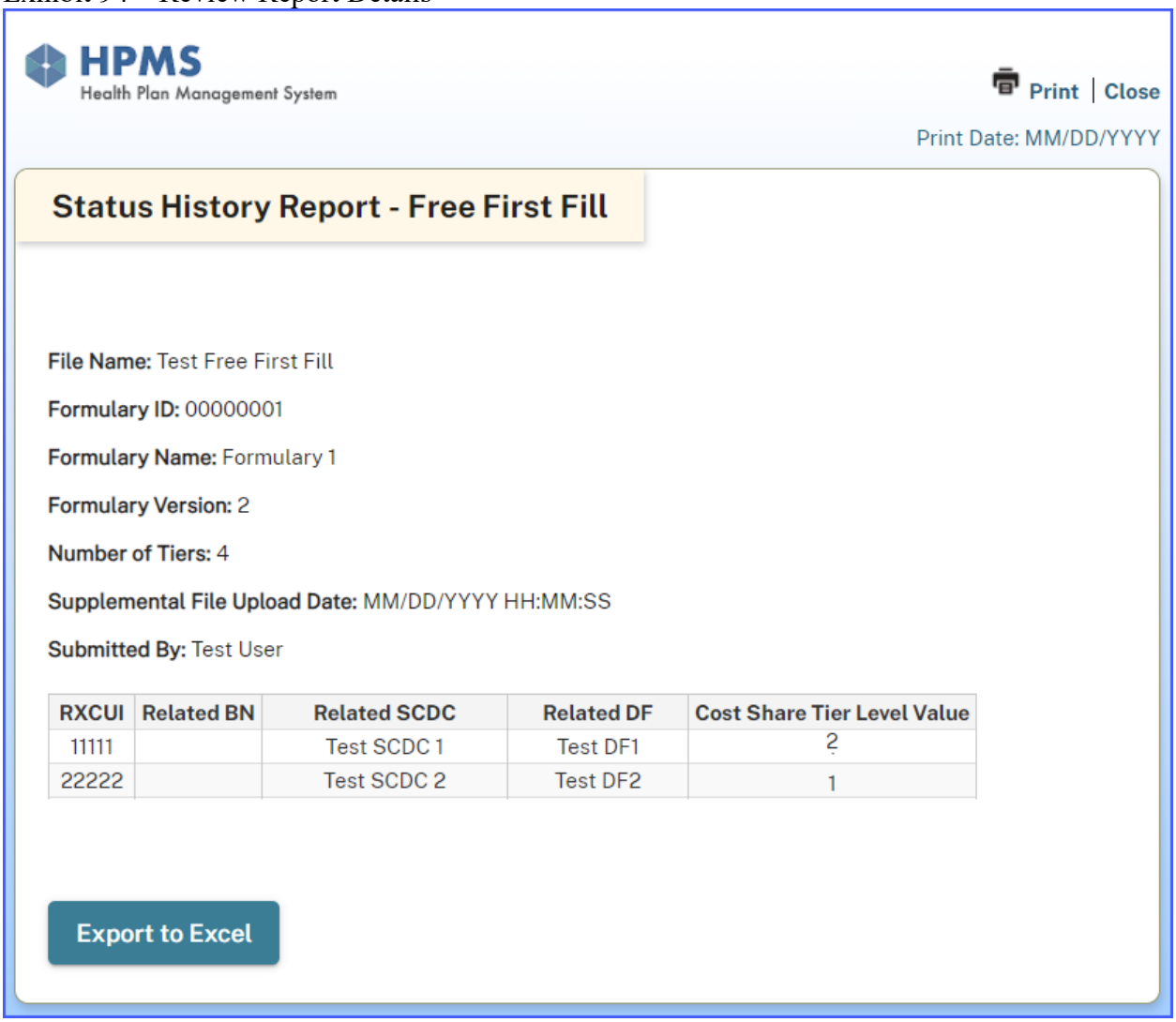
Exhibit 93 – Submitted Text File



STEP 5C – REVIEW REPORT DETAILS

In the "Report View" column, click the View Report hyperlink to view the drug detail page (Exhibit 94). A pop-up window appears. When you have finished reviewing the information, click the "Close" button at the top of the window. To Export the Free First Fill Report to Excel, click the "Export to Excel" button.

Exhibit 94 – Review Report Details



PARTIAL GAP COVERAGE, FREE FIRST FILL AND HOME INFUSION CHANGE NOTIFICATION REPORTS

Note: While the following instructions demonstrate how to access and view the Change Notification Report – Free First Fill, you can also use these instructions to access the Change Notification Report – Partial Gap Coverage and Change Notification Report – Home Infusion, reports. The steps taken to access and view reports are the same for each report.

STEP 1

As shown in Exhibit 2 on the **HPMS Home** page, select the **Plan Formularies** link and select the **Formulary Reports** link. This takes you to the Formulary Reports Contract Year Selection page.

STEP 2

On the **Formulary Reports Contract Year Selection** page (Exhibit 50), select the appropriate Contract Year link. This takes you to the Formulary Reports – Select a Report page.

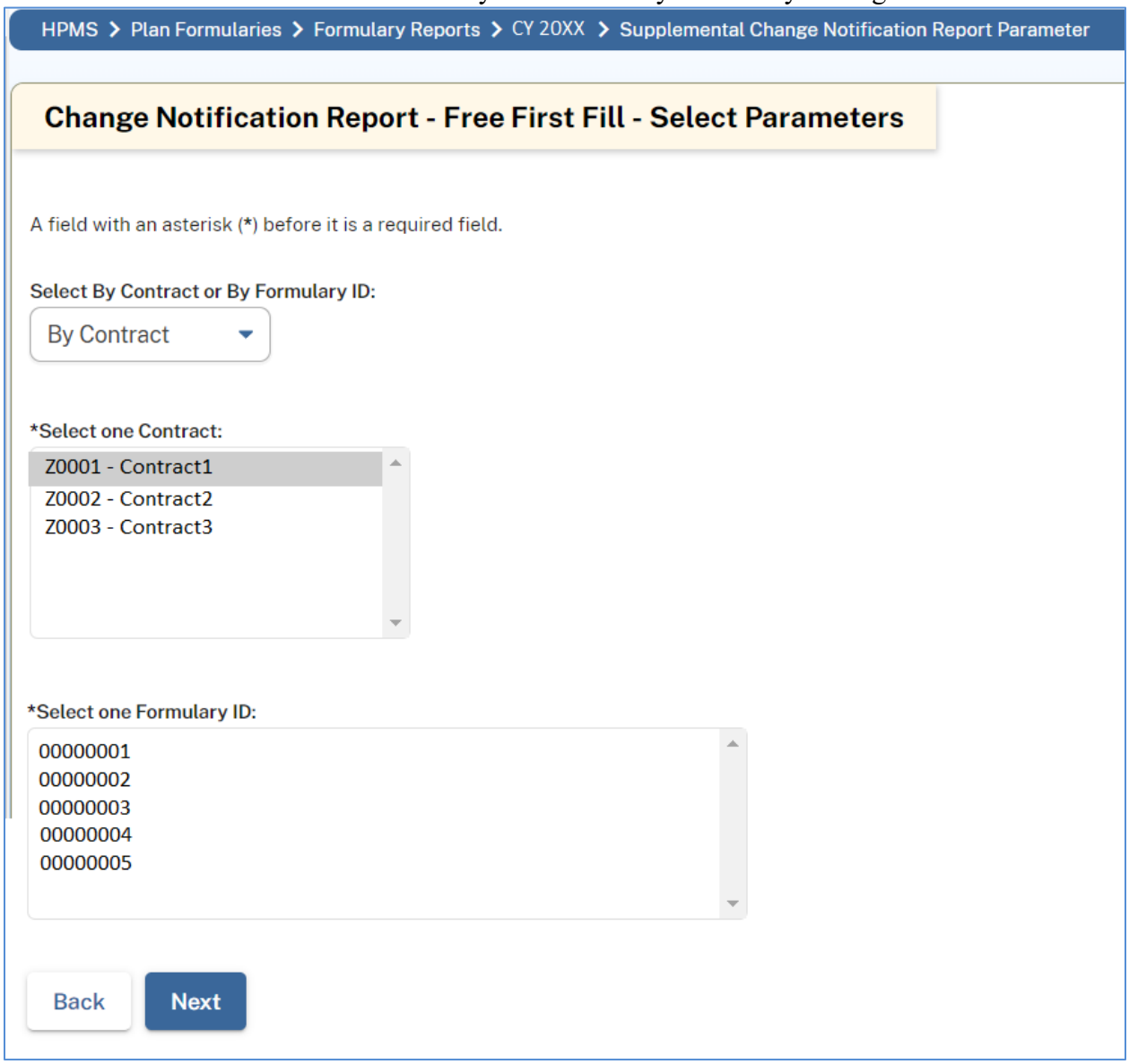
STEP 3

On the **Select a Report** page (Exhibit 51), select "Change Notification Report – Free First Fill." This takes you to the Select By Contract or By Formulary ID Selection page.

STEP 4

On the **Select By Contract or By Formulary ID** page (Exhibit 95), select a contract ID or Formulary ID you want to view in the report and click "Next." This takes you to the Submission Comparison Selection page.

Exhibit 95 – Free First Fill CNR Select By Contract or By Formulary ID Page



STEP 5

On the **Submission Comparison Selection page** (Exhibit 96), select two Formulary versions to view in the report and click "Next." This takes you to the Change Notification Report – Free First Fill Report page (Exhibit 97).

Exhibit 96 – Submission Comparison Selection

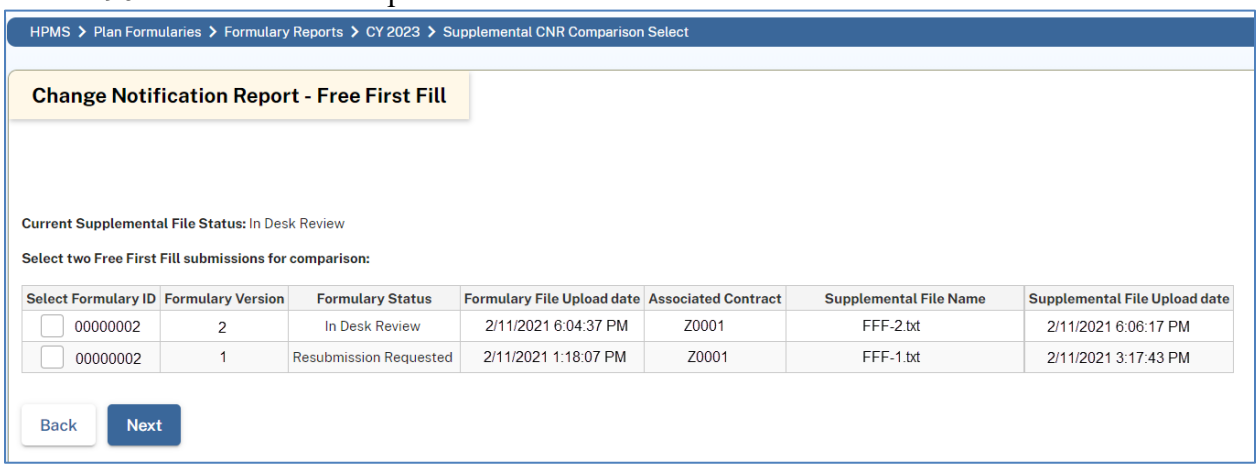
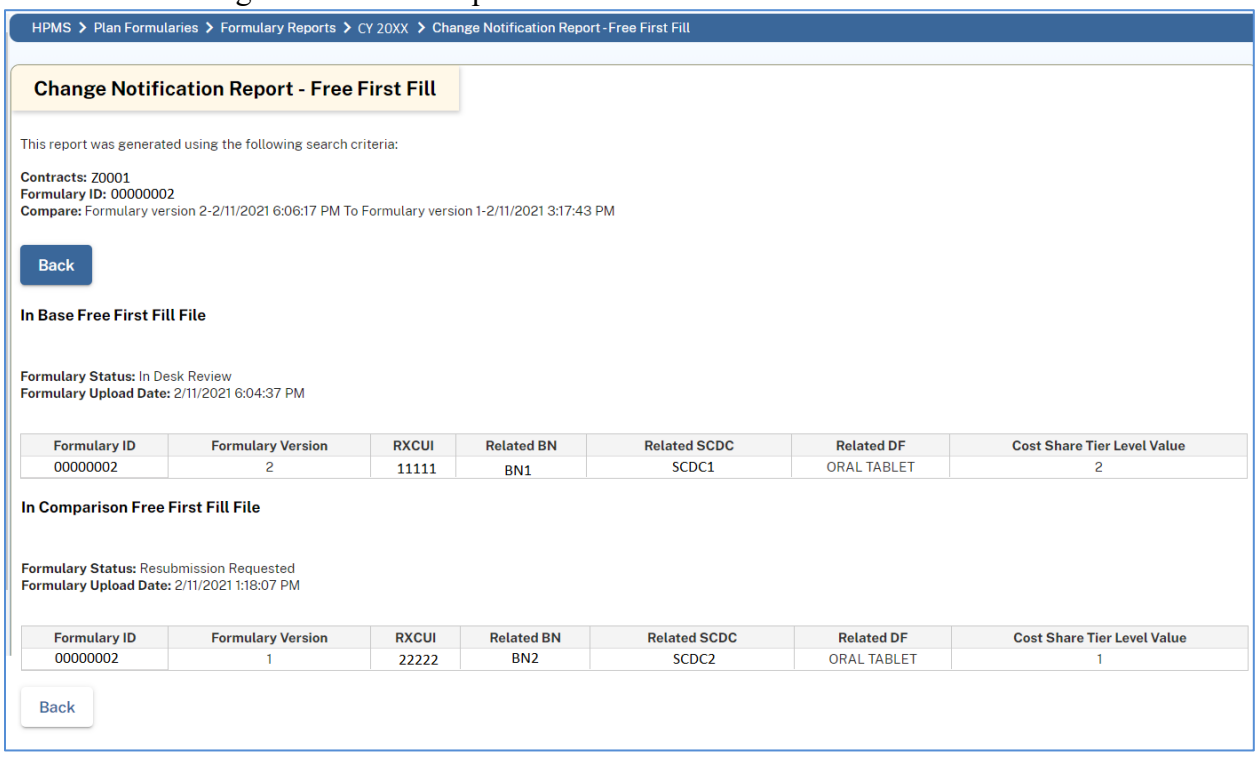


Exhibit 97 – Change Notification Report – Free First Fill



XXIII. SUBMIT VALUE-BASED INSURANCE DESIGN FILE

Organizations must submit the Value-Based Insurance Design (VBID) file for all the plans offering this coverage drugs. The VBID files cannot be loaded until the organization has successfully submitted its related bids, and the bid has migrated to "desk review" in the HPMS system. The VBID file gates will automatically open once your bid is in desk review.

If your bid submission indicated that a plan offers VBID supplemental benefit under Part D, you must submit the VBID file before CMS will fully review the bid. Unique packages of VBID benefits are numbered sequentially in the PBP in the order in which they are entered. Organizations offering Part D VBID benefits should use this numbering in the VBID Formulary file's package number field to indicate to which corresponding VBID benefit package(s) in the PBP a drug relates.

Also, if beneficiary LIS cost sharing is waived for all Part D drugs across the tiers indicated on the VBID package tiers screen in PBP then submission of a VBID Supplemental File is not required.

Note: the VBID file is unique in that it includes a field for contract and plan ID. As such, plans that share a Formulary ID can share a VBID file even if the content of that file varies by plan.

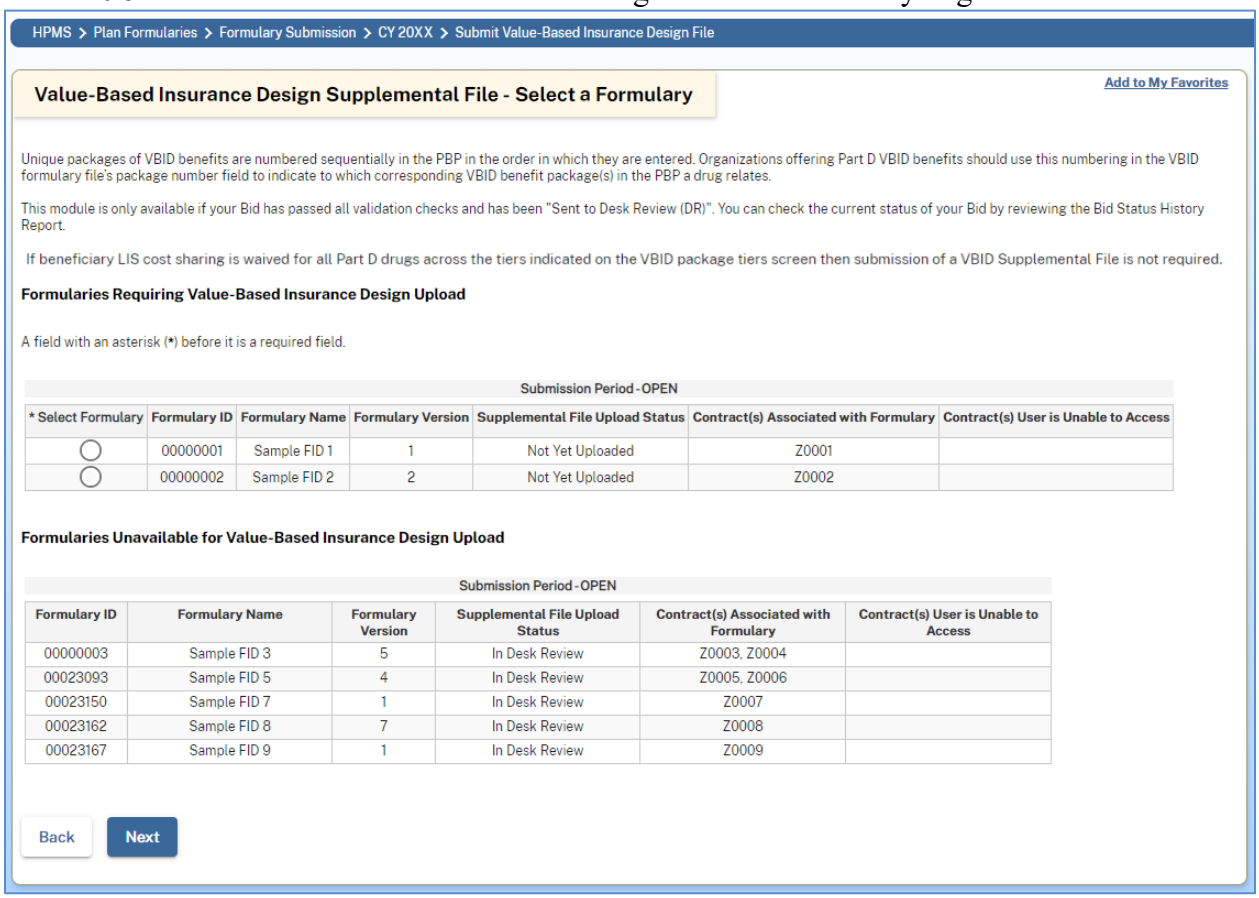
This section provides detailed information on how to submit the VBID files:

STEP 1
As shown in Exhibit 4, select Submit Value-Based Insurance Design File from the **Formulary Submission Start Page.** This takes you to the Value-Based Insurance Design File-Select a Formulary page (Exhibit 98).

STEP 2
The **Value-Based Insurance Design File - Select a Formulary** page contains a table of all formularies that require a VBID file. Note that only one Formulary can be selected at a time. Select the Formulary for which to upload a VBID file and click "Next." This takes you to the VBID Files - Upload File page.

Please note that only those plans with bid submissions that offer this benefit will be displayed. Plans that are linked to this Formulary, but that do not offer this benefit will not be displayed, as the file submission is not applicable to them.

Exhibit 98 – Submit Value-Based Insurance Design Select a Formulary Page

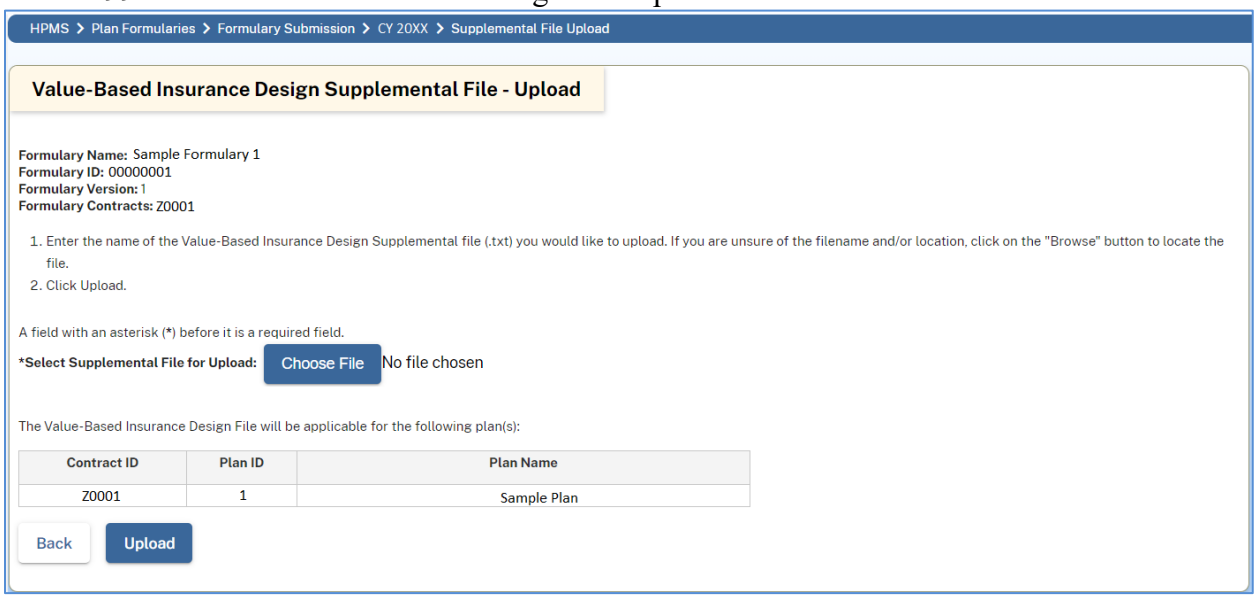


STEP 3

On the **Value-Based Insurance Design File– Upload File** page (Exhibit 99), enter the name of the VBID file (.txt) you wish to upload. If you are unsure of the filename or location, click the "Browse" button to locate the file.

Select the "Upload" button to continue with the VBID File submission process. This takes you to the VBID File-Verify File Upload page.

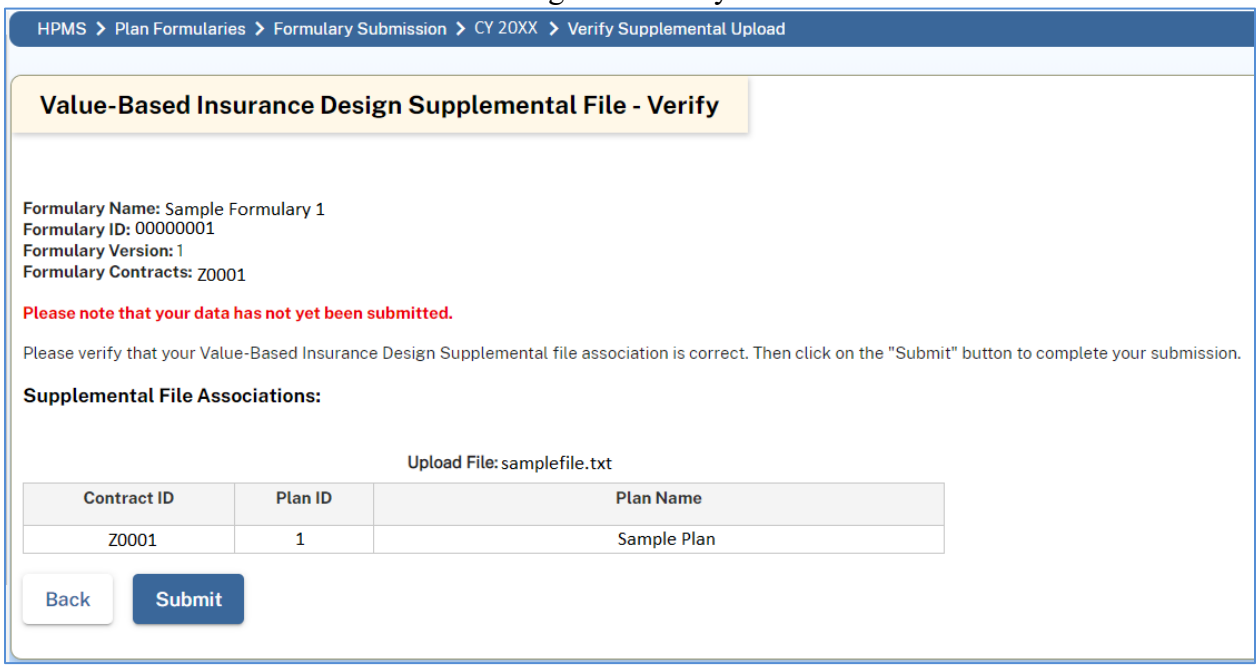
Exhibit 99 – Value-Based Insurance Design File Upload



STEP 4

On the **Value-Based Insurance Design File-Verify File Upload** page (Exhibit 100), click the "Submit" button. This takes you to the Value-Based Insurance Design Supplemental File-Submission Confirmation page.

Exhibit 100 – Value-Based Insurance Design File Verify



STEP 5

On the **Value-Based Insurance Design File-Submission Confirmation** page (Exhibit 101), review the information and click the "OK" button to complete the submission and return to the

Value-Based Insurance Design File-Select a Formulary page.

The Submission Confirmation page provides a status of the successful upload. The system sends an email to the contact identified on this page.

After receiving the uploaded VBID file, the HPMS performs a series of validation checks. At the close of the validation process, a second email is sent to the designated contact listed on this page. If errors were detected, the VBID file submission is rejected. You must correct the VBID file and resubmit the file using the Submit Value-Based Insurance Design File function.

Exhibit 101 – Value-Based Insurance Design Files Submission Confirmation

XXIV. VALUE-BASED INSURANCE DESIGN FILE STATUS HISTORY REPORT

The **Value-Based Insurance Design File Status History Report** provides VBID information to assist you in the VBID file submission process.

STEP 1

As shown in Exhibit 49 , on the **HPMS Home** page, select the **Plan Formularies** drop down from the HPMS top navigation bar. Then select the Formulary Reports menu item. This will take you to Formulary Reports Page.

STEP 2

On the **Formulary Reports** page, select the appropriate contract year from the collapsible navigation menu, on the left side of the page (Exhibit 50). This takes you to the Report Selection page.

STEP 3

On the **Select a Report** page (Exhibit 51), select Status History Report – Value-Based Insurance Design. This takes you to the select by Contract or by Formulary ID Selection page.

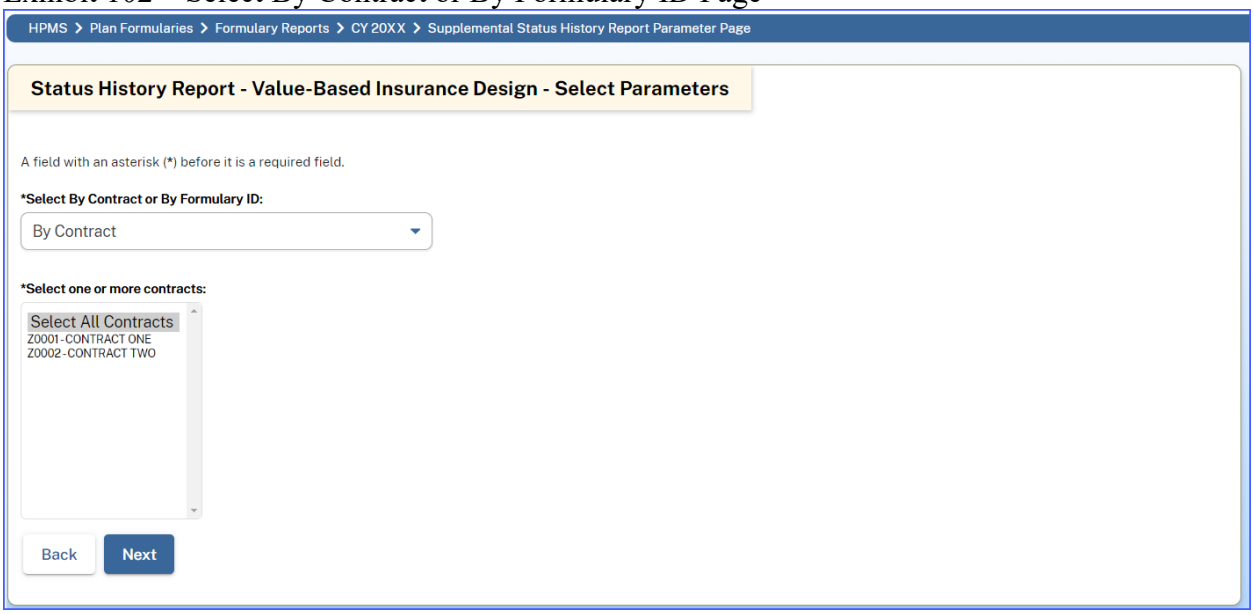
STEP 4

On the **Select By Contract or By Formulary ID** page (Exhibit 102), you have three options to select the contracts or formularies to view:

- Click Select All Contracts or Select All Formularies
- Click a single contract or Formulary ID
- Press the CTRL key and click multiple contracts or formularies

After selecting the appropriate contract or Formulary IDs, click the "Next" button. This takes you to the Status History Report – Value-Based Insurance Design Report page.

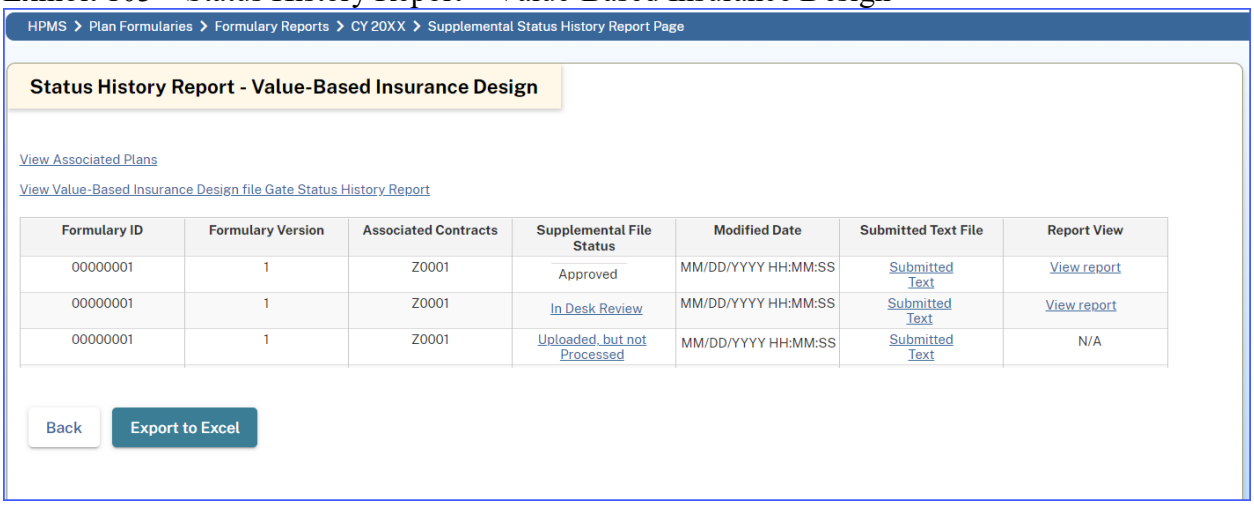
Exhibit 102 – Select By Contract or By Formulary ID Page



STEP 5

On the Status History Report – Value-Based Insurance Design page (Exhibit 103), you can review information about the VBID file status, review the submitted text file, and view report details. You can also view Formulary to plan ID details by clicking the **View Associated Plans** link.

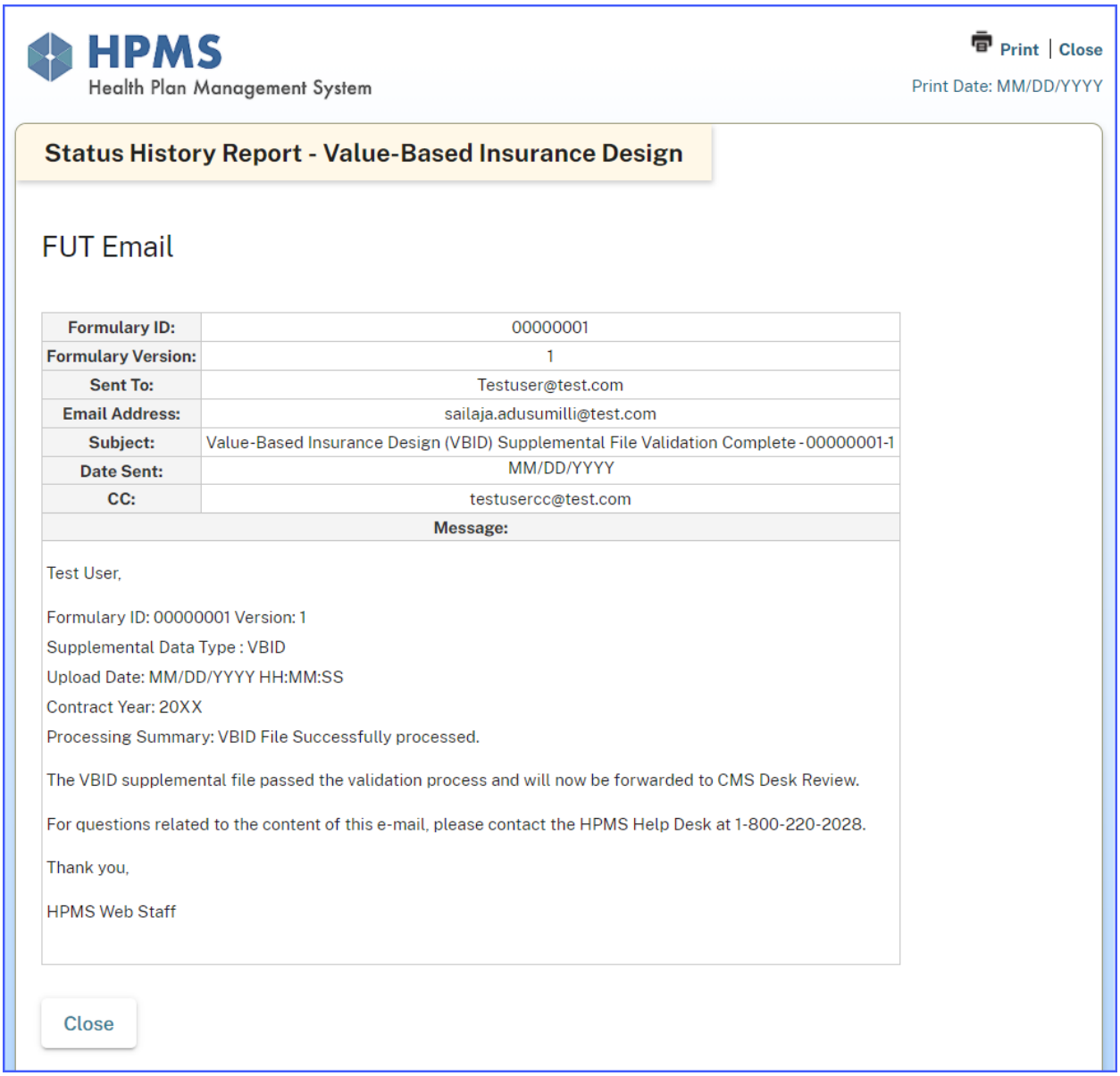
Exhibit 103 – Status History Report – Value-Based Insurance Design



STEP 5A – REVIEW INFORMATION ABOUT VBID FILE STATUS

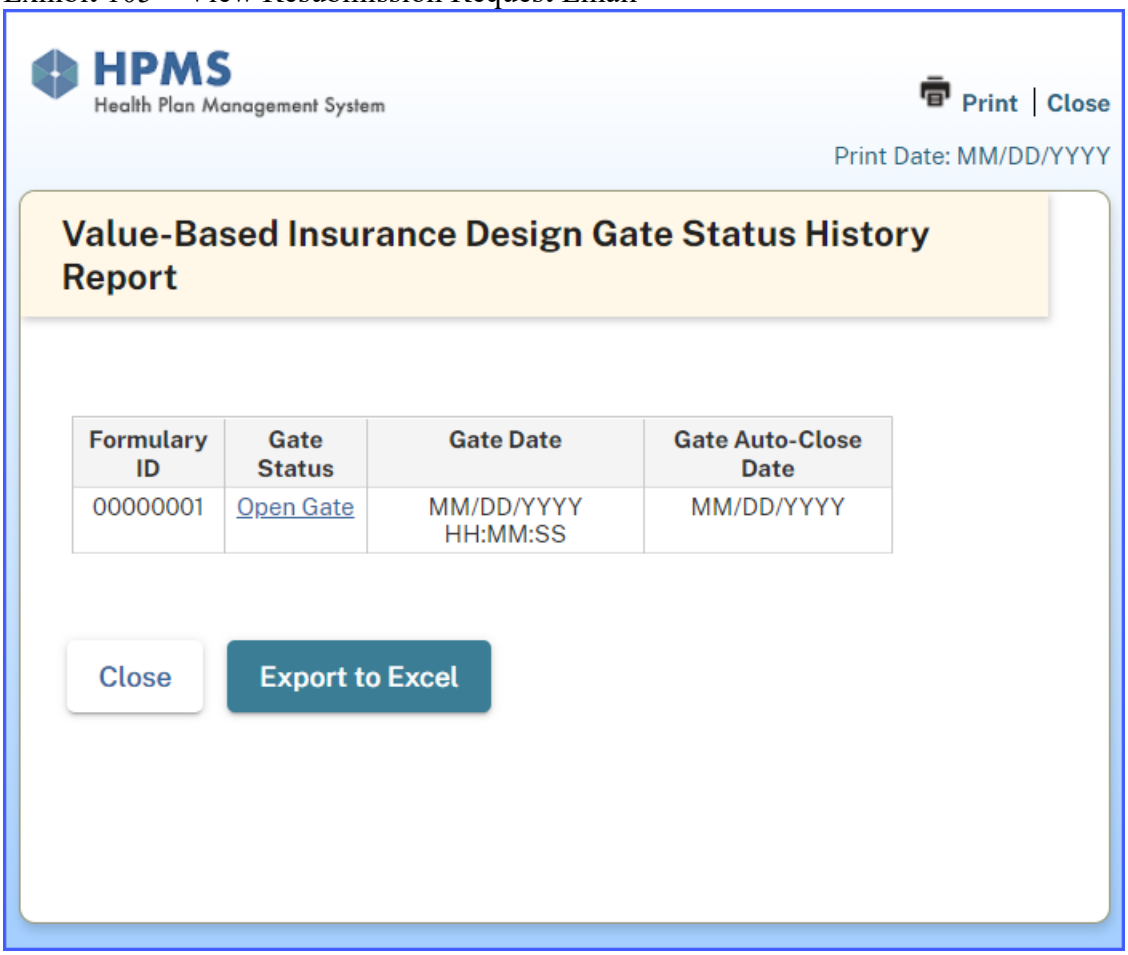
In the VBID File Status column, you may have a Formulary ID assigned the status "Successfully Validated", "In Desk Review" or "Rejected by Validation." If this is the case, the status is displayed as a link. Click the hyperlink to view the email that was sent to you in a pop-up window (Exhibit 104). When you have finished reviewing the information, click the "Close" button at the bottom of the window.

Exhibit 104 – View Submission Email



To view the VBID file gate open/close history, click the link "View VBID File Gate Status History Report" (Exhibit 103). A pop-up window will appear (Exhibit 105). The following details will be displayed in the VBID File Gate History Report pop-up window: Formulary ID, Gate Status (Open Gate/Close Gate), Gate Open/Close Date, Gate Auto-Close Date. Note that the gate status of 'Open Gate' will be a hyperlink to the resubmission request email sent when the gate is open. When you have finished reviewing the information, click the "Close" button at the bottom of the window.

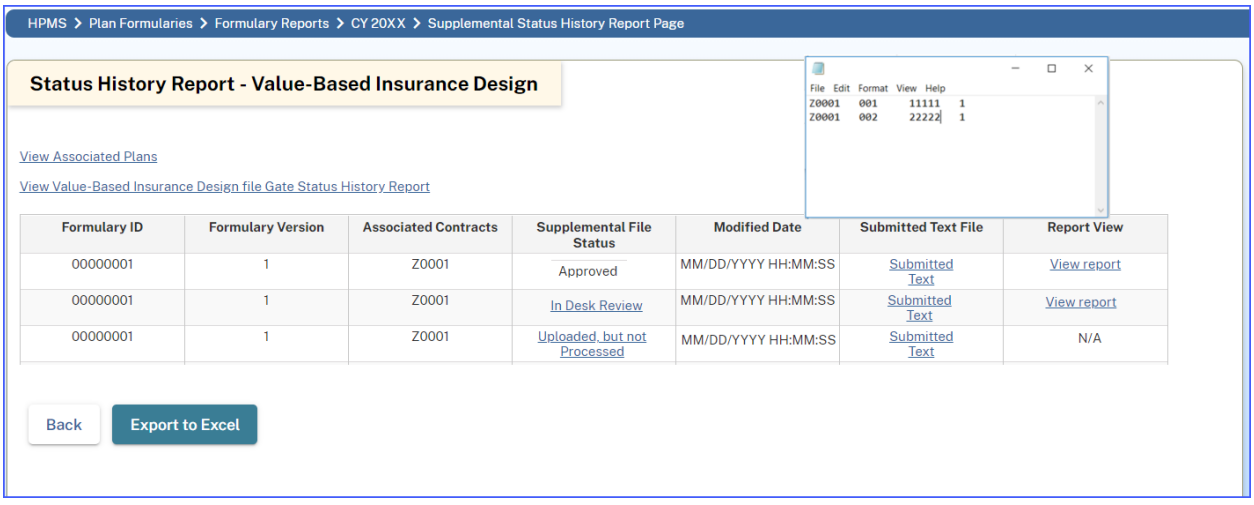
Exhibit 105 – View Resubmission Request Email



STEP 5B – REVIEW THE SUBMITTED TEXT FILE

To view the text file previously submitted, click the Submitted Text link. A pop-up window appears (Exhibit 106). When you have finished reviewing the information, you may close the browser window for the Submitted Text.

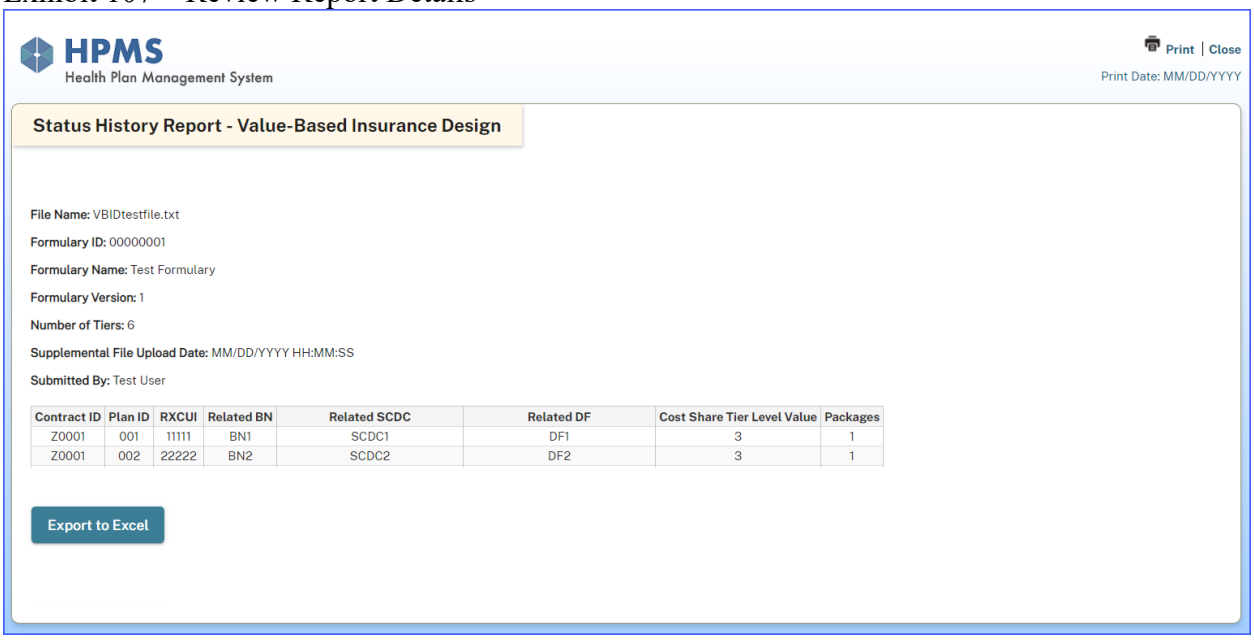
Exhibit 106 – Submitted Text File



STEP 5C – REVIEW REPORT DETAILS

In the "Report View" column, click the View Report hyperlink to view the drug detail page. A pop-up window appears (Exhibit 107). When you have finished reviewing the information, click the "Close" button at the top of the window. To Export the VBID Report to Excel, click the "Export to Excel" button.

Exhibit 107 – Review Report Details



XXV. VALUE-BASED INSURANCE DESIGN FILE – CHANGE NOTIFICATION REPORT

The Value-Based Insurance Design (VBID) File Change Notification Report allows you to compare two versions of VBID files that are associated with a Formulary**.**

STEP 1

As shown in Exhibit 2on the **HPMS Home** page, select the **Plan Formularies** link and **Formulary Reports** link. This takes you to the Formulary Reports Contract Year Selection page.

STEP 2

On the **Formulary Reports Contract Year Selection** page (Exhibit 50), select the appropriate Contract Year link. This takes you to the Formulary Reports – Select a Report page.

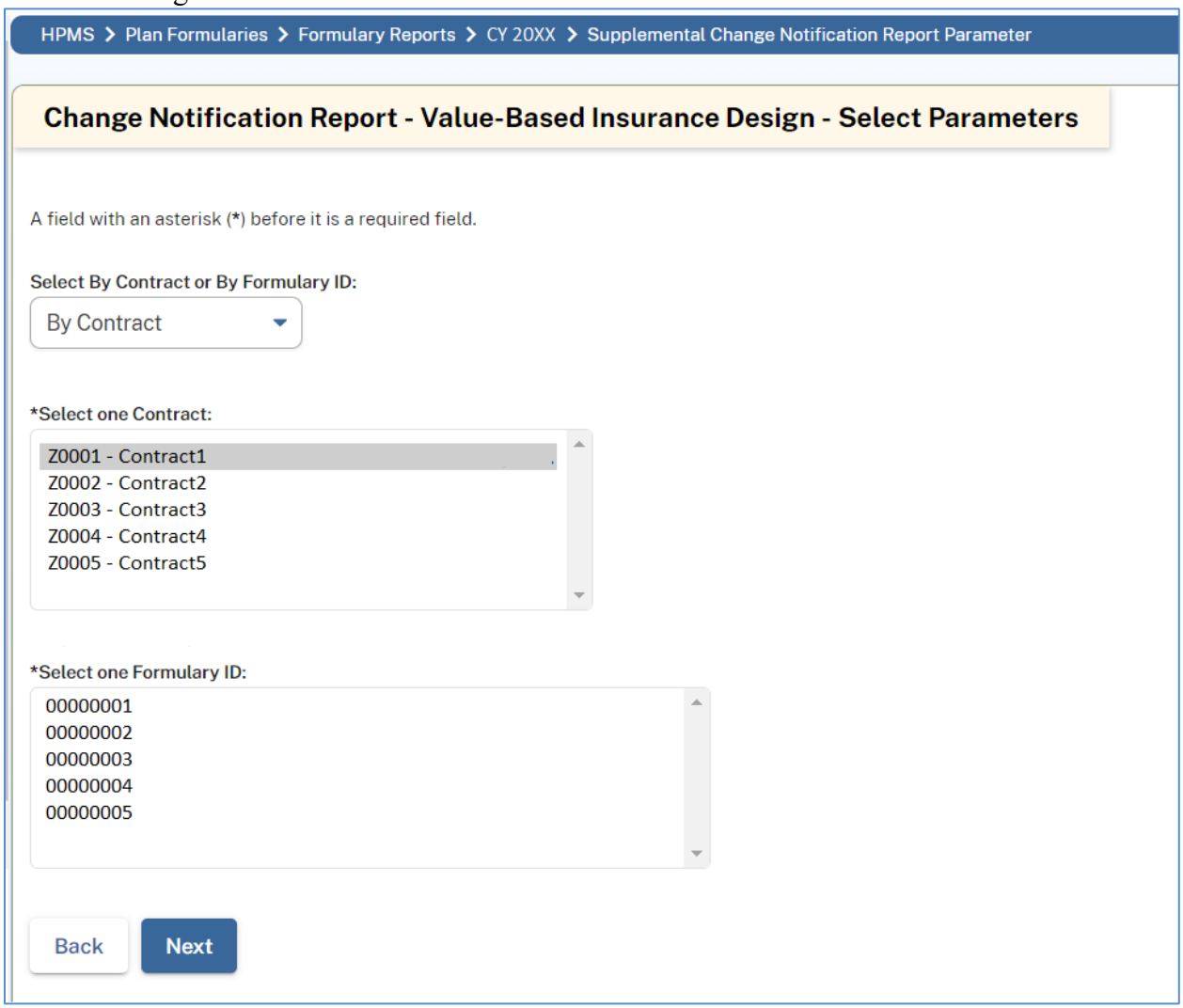
STEP 3

On the **Select a Report** page (Exhibit 51), select "Change Notification Report – Value-Based Insurance Design." This takes you to the Select By Contract or By Formulary ID Selection page.

STEP 4

On the **Select By Contract or By Formulary ID** page (Exhibit 108), select a contract ID or Formulary ID you want to view in the report and click "Next." This takes you to the Change Notification Report - Submission Comparison Selection page.

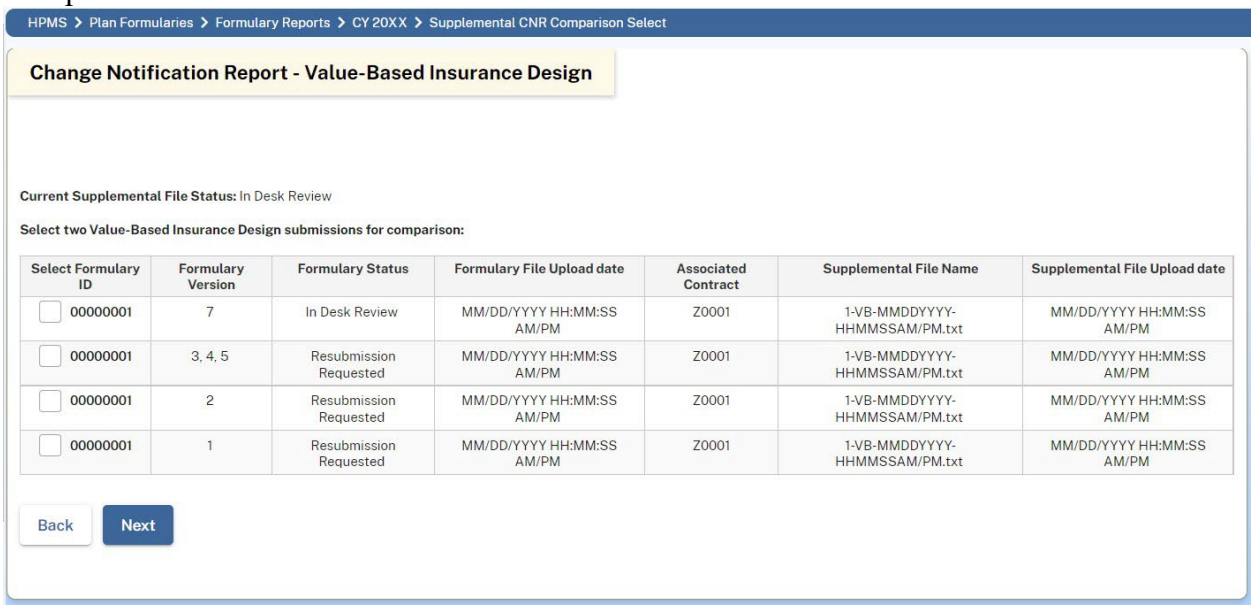
Exhibit 108 – Change Notification Report (CNR) – Value-Based Insurance Design File - Select Parameters Page



STEP 5

On the **Submission Comparison Selection page** (Exhibit 109), select two Formulary versions to view in the report and click "Next." This takes you to the Change Notification Report – Value-Based Insurance Design Report page (Exhibit 110).

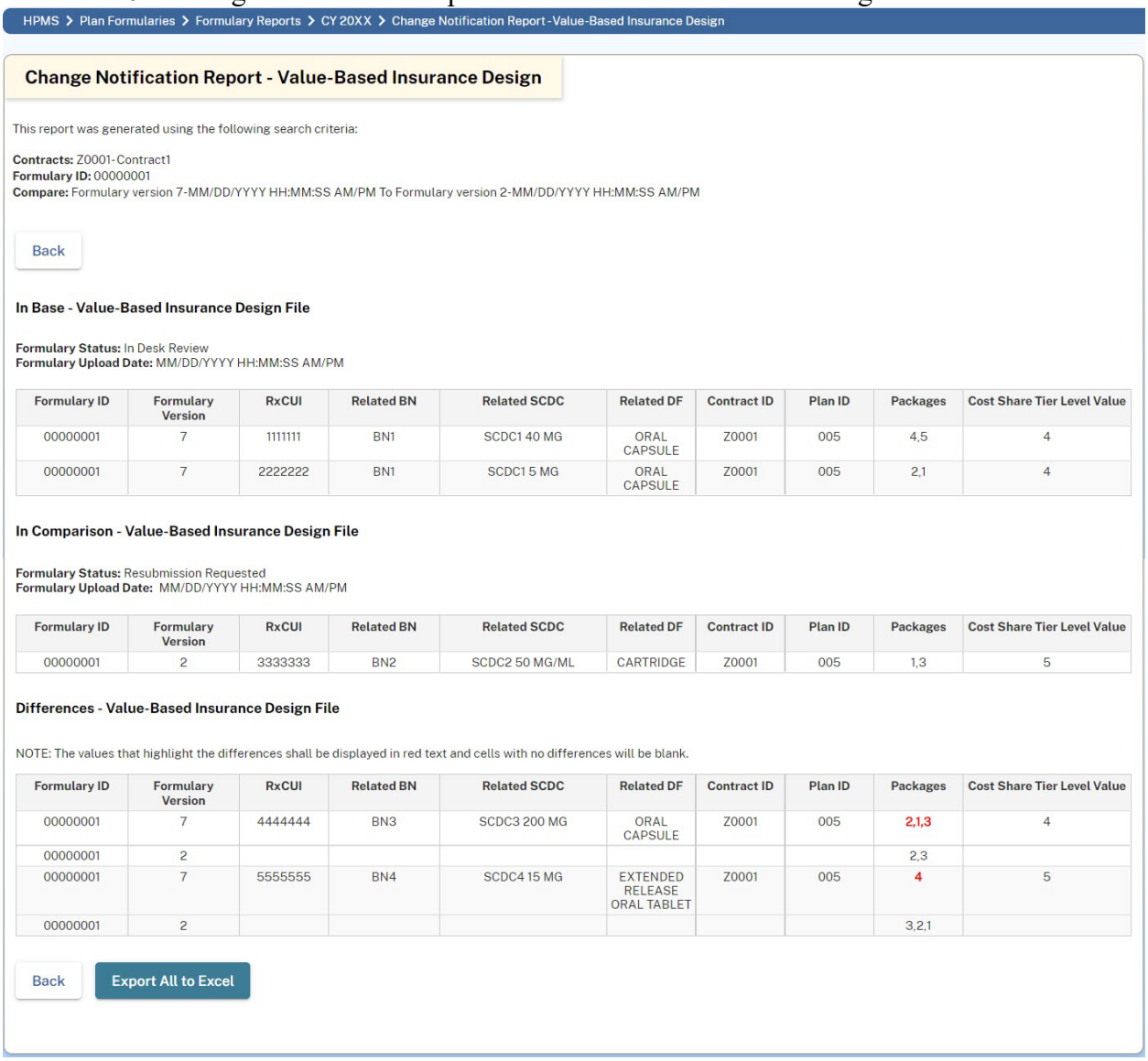
Exhibit 109 – Change Notification Report – Value-Based Insurance Design - Submission Comparison Selection



STEP 6

On the **Change Notification Report – Value-Based Insurance Design report page** (Exhibit 110), select "Export All to Excel" to view the Differences, In Base and In Comparison section collectively in Excel report (Exhibit 111).

Exhibit 110 – Change Notification Report – Value-Based Insurance Design



HPMS > Plan Formularies > Formulary Reports > CY 20XX > Change Notification Report - Value-Based Insurance Design

Change Notification Report - Value-Based Insurance Design

This report was generated using the following search criteria:

Contracts: Z0001- Contract1
Formulary ID: 00000001
Compare: Formulary version 7-MM/DD/YYYY HH:MM:SS AM/PM To Formulary version 2-MM/DD/YYYY HH:MM:SS AM/PM

Back

In Base - Value-Based Insurance Design File

Formulary Status: In Desk Review
Formulary Upload Date: MM/DD/YYYY HH:MM:SS AM/PM

Formulary ID	Formulary Version	RxCUI	Related BN	Related SCDC	Related DF	Contract ID	Plan ID	Packages	Cost Share Tier Level Value
00000001	7	1111111	BN1	SCDC1 40 MG	ORAL CAPSULE	Z0001	005	4,5	4
00000001	7	2222222	BN1	SCDC1 5 MG	ORAL CAPSULE	Z0001	005	2,1	4

In Comparison - Value-Based Insurance Design File

Formulary Status: Resubmission Requested
Formulary Upload Date: MM/DD/YYYY HH:MM:SS AM/PM

Formulary ID	Formulary Version	RxCUI	Related BN	Related SCDC	Related DF	Contract ID	Plan ID	Packages	Cost Share Tier Level Value
00000001	2	3333333	BN2	SCDC2 50 MG/ML	CARTRIDGE	Z0001	005	1,3	5

Differences - Value-Based Insurance Design File

NOTE: The values that highlight the differences shall be displayed in red text and cells with no differences will be blank.

Formulary ID	Formulary Version	RxCUI	Related BN	Related SCDC	Related DF	Contract ID	Plan ID	Packages	Cost Share Tier Level Value
00000001	7	4444444	BN3	SCDC3 200 MG	ORAL CAPSULE	Z0001	005	2,1,3	4
00000001	2							2,3	
00000001	7	5555555	BN4	SCDC4 15 MG	EXTENDED RELEASE ORAL TABLET	Z0001	005	4	5
00000001	2							3,2,1	

Back Export All to Excel

Exhibit 111 – Change Notification Report – Value-Based Insurance Design – Export All to Excel

This report was generated using the following search criteria:
Contracts: Z0001 - Contract1
Formulary ID: 00000001
Compare: Formulary version 7-MM/DD/YYYY HH:MM:SS AM/PMTo Formulary version 2-MM/DD/YYYY HH:MM:SS AM/PM

In Base: Value-Based Insurance Design File

Formulary ID	Formulary Version	RxCUI	Related BN	Related SCDC	Related DF	Contract ID	Plan ID	Packages	Cost Share Tier Level Value
00000001	7	1111111	BN1	SCDC1 40 MG	ORAL CAPSULE	Z0001	005	4,5	4
00000001	7	2222222	BN1	SCDC1 5 MG	ORAL CAPSULE	Z0001	005	2,1	4

In Comparison: Value-Based Insurance Design File

Formulary ID	Formulary Version	RxCUI	Related BN	Related SCDC	Related DF	Contract ID	Plan ID	Packages	Cost Share Tier Level Value
00000001	2	3333333	BN2	SCDC2 50 MG/ML	CARTRIDGE	Z0001	005	1,3	5

Differences: Value-Based Insurance Design File

Formulary ID	Formulary Version	RxCUI	Related BN	Related SCDC	Related DF	Contract ID	Plan ID	Packages	Cost Share Tier Level Value
00000001	7	4444444	BN3	SCDC3 200 MG	ORAL CAPSULE	Z0001	005	2,1,3	4
00000001	2							2,3	
00000001	7	5555555	BN4	SCDC4 15 MG	EXTENDED RELEASE ORAL TABLET	Z0001	005	4	5
00000001	2							3,2,1	

XXVI. SUBMIT MEDICARE – MEDICAID ADDITIONAL DEMONSTRATION DRUG FILE SUBMISSION

As part of the Formulary submission process, Medicare-Medicaid Plan (MMP) applicants are required to submit a supplemental Additional Demonstration Drug (ADD) file. The ADD file cannot be loaded until the organization has successfully submitted its related bids and bids are written off to desk review. Only one ADD file may be submitted for each Formulary. This section provides detailed information on the how to submit the ADD file.

You begin the **MMP Additional Demonstration Drug** file upload process on the **Formulary Submission Start page** (Exhibit 4). If you need help accessing the Formulary Submission Start Page, see the sub-section entitled "How to Access the HPMS Formulary Submission Module" in Chapter I.

STEP 1

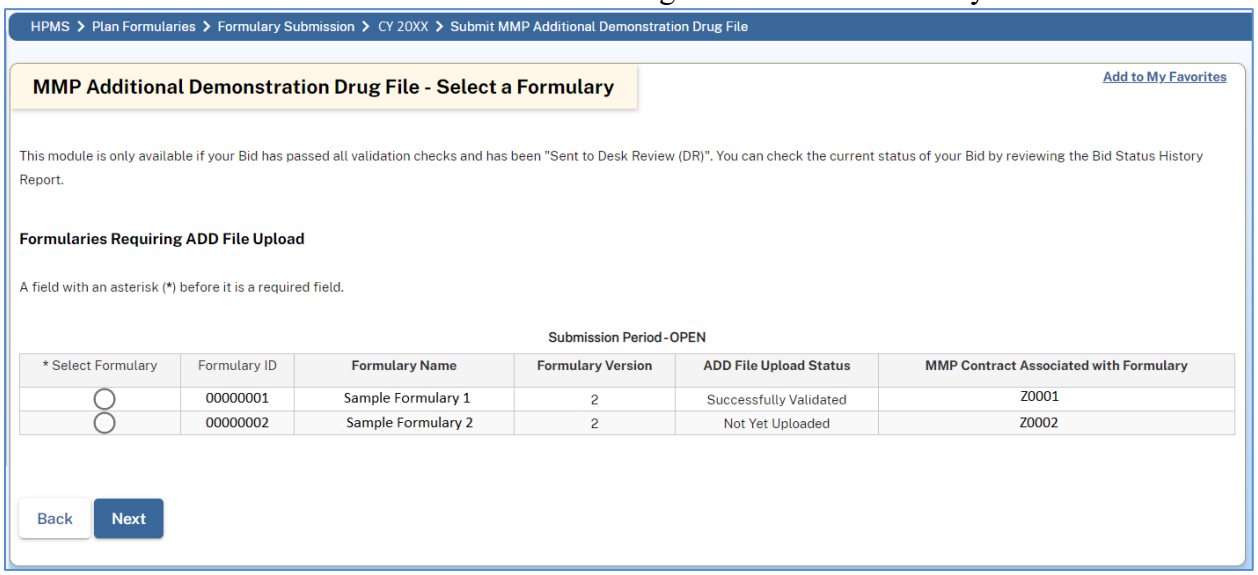
As shown in Exhibit 4, select the **Submit MMP Additional Demonstration Drug File** link from the Formulary Submission Start Page**.** This takes you to the **MMP Additional Demonstration Drug File – Select a Formulary** page.

MMP ADDITIONAL DEMONSTRATION DRUG FILE – SELECT FORMULARY

STEP 2

The **MMP Additional Demonstration Drug File-Select a Formulary** page (Exhibit 112) contains a table of all MMP formularies that are eligible for ADD file upload. Note that only one Formulary can be selected at a time. Select the Formulary for which you will upload an ADD file and click "Next." This takes you to the **MMP Additional Demonstration Drug File – Upload ADD File** page.

Exhibit 112 – MMP Additional Demonstration Drug File – Select Formulary

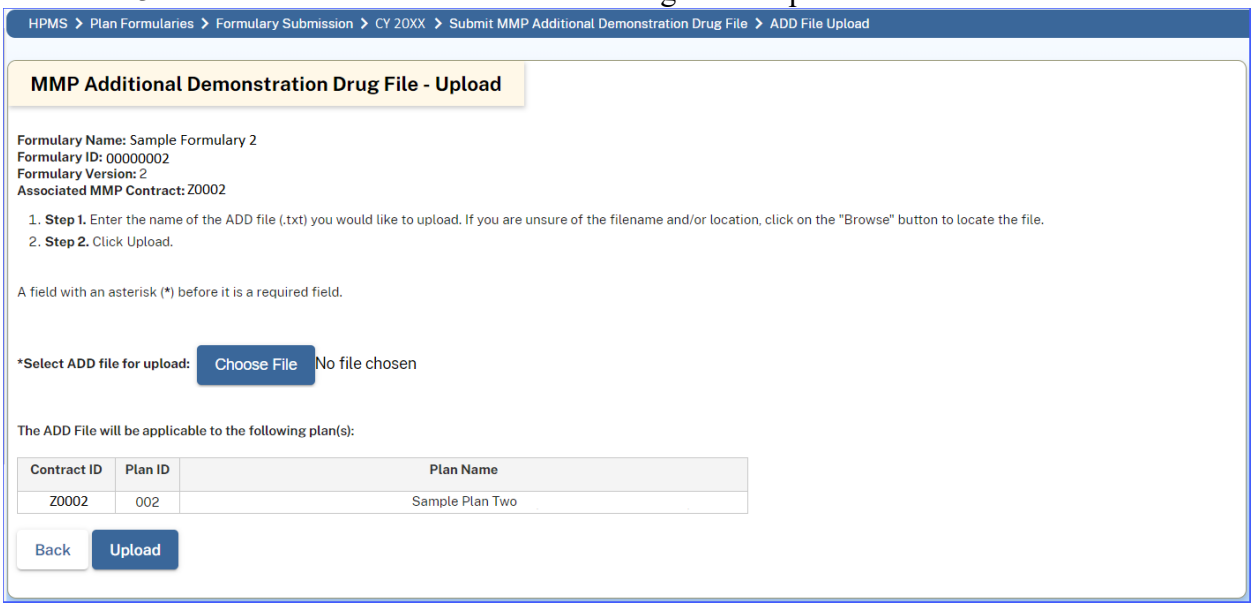


MMP Additional Demonstration Drug File – Upload File

Step 3

On the **MMP Additional Demonstration Drug File** – **Upload File** page (Exhibit 113), enter the name of the ADD file (.txt) you wish to upload. If you are unsure of the filename or location, click the "Browse" button to locate the file.

Exhibit 113 – MMP Additional Demonstration Drug File – Upload



Step 4

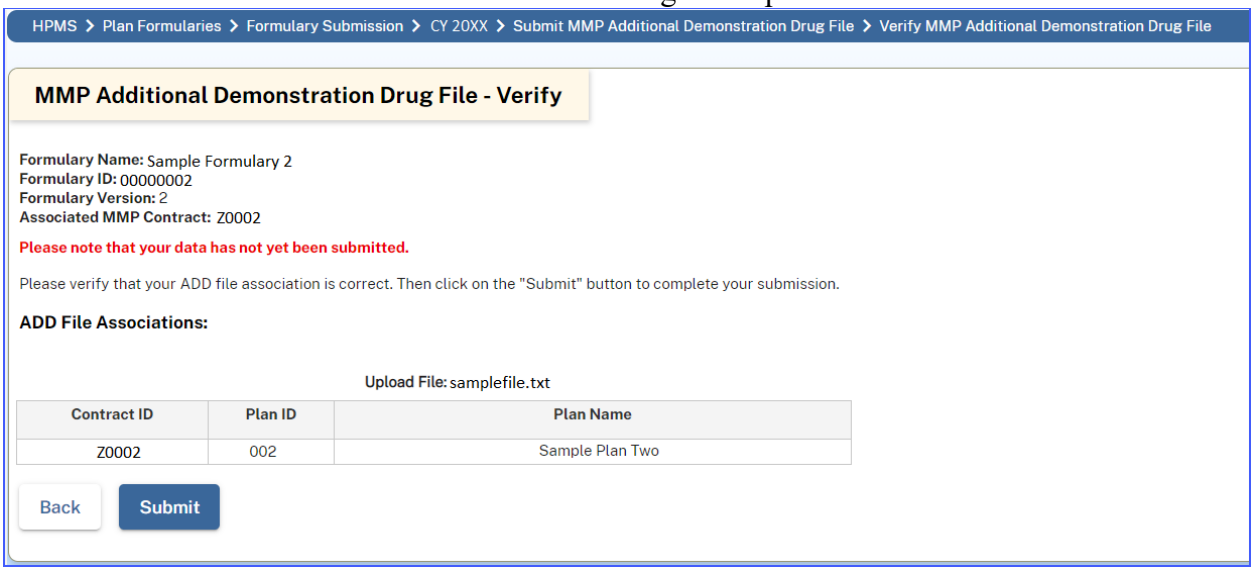
Click the "Upload" button to continue with the submission process. This takes you to the **MMP Additional Demonstration Drug File–Verify Upload** page.

MMP Additional Demonstration Drug File – Verify Upload

Step 5

On the **MMP Additional Demonstration Drug File-Verify Upload** page, review the information and click the "Submit" button. This takes you to the Additional Demonstration Drug File-Submission Confirmation page.

Exhibit 114 – MMP Additional Demonstration Drug File Upload Verification

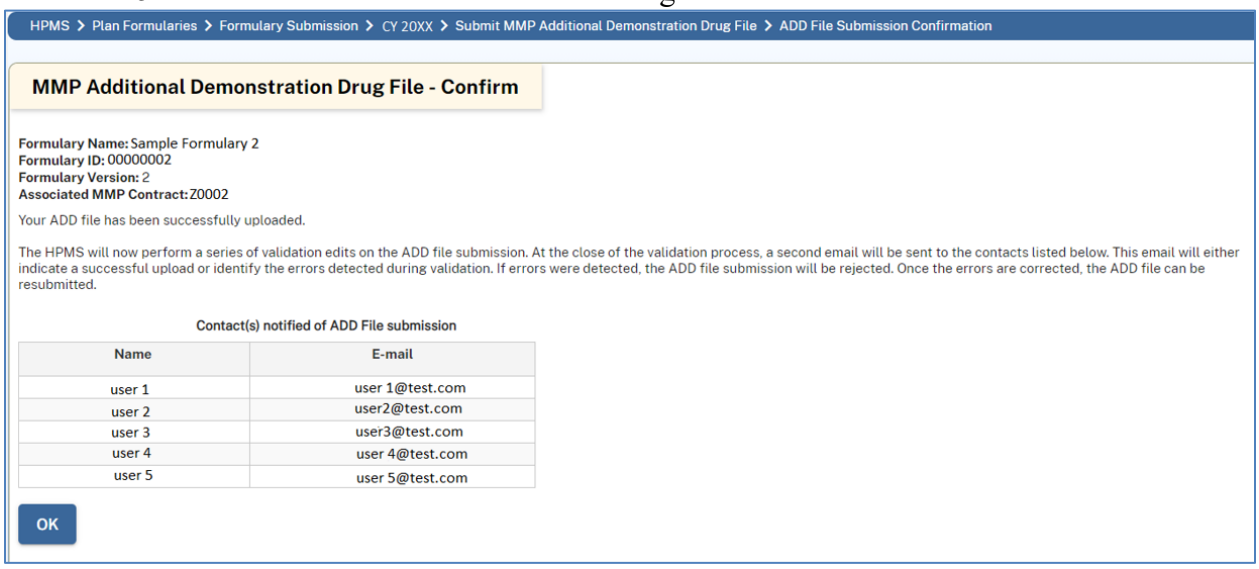


MMP Additional Demonstration Drug File – Confirm Submission

The MMP **Additional Demonstration Drug File – Submission Confirmation** page (Exhibit 115) provides a status of the successful upload. The system sends an email to the contact identified on this page.

After receiving the uploaded ADD file, the HPMS performs a series of validation checks. At the close of the validation process, a second email is sent to the designated contacts listed on this page. If errors were detected, the ADD file submission is rejected. You must correct the ADD file and resubmit the file using the Submit ADD file function.

Exhibit 115 – MMP Additional Demonstration Drug File – Confirm Submission



If you need to re-submit your ADD file, follow the same steps listed above. Previous submissions will be overwritten with the most recent file uploaded. To view the latest submitted file, you can view the "**Status History Report – Additional Demonstration Drug File**" under Formulary Reports.

XXVII. MEDICARE-MEDICAID PLAN (MMP) SUBMISSION DETAIL REPORT

The **Medicare-Medicaid Plan (MMP) – Submission Detail Report** displays the status (In Desk Review, Successfully Validated, Approved, Resubmission Requested and Not Submitted) of most recent submitted Additional Demonstration Drug File uploaded for the Formulary. The report also lists MMP formularies for which ADD files are missing .The ADD files are considered missing if the status is "not submitted" or “rejected by validation" or "resubmission requested.”

Note: This report is accessible to Medicare-Medicaid Plan users only.

STEP 1

As shown in Exhibit 49 , on the HPMS Home page, select the **Plan Formularies** drop down from the HPMS top navigation bar. Then select the Formulary **Reports** menu item. This will take you to Formulary Reports Page (Exhibit 50).

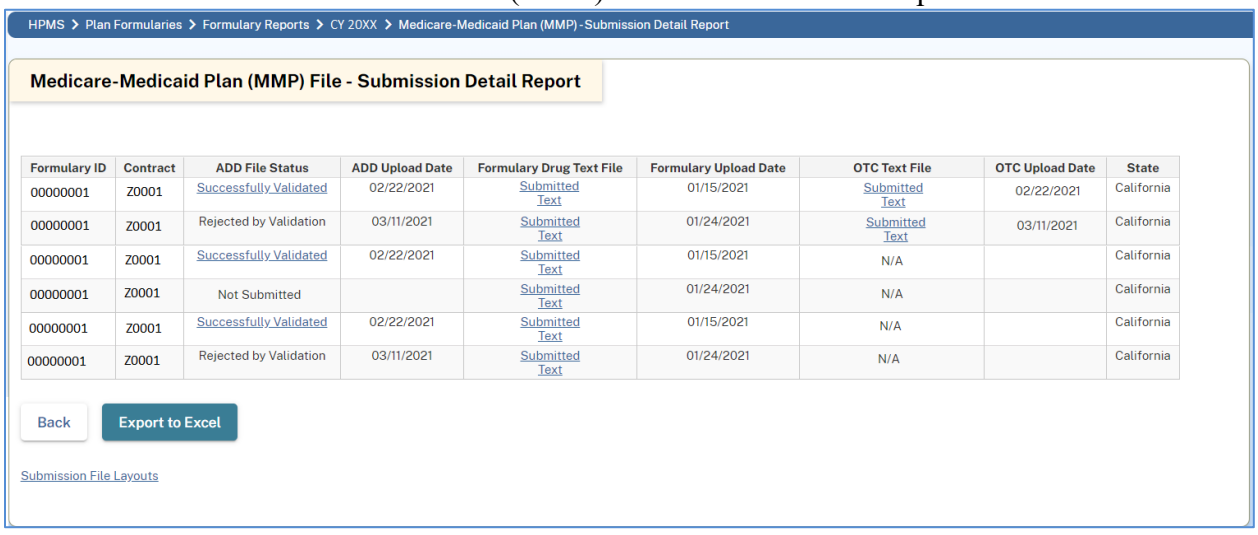
STEP 2

On the **Formulary Reports** page (Exhibit 50), select the appropriate Contract Year from the left navigation menu. This takes you to the Report Selection page (Exhibit 51).

STEP 3

On the **Select a Report** page (Exhibit 51), select **Medicare-Medicaid Plan (MMP) – Submission Detail** Report.

Exhibit 116 – Medicare-Medicaid Plan (MMP) – Submission Detail Report



On the **Medicare-Medicaid Plan (MMP) – Submission Detail Report** page (Exhibit **116**), you can view the latest ADD-submitted text file. The report also displays the submitted Formulary drug files and supplemental Over the Counter drug files associated with the Formulary. The submission file layouts are available for download on clicking the submission file layouts hyperlink.

STEP 4

To view the most recent ADD file successfully submitted, click the "In Desk Review" link in the "ADD File Status" column. A pop-up window appears. When you have finished reviewing the information, click the "Close" button at the bottom of the window.

Note: A Submitted text file is only available if its status is Successfully Validated or In Desk Review.

STEP 5

To view the Formulary drug text file submitted for that Formulary, click the "Submitted Text" link under the "Formulary Drug Text File" column. A window is displayed. When you have finished reviewing the information, "Close" the window.

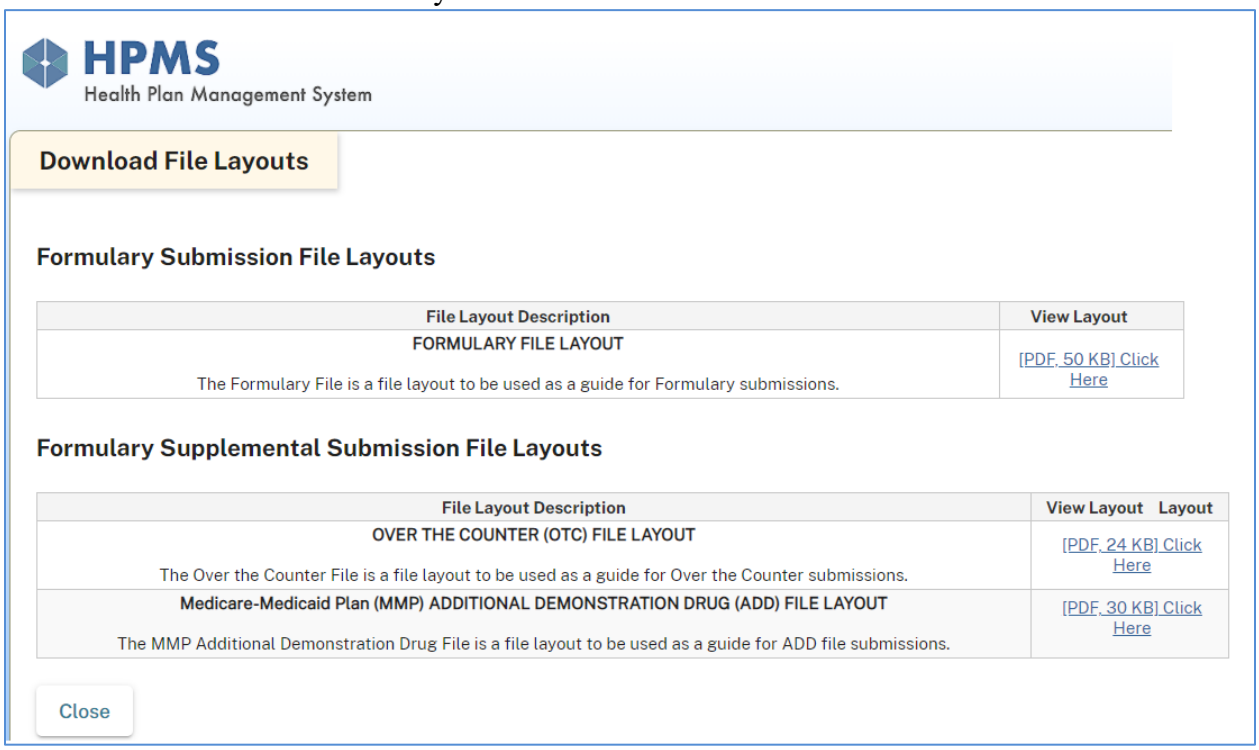
STEP 6

To view the over the counter drug text file submitted for that Formulary, click the "Submitted Text" link under the "Over The Counter Text File" column. A pop-up window appears. When you have finished reviewing the information, click the "Close" button at the bottom of the window.

STEP 7

To view the submission file layouts, click the "Submission file layouts" hyperlink. A pop-up window appears. Click on the respective layouts to download Formulary submission layout, supplemental over the counter drug text layout and MMP Additional Demonstration Drug file layout. When you have finished reviewing or downloading the information, click the "Close" button at the bottom of the window.

Exhibit 117 – Submission File Layouts



XXVIII. ADDITIONAL DEMONSTRATION DRUG FILE - STATUS HISTORY REPORT

The **Additional Demonstration Drug File Status History Report** provides detailed status information about all versions of the ADD file for a given Formulary ID.

STEP 1

On the **Formulary Reports – Select a Report** page (Exhibit 51), select **Status History Report – Additional Demonstration Drug (ADD) File** report. This will take you to the ADD Status History report selection criteria page.

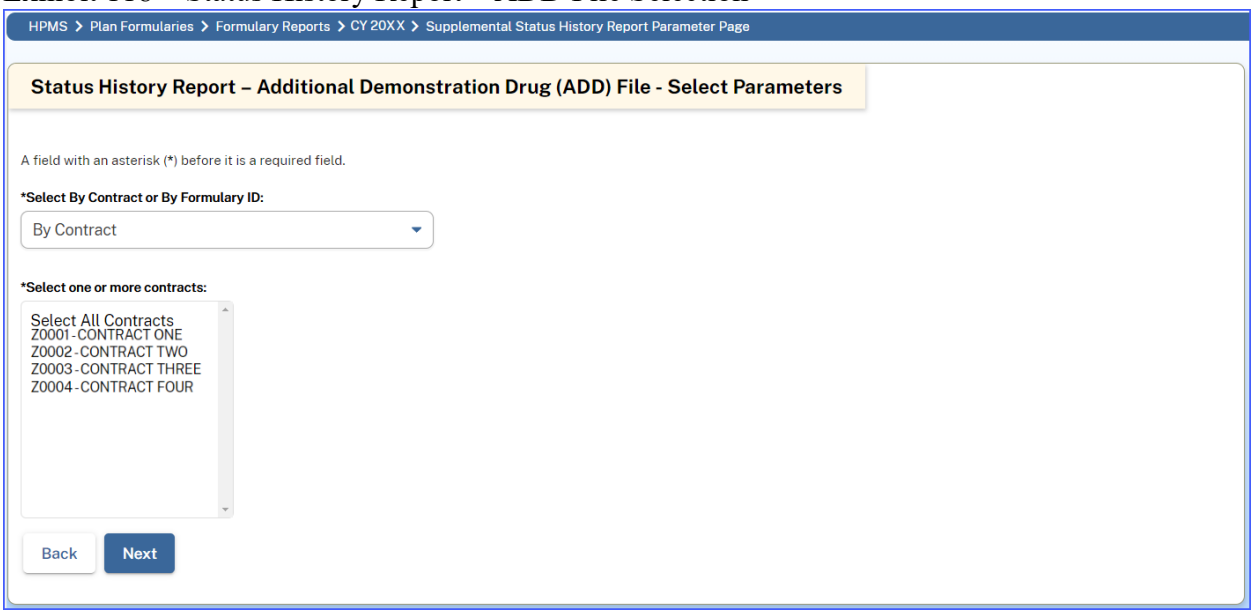
STEP 2

On the **Selection Criteria** page (Exhibit 118), you have three options to select the contracts or formularies to view:

- Click Select All Contracts or Select All Formularies
- Click a single contract or Formulary ID
- Press the CTRL key and click multiple contracts or formularies

After selecting the appropriate contract or Formulary IDs, click the "Next" button. This takes you to the Status History Report – ADD File Report page.

Exhibit 118 – Status History Report – ADD File Selection



STEP 3

On the Status History Report – ADD File page (Exhibit 119), you can review information about the ADD file status, review the submitted text file, and view report details. You can also view

ADD file Gate Status History and PBP and ADD Justification history for all the contracts displayed on the ADD Status History report.

On the Status History Report – ADD File page (Exhibit 119), there are several actions you can take to view more details or get background information:

- To view the email sent regarding the ADD file upload, click the link provided under the ADD file status column. A pop-up window will appear. When you have finished reviewing the information, click the "Close" button at the bottom of the window.

- To view the text file previously submitted, click the "Submitted Text" hyperlink. A pop-up window will appear. When you have finished reviewing the information, click the "Close" button at the bottom of the window.

- To view the ADD file gate history, click the link "View ADD File Gate Status History." A pop-up window will appear. The following details will be displayed in the ADD Gate History Report pop-up window: Formulary ID, Gate Status (Open Gate/Close Gate), Gate Open/Close Date, Gate Auto-Close Date. Note that the gate status of 'Open Gate' will be a hyperlink to the email sent to users from Bid Desk Review. When you have finished reviewing the information, click the "Close" button at the bottom of the window.

- To view the PBP and ADD deficiencies report, click the link "View PBP and ADD Deficiencies Report." A pop-up window will appear. The following details will be displayed in the pop-up window: Formulary ID, Contract Plan Segment, PBP/ADD Deficiencies Email, PBP/ADD Deficiency File, and PBP/ADD Upload Date. The 'PBP/ADD Deficiency Email' column will have a hyperlink to the justification request email sent to users. The 'PBP/ADD Justification File' will have a hyperlink to the PBP/ADD Deficiencies file sent to the users when the deficiencies are communicated. When you have finished reviewing the information, click the "Close" button at the bottom of the window.

- To export the ADD Status History Report to Excel, click the "Export to Excel" button.

Exhibit 119 – Status History Report – ADD File

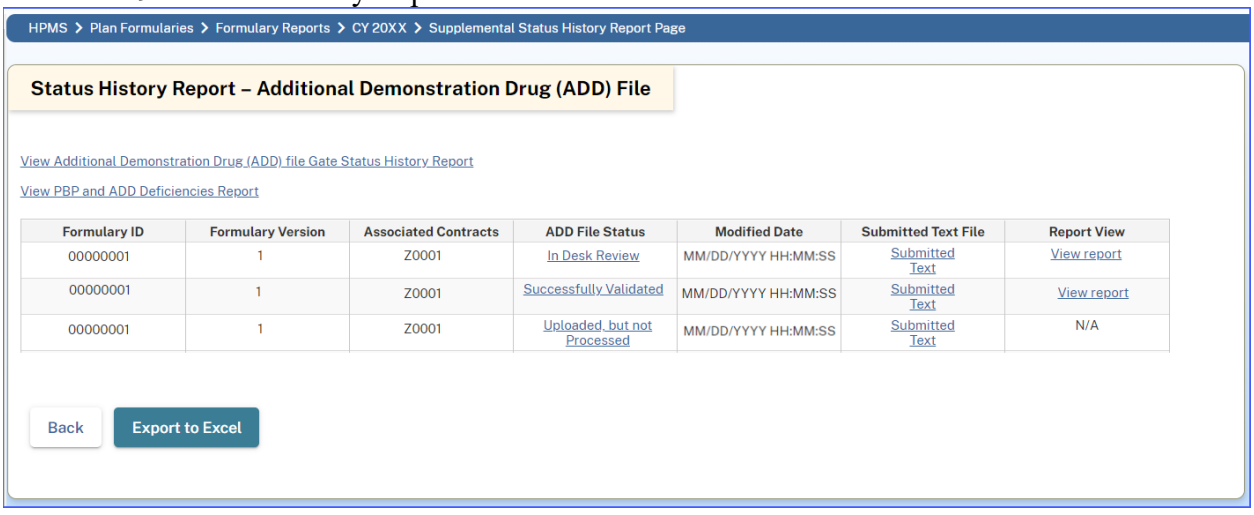


Exhibit 120 – View Submission Email

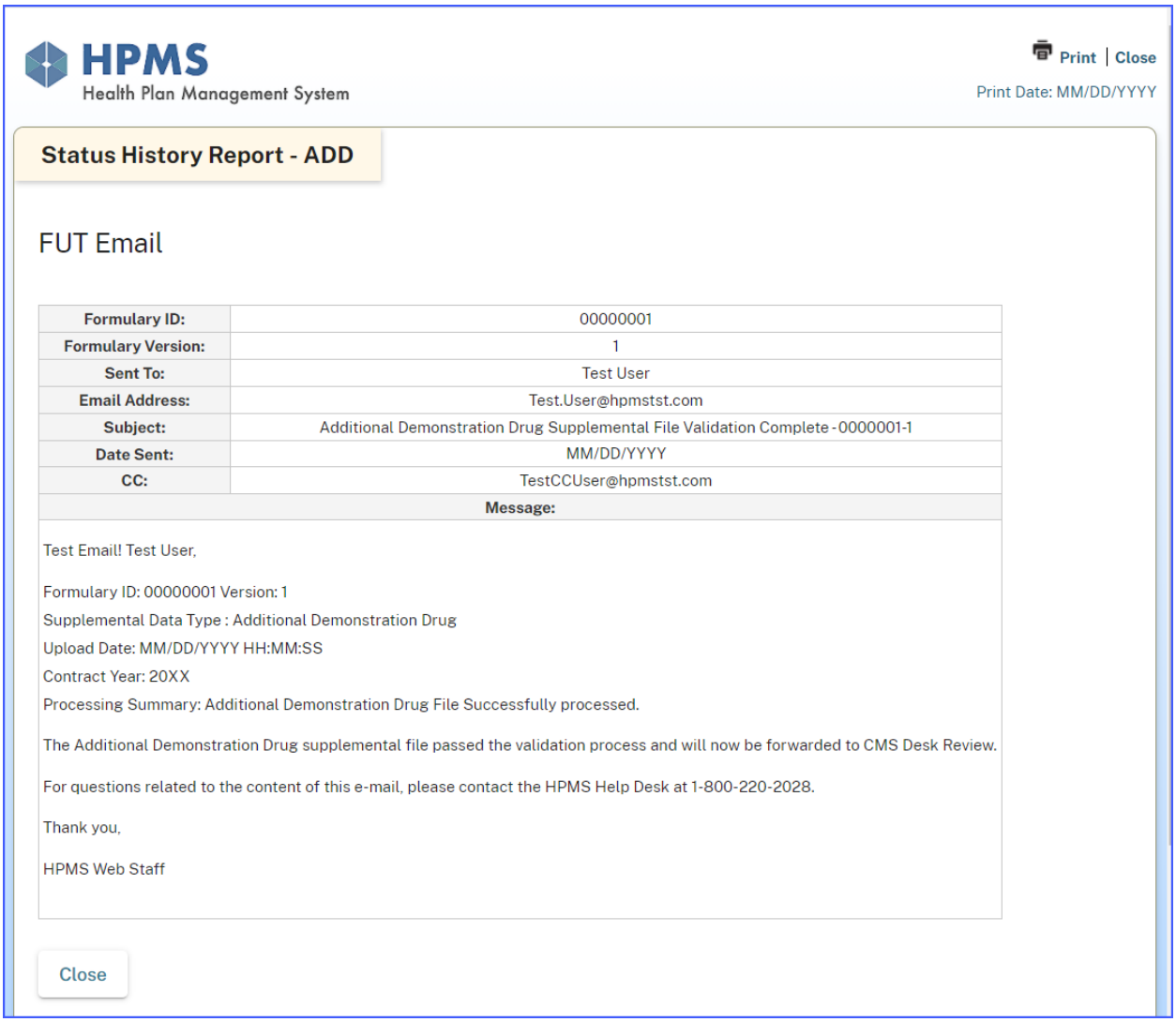
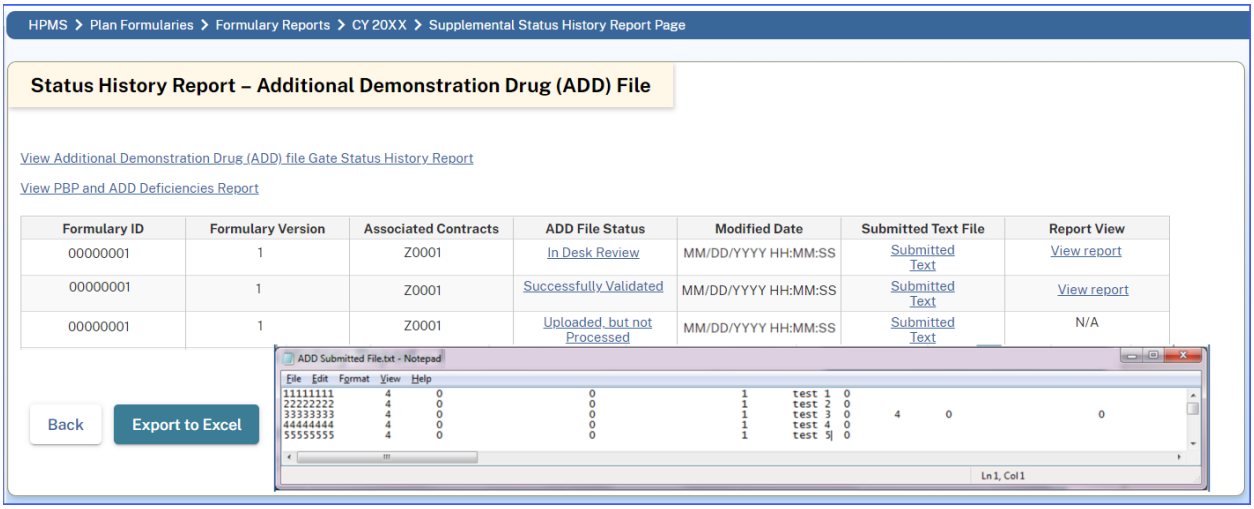


Exhibit 121 – Submitted Text File



XXIX. SUBMIT PART D SENIOR SAVINGS MODEL FILE

Part D sponsors must submit the Part D Senior Savings Model Supplemental File for all contracts/plans participating in the Part D Senior Savings Model during the June 8-10, 2022, supplemental file submission window. This module is only available if your Bid has migrated to "desk review" in the HPMS system.

If your bid submission indicated that a contract/plan offers the Part D Senior Savings Model under Part D, you must submit the Part D Senior Savings Model Supplemental File to CMS as part of your bid.

- Part D sponsors can select one or multiple plans at a time and submit a single Part D Senior Savings Model file.
  Note: The content of the Part D Senior Savings Model file shared between multiple Plans must be identical. As long as Plans that offer Part D Senior Savings Model with the exact same coverage (Drugs and Cohorts) and are able to share the same Part D Senior Savings file, then these plans can be selected to be associated with the same file.
- The supplemental file submission must include the RxCUI and the Cohort for each Model drug.
- Each RxCUI included on the supplemental file is validated against the formulary that is associated with the contract/plan.
- The Part D Senior Savings Model file must contain **at least one RxCUI in each cohort** based on the cohort number in the PBP.
- For Cohort number identified in PBP is 2, the **Cohort** field must only include a value of 1 through 2. For Cohort number identified in PBP is 3, the Cohort field must only include a value of 1 through 3.
- The tier and cohort of a RxCUI in the Part D Senior Savings Model supplemental file must be same as the tier associated to the cohort in the PBP.
- Users may submit their supplemental files as many times as necessary during the submission window. Only the last successful submission is processed for review.

This section below provides detailed information on how to submit the Part D Senior Savings Model Supplemental files:

STEP 1

As shown in Exhibit 4, select Submit Part D Senior Savings Model File from the **Formulary Submission Start Page.** This takes you to the Part D Senior Savings Model Files-Select Contract-Plan(s) page (Exhibit 122).

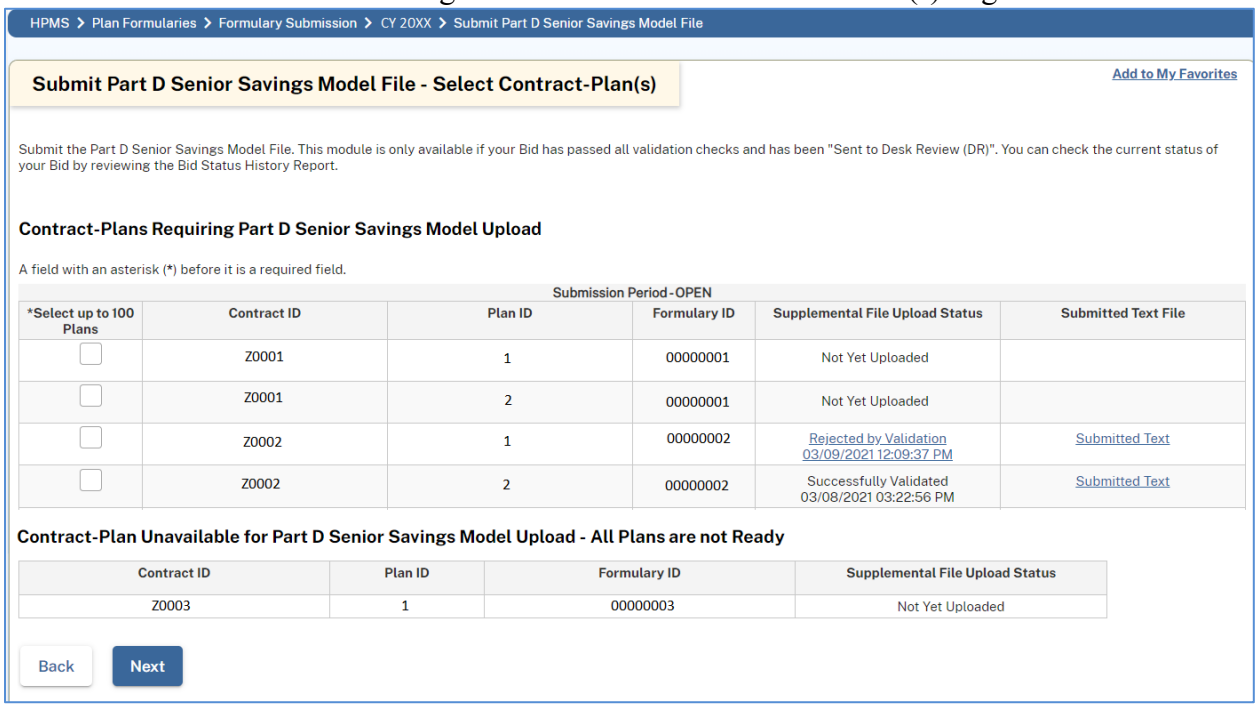
STEP 2

The **Part D Senior Savings Model File - Select Contract-Plan(s)** page contains a table of all Contracts-Plans that require a Part D Senior Savings Model file.

Please note that only those plans with bid submissions that offer this benefit will be displayed. Plans that do not offer this benefit will not be displayed, as the file submission is not applicable to them.

Part D sponsors can select one or multiple plans at a time and submit a single Part D Senior Savings Model file. Select the Contract-Plan(s) for which to upload a Part D Senior Savings Model file and click "Next." This takes you to the Part D Senior Savings Model File – Upload page.

Exhibit 122 – Part D Senior Savings Model File - Select Contract-Plan(s) Page



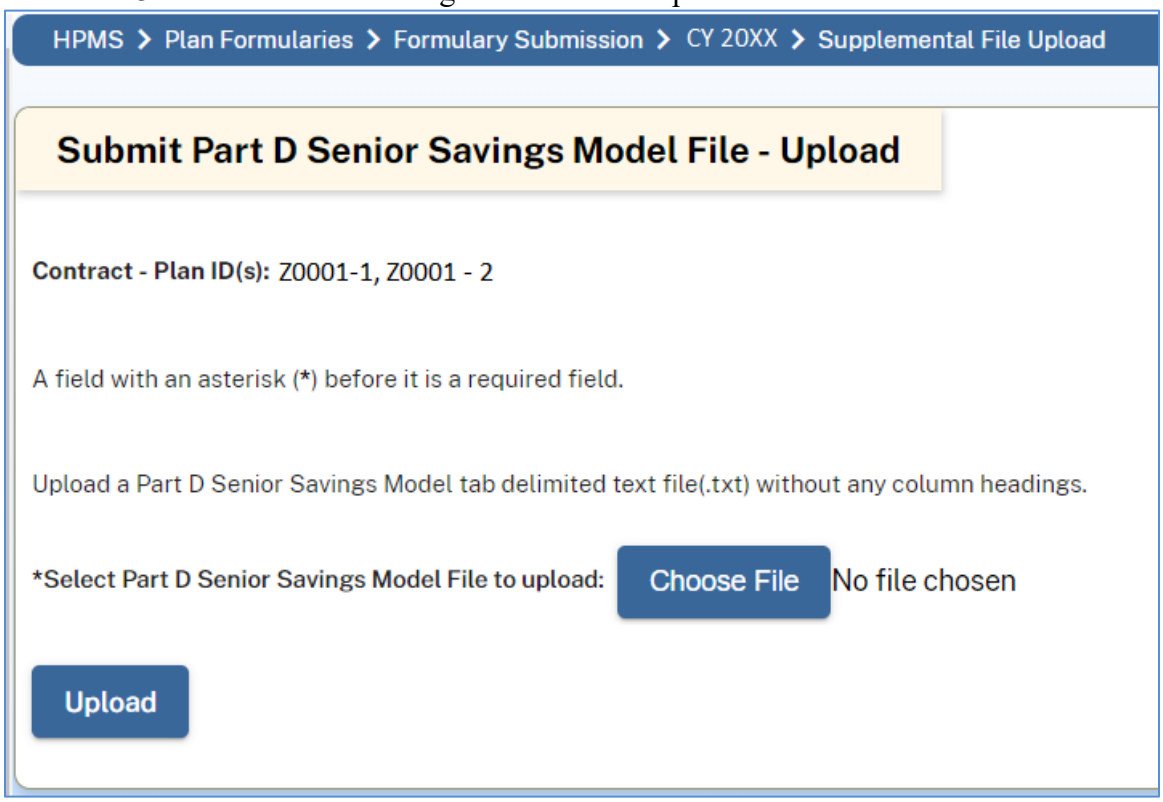
STEP 3

On the **Part D Senior Savings Model File– Upload** page (Exhibit 123), select the "Browse" button to locate the file.

Select the "Upload" button to continue with the Part D Senior Savings Model file submission process.

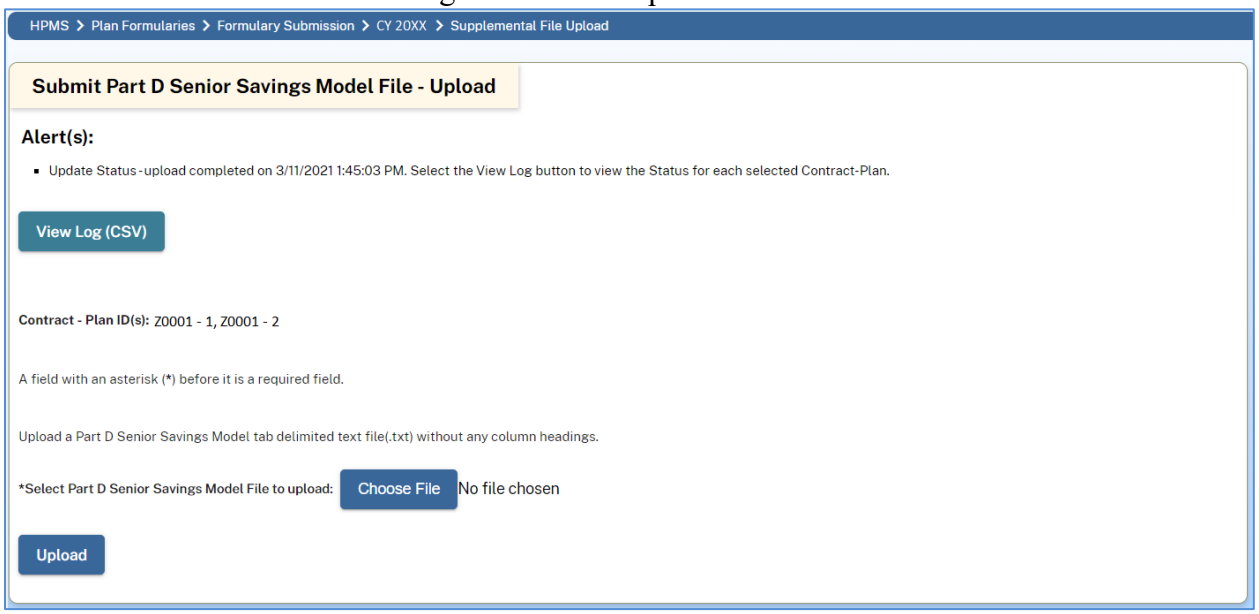
Note: The Part D Senior Savings Model file layout is available under "Documentation - Submission File Layouts" page.

Exhibit 123 – Part D Senior Savings Model File – Upload



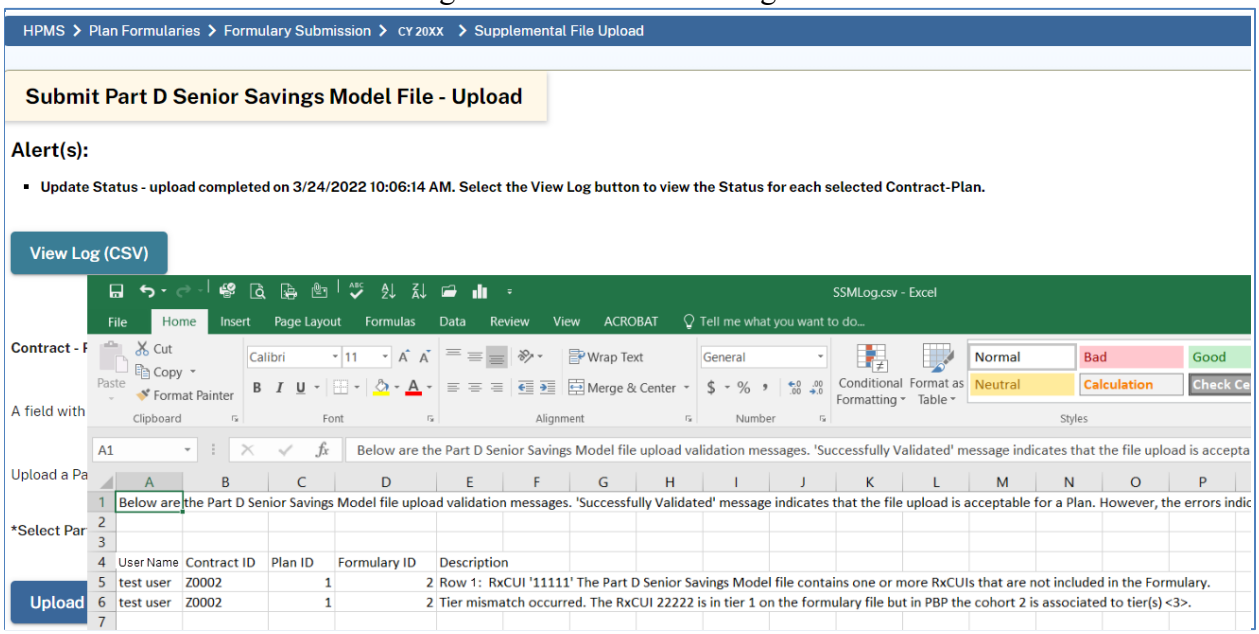
After receiving the uploaded Part D Senior Savings Model file, the HPMS performs a series of validation checks on the submitted file for each plan selected. At the close of the validation process, a status message with a View Log File button is displayed on the **Submit Part D Senior Savings Model File** page (Exhibit 124).

Exhibit 124 – Part D Senior Savings Model File Upload Confirmation



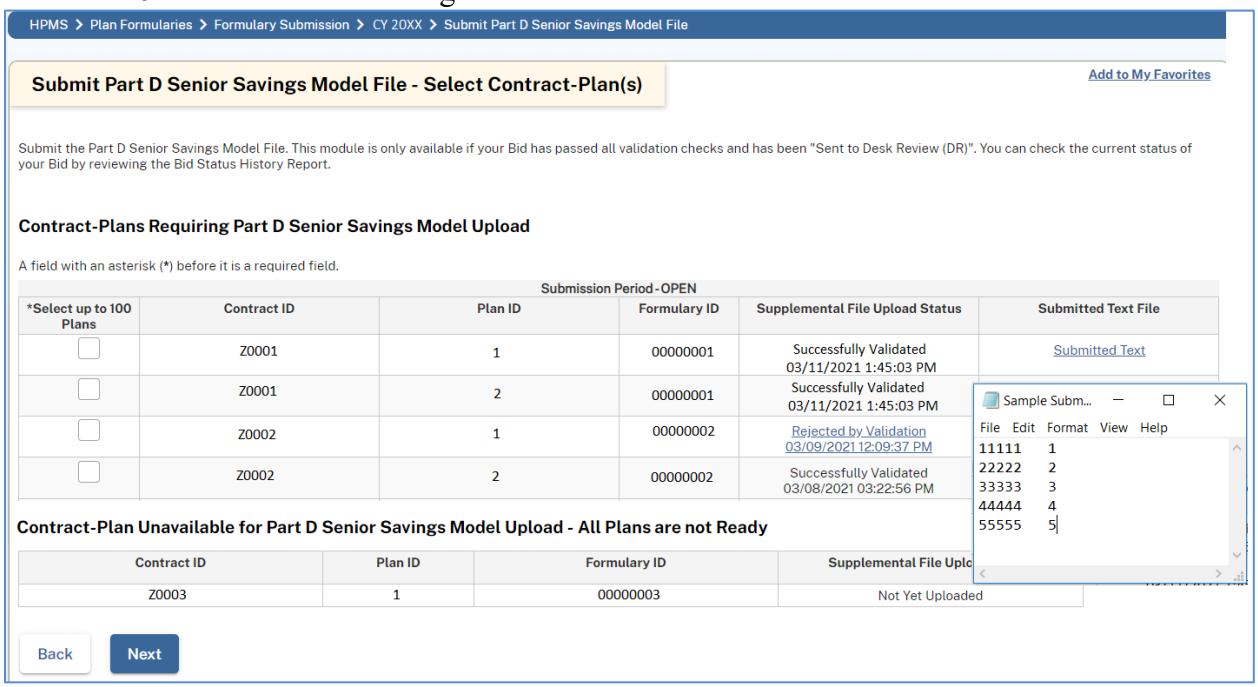
Select the View Log (CSV) button to view the upload status for selected contract-plan ID(s) (Exhibit 125).

Exhibit 125 – Part D Senior Savings Model File – Error Log CSV File



The log file displays the message for each plan selected ('Successfully Validated' or errors). "Successfully Validated" message indicates that the file upload is acceptable for a plan. In case of any error, a plan will be 'Rejected by Validation' and you must correct the Part D Senior Savings Model file and resubmit the file for a contract-plan with error(s).

Exhibit 126 – Part D Senior Savings Model File – Submitted Text File



On the Part D Senior Savings Model – Select a Contract-Plan page, select the "Rejected by Validation" status hyperlink under "Supplemental File Upload Status" column to view the validation log file. The "Submitted Text" file hyperlink displays the latest submitted Part D Senior Savings Model file (Exhibit 126).

XXX. PART D SENIOR SAVINGS MODEL – CHANGE NOTIFICATION REPORT

The Part D Senior Savings Model (PDSSM) File Change Notification Report allows you to compare any two successfully submitted PDSSM files that are associated with a Contract/plan.

STEP 1

As shown in Exhibit 2 on the **HPMS Home** page, select the **Plan Formularies** lnk and **Formulary Reports** link. This takes you to the Formulary Reports Contract Year Selection page.

STEP 2

On the **Formulary Reports Contract Year Selection** page (Exhibit 50), select the appropriate Contract Year link. This takes you to the Formulary Reports – Select a Report page.

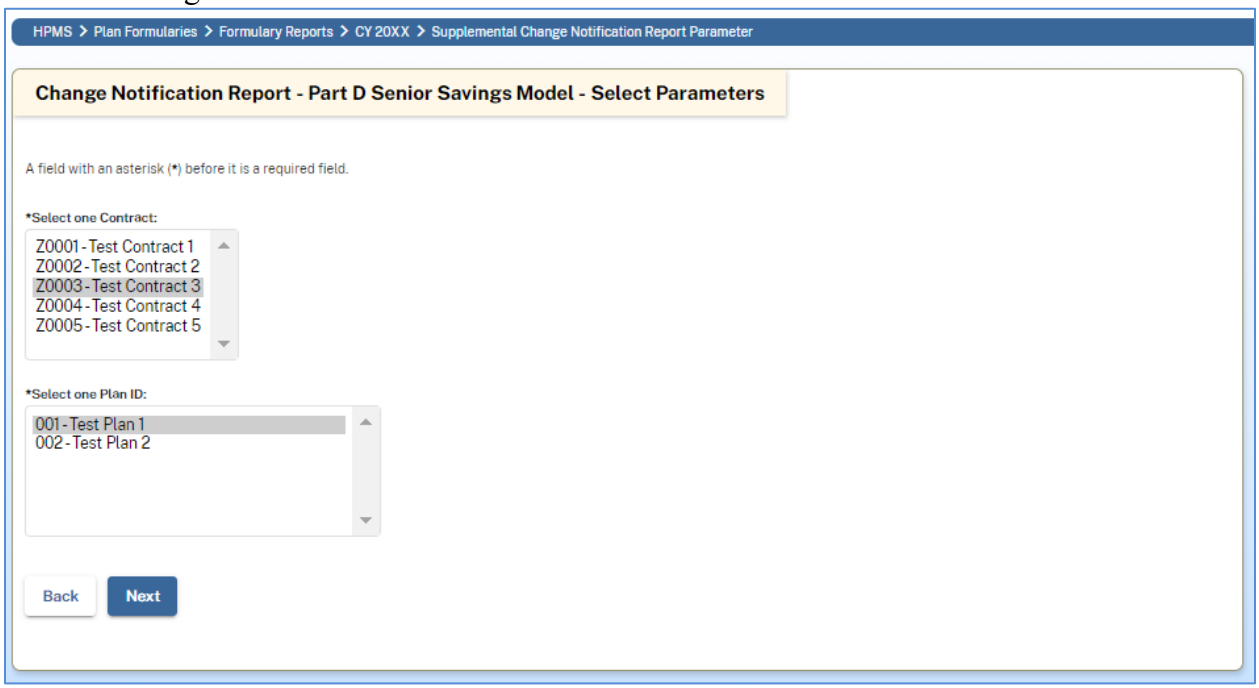
STEP 3

On the **Select a Report** page (Exhibit 51), select "Change Notification Report – Part D Senior Savings Model" This takes you to the Change Notification Report – Part D Senior Savings Model – Select Parameters page.

STEP 4

On the Change Notification Report – Part D Senior Savings Model select parameters page (Exhibit 127), selection of Contract ID, Plan ID and click "Next". This takes you to the Change Notification Report – Part D Senior Savings Model Comparison Selection page.

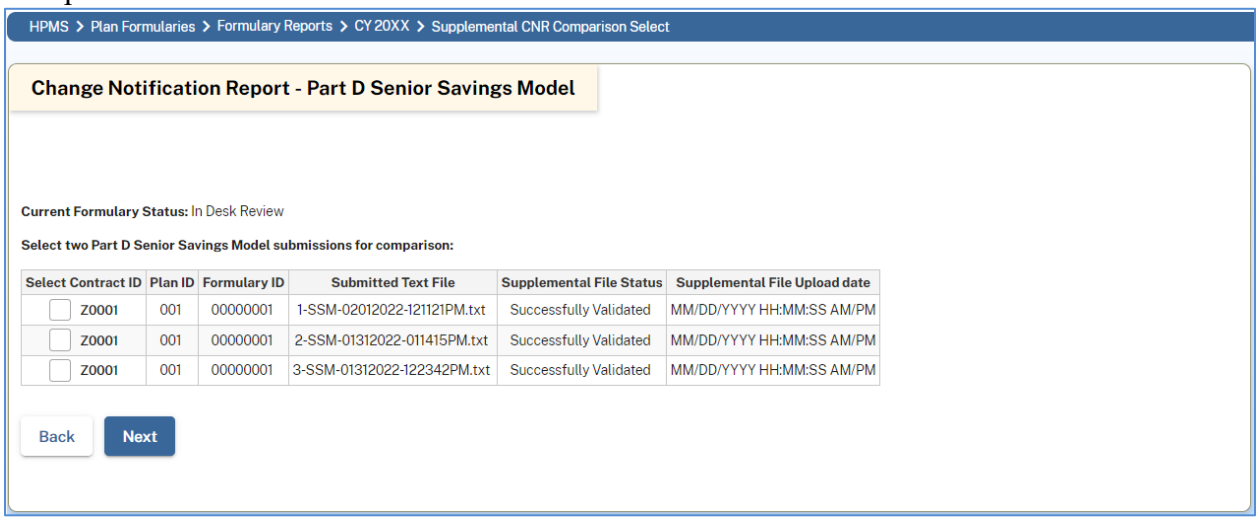
Exhibit 127 - Change Notification Report (CNR) – Part D Senior Savings Model - Select Parameters Page



STEP 5

On the **Submission Comparison Selection page** (Exhibit 128), select two PDSS supplemental file submissions to view in the report and click "Next." This takes you to the Change Notification Report – Part D Senior Savings Model Report page (Exhibit 129).

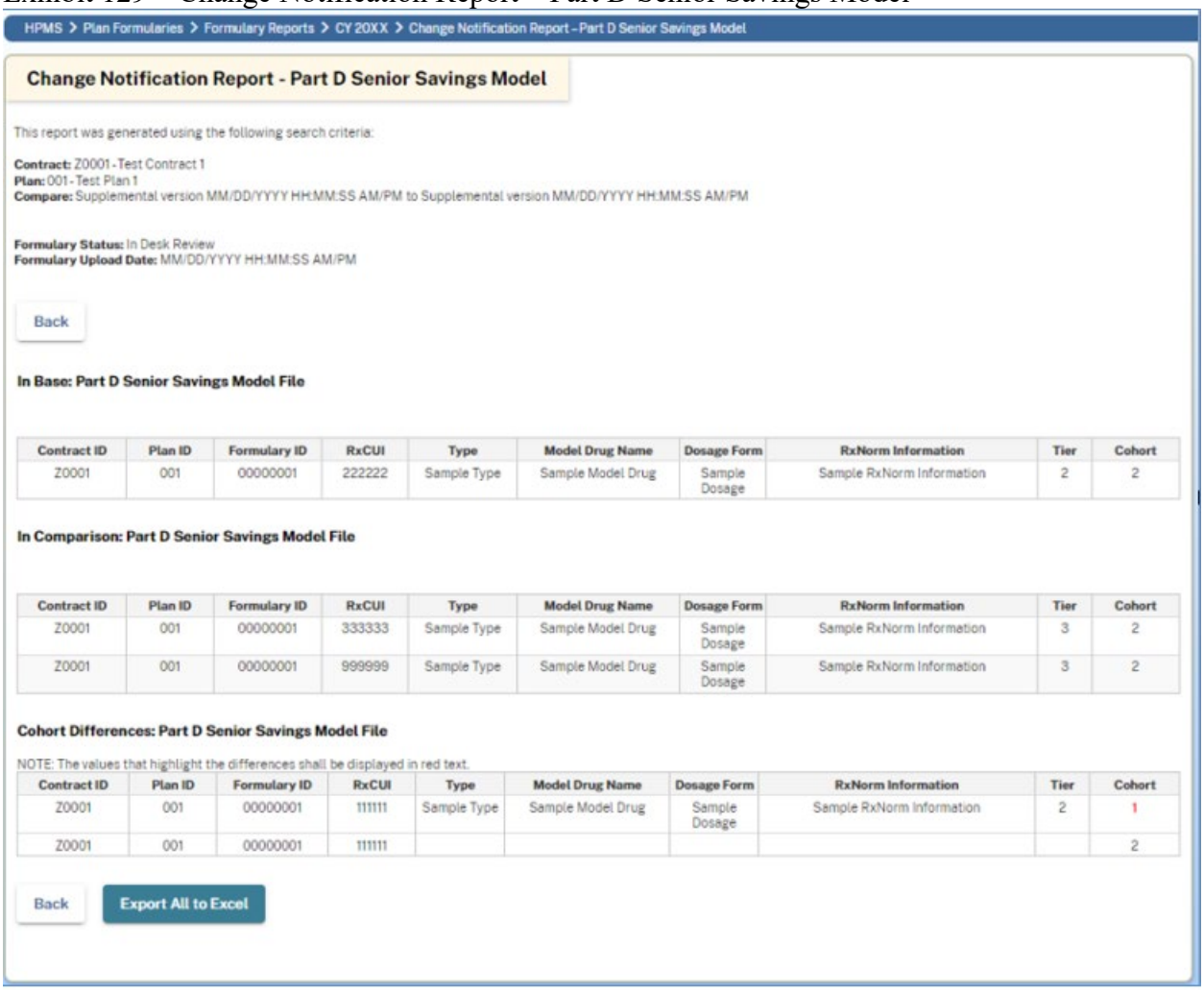
Exhibit 128 - Change Notification Report – Part D Senior Savings Model - Submission Comparison Selection



STEP 6

On the **Change Notification Report – Part D Senior Savings Model report page** (Exhibit 129), select "Export All to Excel" to view the Differences, In Base and In Comparison sections collectively in an Excel report (Exhibit 130).

Exhibit 129 – Change Notification Report – Part D Senior Savings Model



HPMS > Plan Formularies > Formulary Reports > CY 20XX > Change Notification Report – Part D Senior Savings Model

Change Notification Report - Part D Senior Savings Model

This report was generated using the following search criteria:

Contract: Z0001 - Test Contract 1
Plan: 001 - Test Plan 1
Compare: Supplemental version MM/DD/YYYY HH:MM:SS AM/PM to Supplemental version MM/DD/YYYY HH:MM:SS AM/PM

Formulary Status: In Desk Review
Formulary Upload Date: MM/DD/YYYY HH:MM:SS AM/PM

Back

In Base: Part D Senior Savings Model File

Contract ID	Plan ID	Formulary ID	RxCUI	Type	Model Drug Name	Dosage Form	RxNorm Information	Tier	Cohort
Z0001	001	00000001	222222	Sample Type	Sample Model Drug	Sample Dosage	Sample RxNorm Information	2	2

In Comparison: Part D Senior Savings Model File

Contract ID	Plan ID	Formulary ID	RxCUI	Type	Model Drug Name	Dosage Form	RxNorm Information	Tier	Cohort
Z0001	001	00000001	333333	Sample Type	Sample Model Drug	Sample Dosage	Sample RxNorm Information	3	2
Z0001	001	00000001	999999	Sample Type	Sample Model Drug	Sample Dosage	Sample RxNorm Information	3	2

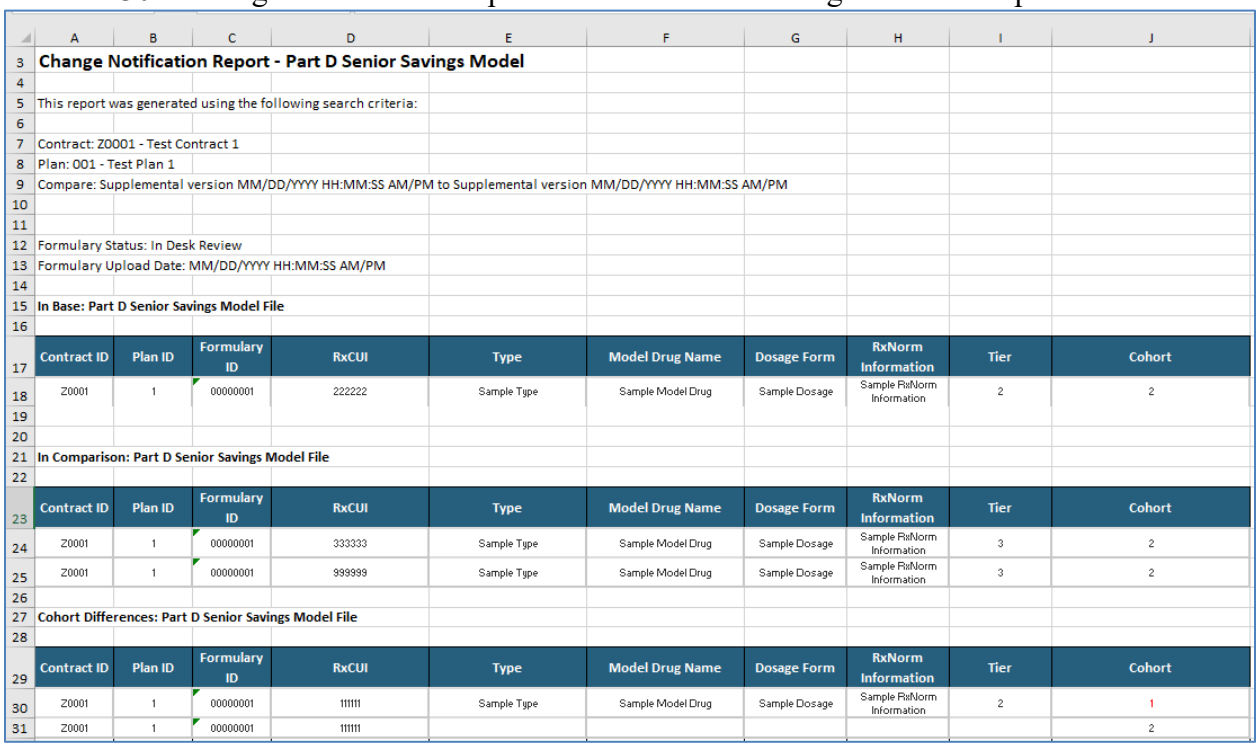
Cohort Differences: Part D Senior Savings Model File

NOTE: The values that highlight the differences shall be displayed in red text.

Contract ID	Plan ID	Formulary ID	RxCUI	Type	Model Drug Name	Dosage Form	RxNorm Information	Tier	Cohort
Z0001	001	00000001	111111	Sample Type	Sample Model Drug	Sample Dosage	Sample RxNorm Information	2	1
Z0001	001	00000001	111111						2

Back Export All to Excel

Exhibit 130 – Change Notification Report – Part D Senior Savings Model – Export All to Excel



Change Notification Report - Part D Senior Savings Model

This report was generated using the following search criteria:

Contract: Z0001 - Test Contract 1
Plan: 001 - Test Plan 1
Compare: Supplemental version MM/DD/YYYY HH:MM:SS AM/PM to Supplemental version MM/DD/YYYY HH:MM:SS AM/PM

Formulary Status: In Desk Review
Formulary Upload Date: MM/DD/YYYY HH:MM:SS AM/PM

In Base: Part D Senior Savings Model File

Contract ID	Plan ID	Formulary ID	RxCUI	Type	Model Drug Name	Dosage Form	RxNorm Information	Tier	Cohort
Z0001	1	00000001	222222	Sample Type	Sample Model Drug	Sample Dosage	Sample RxNorm Information	2	2

In Comparison: Part D Senior Savings Model File

Contract ID	Plan ID	Formulary ID	RxCUI	Type	Model Drug Name	Dosage Form	RxNorm Information	Tier	Cohort
Z0001	1	00000001	333333	Sample Type	Sample Model Drug	Sample Dosage	Sample RxNorm Information	3	2
Z0001	1	00000001	999999	Sample Type	Sample Model Drug	Sample Dosage	Sample RxNorm Information	3	2

Cohort Differences: Part D Senior Savings Model File

Contract ID	Plan ID	Formulary ID	RxCUI	Type	Model Drug Name	Dosage Form	RxNorm Information	Tier	Cohort
Z0001	1	00000001	111111	Sample Type	Sample Model Drug	Sample Dosage	Sample RxNorm Information	2	1
Z0001	1	00000001	111111						2

XXXI. SUBMIT OR WITHDRAW PA/ST CRITERIA CHANGE REQUEST FILE SUBMISSION

The Submit or Withdraw PA/ST Criteria Change Request provide capability for the users to perform the following PA/ST Criteria Change Requests.

- Submit PA/ST Criteria Change Request
- Withdraw PA/ST Criteria Change Request

Submit PA/ST Criteria Change Request: The Submit PA/ST Criteria Change Request functionality provides the capability to request changes to PA or ST criteria updates.

Withdraw PA/ST Criteria Change Request: The Withdraw PA/ST Criteria Change Request functionality will allow the Plan sponsors to withdraw PA/ST Criteria Change Requests they made in the latest PA/ST Criteria Change Request window.

STEP 1

As shown in Exhibit 4, select the **Submit or Withdraw PA/ST Criteria Change Request** link from the Formulary Submission Start Page**.** This takes you to the **Submit PA/ST Criteria Change Request** page (Exhibit 131).

SUBMIT PA/ST CRITERIA CHANGE REQUEST

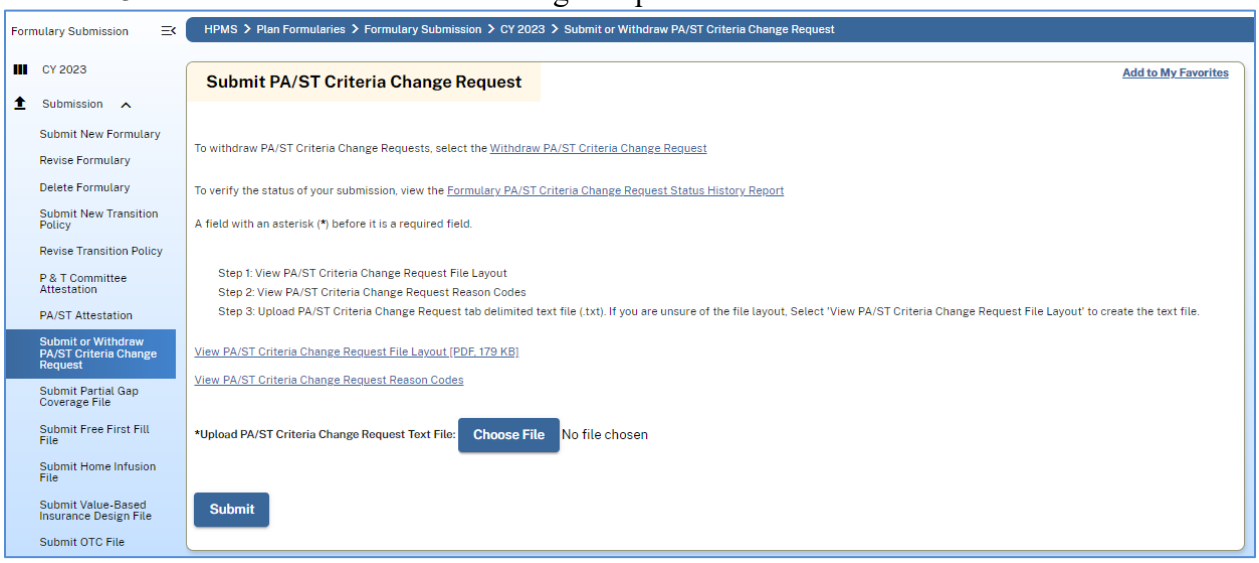
STEP 2

On the Submit PA/ST Criteria Change Request page (Exhibit 131), enter the full path and name of the PA/ST Criteria Change Request File (tab delimited .txt file only) or click the "Choose File" button to locate and attach the file. The upload file layout is displayed on the PA/ST Criteria Change Request – Upload File page.

STEP 3

Click the "Upload" button to submit your files.

Exhibit 131 – Submit PA/ST Criteria Change Request



At this point, you have finished submitting your PA/ST Criteria Change Request file.

After receiving the uploaded PA/ST Criteria Change Request file, the HPMS performs a series of validation checks. If the files are successful, upload user will receive "PA/ST Criteria Request Successful Upload" email. If the file fails validation, an email with the subject "PA/ST Criteria Request - Action Required" is sent to the Upload user. You must correct the PA/ST Criteria file and resubmit the file using the Submit PA/ST Criteria Change Request file function.

If you need to re-submit your PA/ST Criteria Change Request file, follow the same steps listed above. To view the submitted files, you can view the "**PA/ST Criteria Change Request Report**" under Formulary Reports.

When the PA/ST Criteria Change Requests are submitted, the requests will go through review process. When review is completed and passed, Plan Sponsors will be able to submit appropriate changes to PA, ST files through the 'Revise PA/ST Criteria Only' link available on the 'Revise Formulary' page. Refer to Revise PA/ST Criteria Only section on how to submit changes to PA, ST files.

WITHDRAW PA/ST CRITERIA CHANGE REQUEST

STEP 1

As shown in Exhibit 4, select the **Submit or Withdraw PA/ST Criteria Change Request** link from the Formulary Submission Start Page**.** This will take you to the **Submit PA/ST Criteria Change Request** page (Exhibit 131). Select the **Withdraw PA/ST Criteria Change Request** to proceed with Withdraw PA/ST Change Requests Formulary ID(s) selection page.

STEP 2

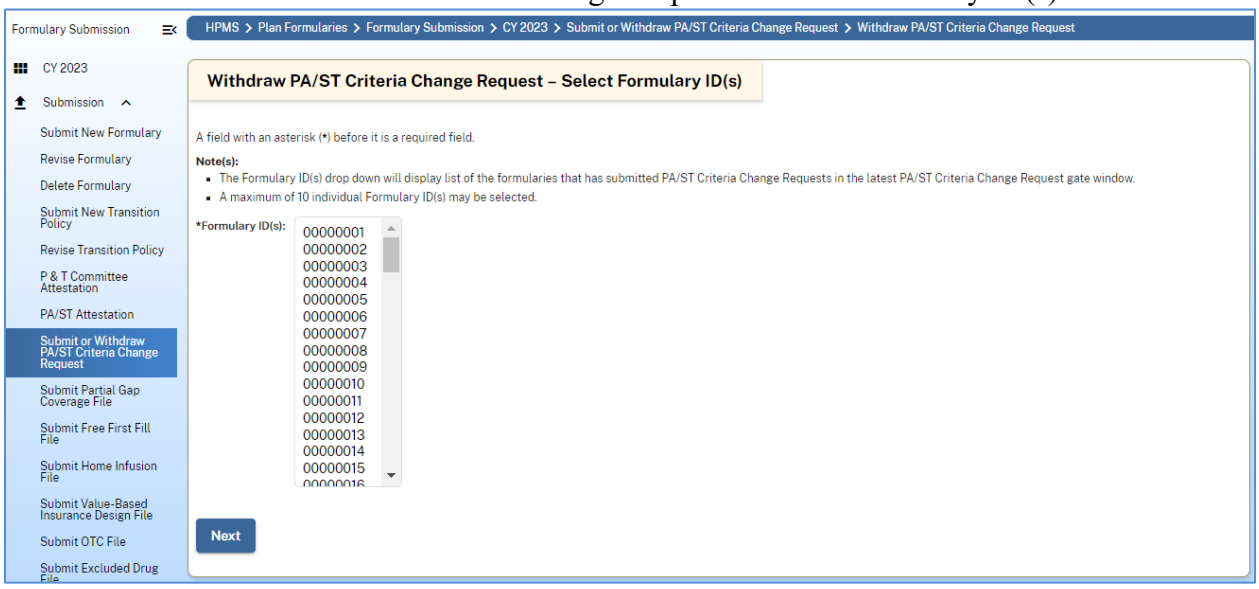
The Withdraw PA/ST Criteria Change Request Formulary ID(s) selection page (Exhibit 132) displays with Formulary ID(s) drop down.

- The Formulary ID(s) dropdown list displays Formulary ID(s) that has at least one submitted PA/ST criteria change request by the plan from the latest PA/ST change request window.

- User is allowed to withdraw PA/ST criteria change requests only prior to the next formulary monthly window opening.

Select one or multiple Formulary ID(s) and the "Next" button to proceed to the **Submit to Withdraw** page with the formularies indicated on the selection page. (Exhibit 133).

Exhibit 132 – Withdraw PA/ST Criteria Change Request – Select Formulary ID(s)



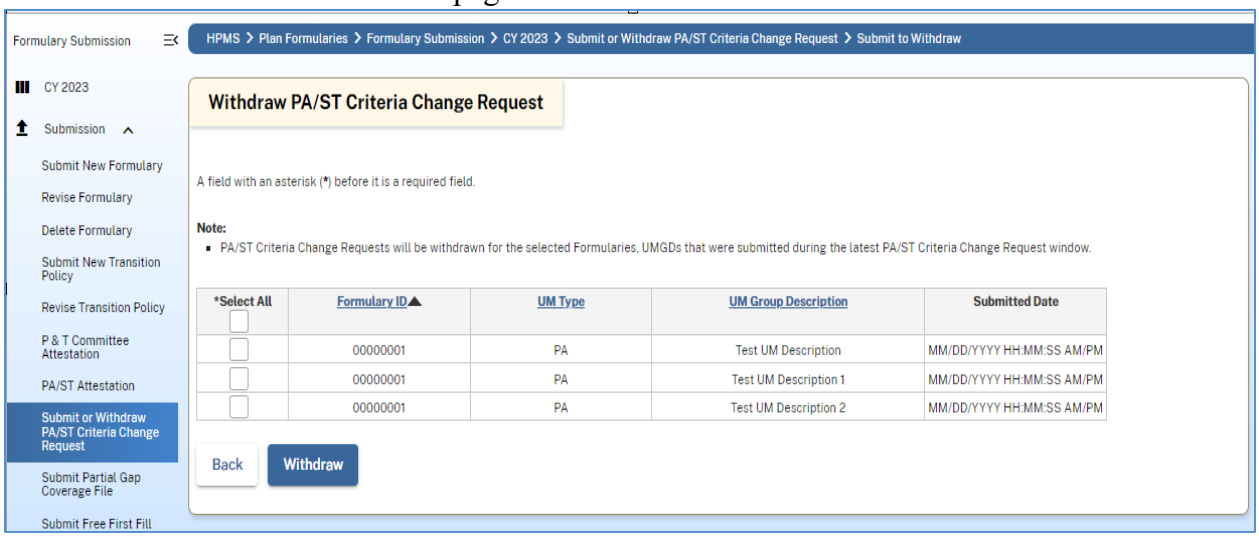
STEP 3

The **Submit to Withdraw** page (Exhibit 133) will display a table with list of records with Formulary ID, UM Type, UM Group Description and Submitted Date. Select the record(s) for which you would like to withdraw the submitted PA/ST criteria change requests and select Withdraw button.

- The PA/ST criteria change requests will be withdrawn for all the selected records and the page navigates to the "Withdraw PA/ST Criteria Change Request – Select Formulary ID(s)" page. A note will display in the page with update status. A confirmation message will be displayed to notify the user that the PA/ST criteria change requests were successfully withdrawn.

- The 'Revise PA/ST edit' gates will not open for the UM group descriptions that has been Withdrawn.

Exhibit 133 – Submit to Withdraw page



XXXII. FORMULARY PA/ST CRITERIA CHANGE REQUEST - STATUS HISTORY REPORT

The **PA/ST Criteria Change Request File - Status History Report** provides detailed status information about the submitted PA/ST Criteria Change Request files.

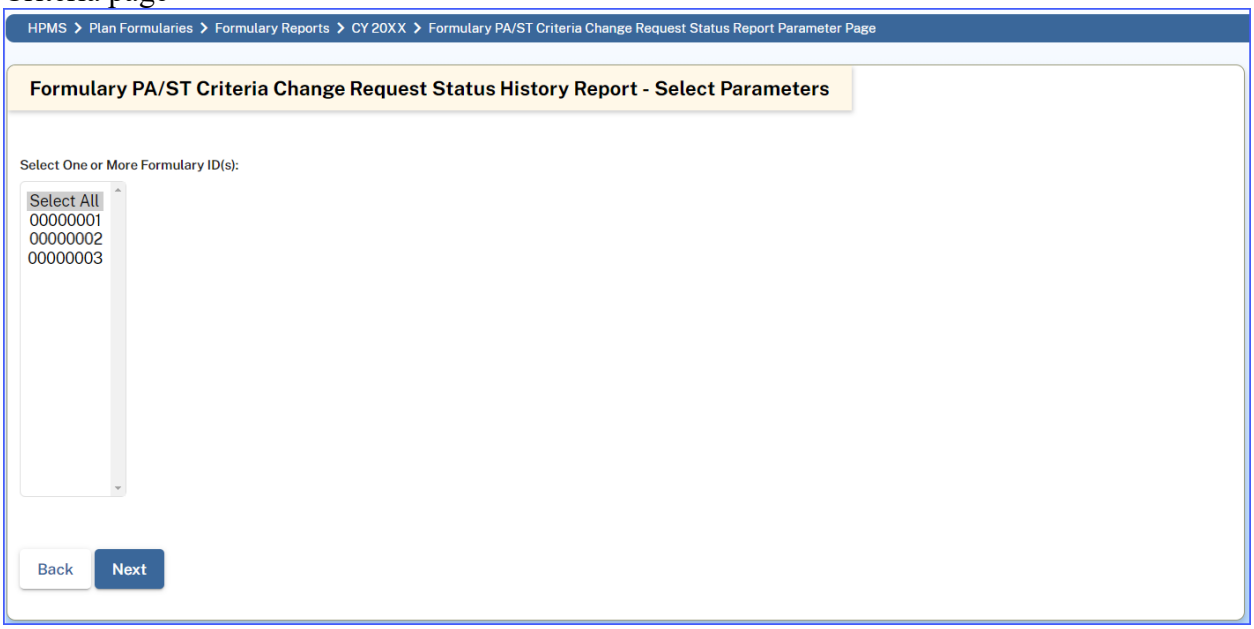
STEP 1

On the **Formulary Reports – Select a Report** page (Exhibit 42), select **Formulary PA/ST Criteria Change Request Status History Report**. This will take you to the report's selection criteria page.

STEP 2

On the **Report Selection Criteria** page (Exhibit 134), select the desired formularies, and then click the "Next" button. This will take you to the **Formulary PA/ST Criteria Change Request Status History Report**.

Exhibit 134 – Formulary PA/ST Criteria Change Request Status History Report – Selection Criteria page



STEP 3

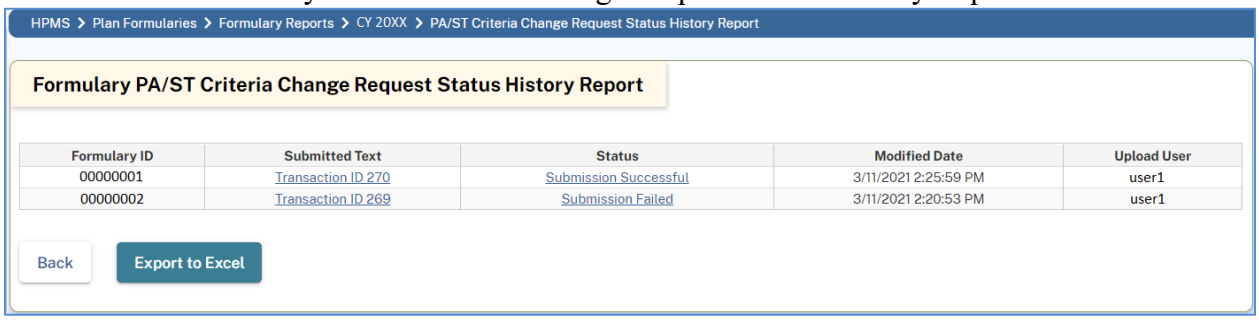
On the **Formulary PA/ST Criteria Change Request Status History Report** page (Exhibit 135), there are several actions you can take to view more details or get background information:

- To view the email sent regarding the PA/ST Criteria Change Request file upload, click the link provided under the Status column. A pop-up window will appear. When you have finished reviewing the information, click the "Close" button at the bottom of the window.

- To view the text file previously submitted, click the "Submitted Text" hyperlink. A pop-up window will appear. When you have finished reviewing the information, click the "Close" button at the bottom of the window.

- To export the PA/ST Criteria Change Request Status History Report to Excel, click the "Export to Excel" button.

Exhibit 135 – Formulary PA/ST Criteria Change Request Status History Report

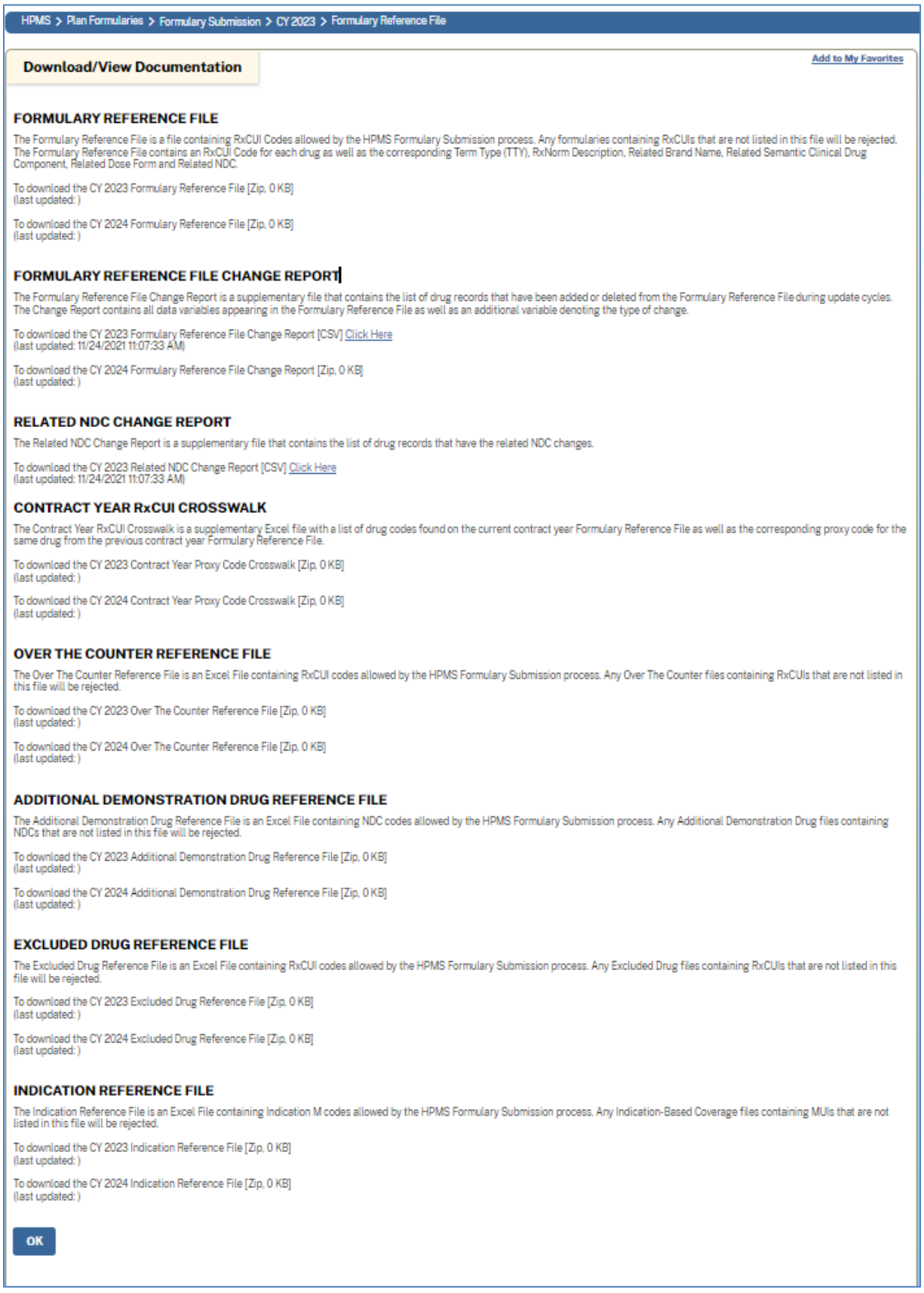


XXXIII. FORMULARY REFERENCE FILE

The Formulary Reference File page (Exhibit 136) provides following documents:

- Formulary Reference File
- Formulary Reference File Change Report
- Related NDC Change Report
- Contract Year RxCUI Crosswalk File
- Over The Counter Reference File
- Additional Demonstration Drug Reference File
- Excluded Drug Reference File
- Indication Reference File

Exhibit 136 – Download/View Documentation



XXXIV. UMGD REVIEW DETAIL REPORT

The UMGD Review Detail Report provides UMGD criteria level status information for a latest version of a given Formulary ID.

STEP 1

On the **Formulary Reports – Select a Report** page (Exhibit 51), select **UMGD – Review Detail Report**. This will take you to the UMGD – Review Detail Report page.

STEP 2

On the UMGD – Review Detail Report page (Exhibit 137), select the desired formularies, file type and then select the "Export to CSV" button. This will open the UMGD – Review Detail Report [CSV] (Exhibit 138).

Exhibit 137 – UMGD Review Detail Report

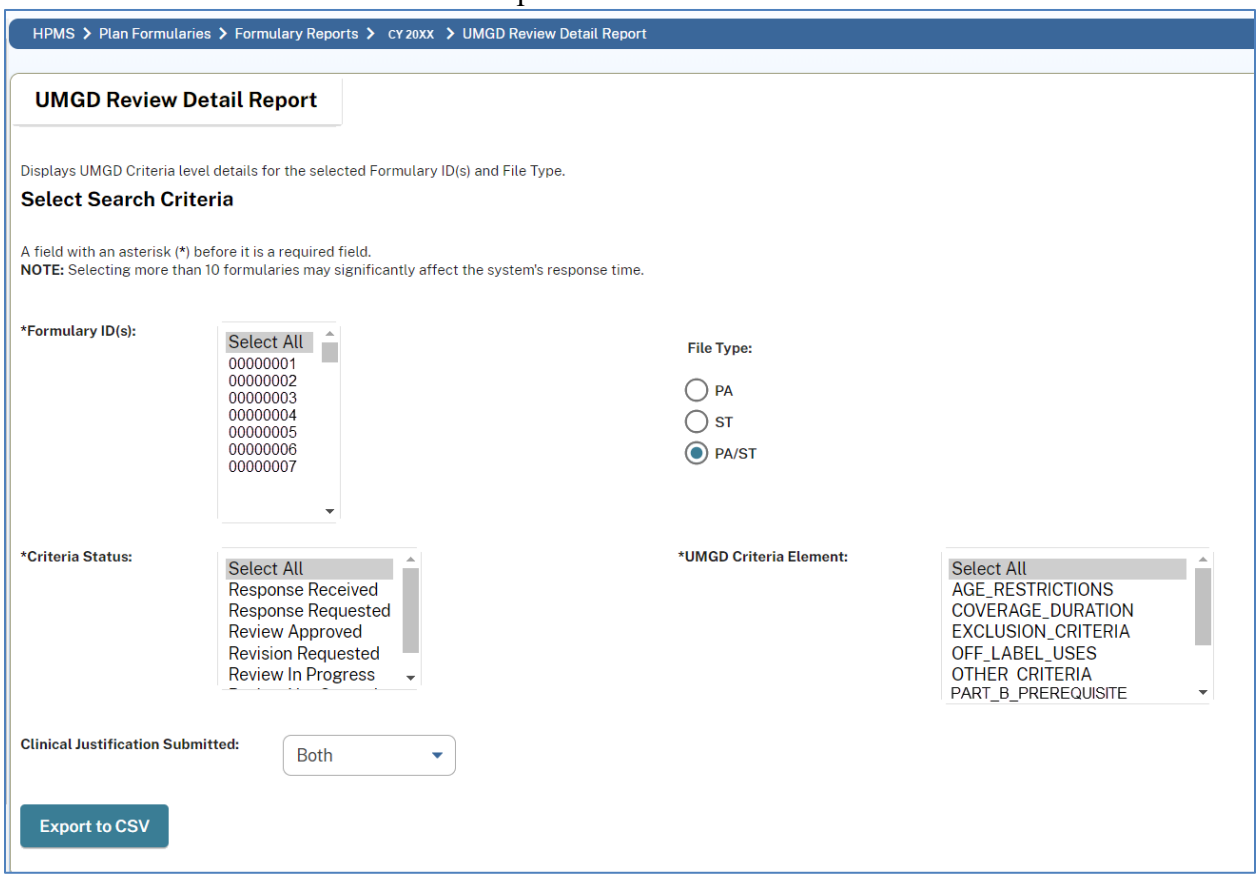
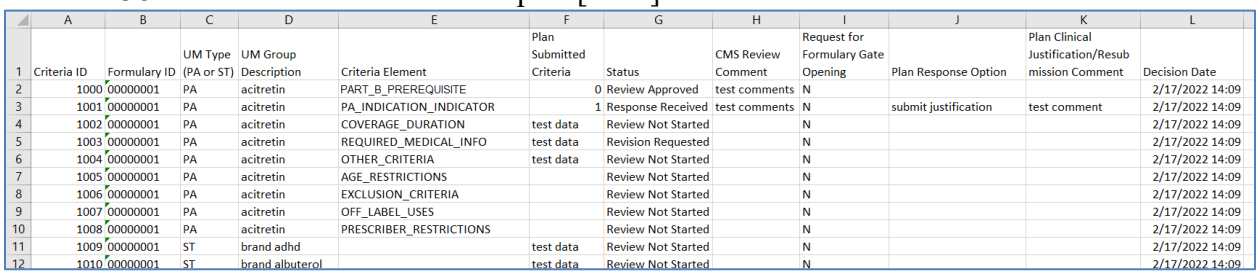


Exhibit 138 – UMGD Review Detail Report [CSV]



	A	B	C	D	E	F	G	H	I	J	K	L
1	Criteria ID	Formulary ID	UM Type (PA or ST)	UM Group Description	Criteria Element	Plan Submitted Criteria	Status	CMS Review Comment	Request for Formulary Gate Opening	Plan Response Option	Plan Clinical Justification/Resubmission Comment	Decision Date
2	1000	00000001	PA	acitretin	PART_B_PREREQUISITE	0	Review Approved	test comments	N			2/17/2022 14:09
3	1001	00000001	PA	acitretin	PA_INDICATION_INDICATOR	1	Response Received	test comments	N	submit justification	test comment	2/17/2022 14:09
4	1002	00000001	PA	acitretin	COVERAGE_DURATION	test data	Review Not Started		N			2/17/2022 14:09
5	1003	00000001	PA	acitretin	REQUIRED_MEDICAL_INFO	test data	Revision Requested		N			2/17/2022 14:09
6	1004	00000001	PA	acitretin	OTHER_CRITERIA	test data	Review Not Started		N			2/17/2022 14:09
7	1005	00000001	PA	acitretin	AGE_RESTRICTIONS		Review Not Started		N			2/17/2022 14:09
8	1006	00000001	PA	acitretin	EXCLUSION_CRITERIA		Review Not Started		N			2/17/2022 14:09
9	1007	00000001	PA	acitretin	OFF_LABEL_USES		Review Not Started		N			2/17/2022 14:09
10	1008	00000001	PA	acitretin	PRESCRIBER_RESTRICTIONS		Review Not Started		N			2/17/2022 14:09
11	1009	00000001	ST	brand adhd		test data	Review Not Started		N			2/17/2022 14:09
12	1010	00000001	ST	brand albuterol		test data	Review Not Started		N			2/17/2022 14:09

The following table contains a description of each field on the UMGD Review Detail Report.

Table 2: UMGD Review Detail Report Field Descriptions

Field Name	Field Type
CRITERIA ID	The unique identifier for the UMGD Criteria of every Formulary
FORMULARY ID	The identification number assigned to the formulary
UM TYPE (PA or ST)	Current UM Type values: PA or ST
UM GROUP DESCRIPTION	PA or ST Group Description
CRITERIA ELEMENT	Displays PAGD criteria element name. For STGD criteria element is blank
PLAN SUBMITTED CRITERIA	Displays plan submitted criteria value for each PAGD criteria element
STATUS	Valid UMGD Criteria statuses: Review Not Started, Review In progress, Revision Requested, Review Approved, Response Requested, Response Received
CMS REVIEW COMMENTS	CMS review comments
REQUEST FOR FORMULARY GATE OPENING	Displays request for formulary gate opening value for each UMGD criteria element
PLAN RESPONSE OPTION	Valid Plan response options: 1-Remove Entire UMGD, 2-Remove PA Element, 3-Revise UMGD Criteria, 4-Submit Clinical Justification
PLAN CLINICAL JUSTIFICATON/RESUB MISSION COMMENTS	Plan clinical justification
DECISION DATE	Displays date and time that the UMGD Criteria Status decisions are released by CMS Reviewer for Plans to view.

XXXV. UMGD STATUS REPORT

The UMGD Status Report provides UMGD overall status information for the latest version of a given Formulary ID.

STEP 1

On the **Formulary Reports – Select a Report** page (Exhibit 51), select **UMGD – Status Report**. This will take you to the UMGD – Status Report page.

STEP 2

On the UMGD – Status Report page (Exhibit 139), select the desired formularies, file type and then select the "Export to CSV" button. This will open the UMGD – Status Report [CSV] (Exhibit 140).

Exhibit 139 – UMGD Status Report

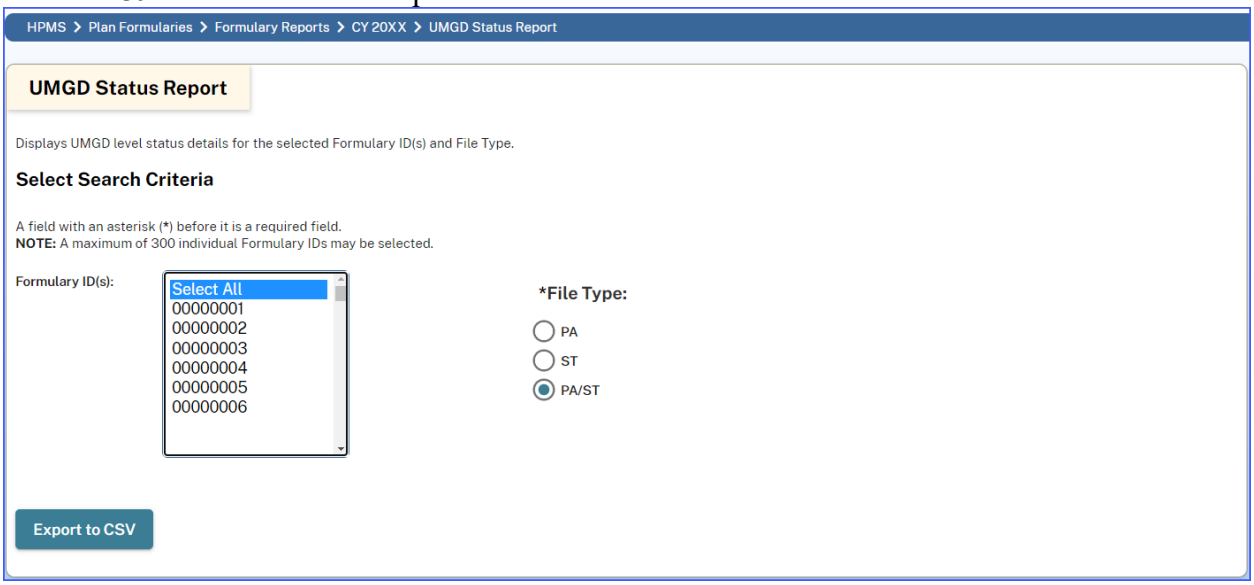
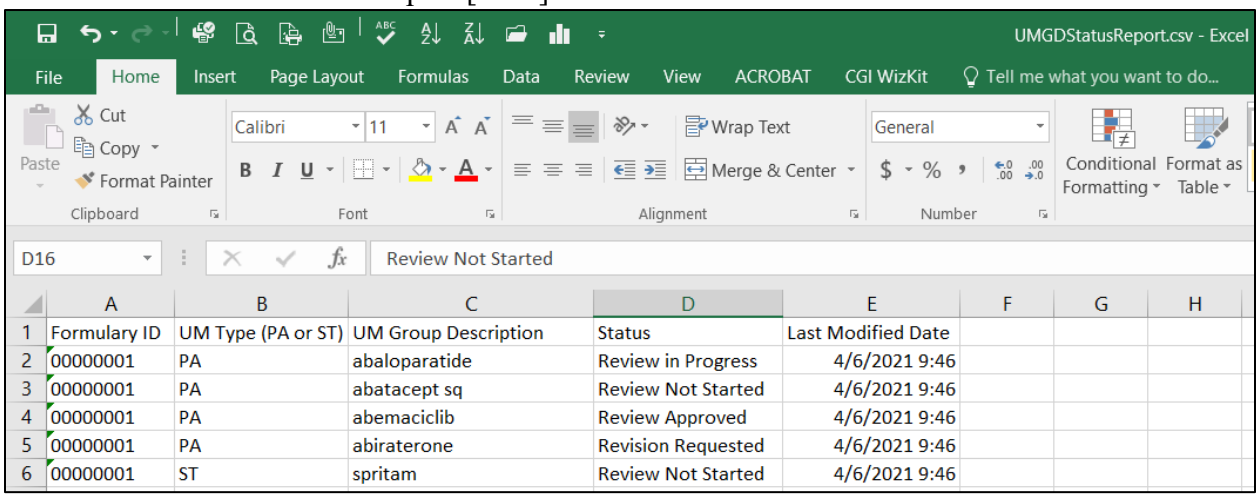


Exhibit 140 - UMGD Status Report [CSV]



	A	B	C	D	E	F	G	H
1	Formulary ID	UM Type (PA or ST)	UM Group Description	Status	Last Modified Date			
2	00000001	PA	abaloparatide	Review in Progress	4/6/2021 9:46			
3	00000001	PA	abatacept sq	Review Not Started	4/6/2021 9:46			
4	00000001	PA	abemaciclib	Review Approved	4/6/2021 9:46			
5	00000001	PA	abiraterone	Revision Requested	4/6/2021 9:46			
6	00000001	ST	spritam	Review Not Started	4/6/2021 9:46			

The following table contains a description of each field on the UMGD Status Report.

Table 3: UMGD Status Report Field Descriptions

Field Name	Field Type
FORMULARY ID	The identification number assigned to the formulary.
UM TYPE (PA or ST)	Current UM Type values: PA or ST.
UM GROUP DESCRIPTION	PA or ST Group Description.
STATUS	Valid UMGD statuses: Review Not Started, Review In progress, Revision Requested, Review Approved.
LAST MODIFIED DATE	Displays date and time of the UMGD changes.

APPENDIX A: CY 2023 FILE LAYOUTS

Required File Format = ASCII File – Tab Delimited
Do not include a header record.
Filename extension is ".txt"

During the initial Formulary submission period, the file must include all drugs in the Formulary. After the initial Formulary submission period, the file must include only changes.

For changes that take place after the initial submission period, plan sponsors are required to request that the gates be opened for future submission opportunities.

Table 4: CY 2023 Formulary File Record Layout

Field Name	Field Type	Maximum Field Length	Field Description	Sample Field Value(s)
Change_Type	CHAR Always Required	3	Defines the type of change that is being made to the Formulary. During the initial Formulary submission period, all rows must be "ADD."	ADD = Add RxCUI to Formulary DEL = Delete RxCUI from Formulary UPD = Change fields in the existing RxCUI
RxCUI	NUMBER Always Required	Maximum of 8 digits	RxNorm concept unique identifier from the active Formulary Reference File.	210597
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
Quantity_Limit_Type	CHAR Always Required	1	Does the drug have a quantity limit restriction?	0 = Quantity Limits Do Not Apply 1 = Daily Quantity Limit 2 = Quantity Limit Over Time

Field Name	Field Type	Maximum Field Length	Field Description	Sample Field Value(s)
Quantity_Limit_Amount	NUM Sometimes Required	7	If the Quantity_Limit_ Type = 0 (No Limits), leave this field blank. If the Quantity_Limit_Type = 1 (Daily QL), enter the quantity limit unit amount per day for a given prescription. The units for this amount must be defined by the unit of measure indicated by the FRF. If the Quantity_Limit_Type = 2 (QL Over Time), enter the quantity limit unit amount for a given time period when the QL is not based on a maximal daily dose. The units for this amount must be defined by the unit of measure indicated by the FRF. The maximum number of decimal points that will be accepted is 5, i.e., "9.99999." The maximum number that will be accepted is "9999.99."	9
Quantity_Limit_Days	NUM Sometimes Required	3	Enter the number of days associated with the quantity limit. If the Quantity_Limit_Type field is 0 (No Limits), then leave this field blank. If the Quantity_Limit_Type field is 1 (Daily QL), then enter 1 in this field. If the Quantity_Limit_Type field is 2 (QL Over Time), then enter the time period in days associated to the quantity limit. The minimum number that will be accepted is 2 and the maximum number that will be accepted is "999."	30 (e.g. 9 tablets every 30 days) (e.g. 9 mls every 30 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

Field Name	Field Type	Maximum Field Length	Field Description	Sample Field Value(s)
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 Prior_Authorization_Type is 0 (No) or 3 (Part D. vs. Part B Authorization Only), then leave this field blank.	Antiemetics
Limited_Access_YN	CHAR Always Required	1	Is access to this drug limited to certain pharmacies?	0 = No 1 = Yes
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 = No Step Therapy Applies 1 = Step Therapy Applies 2 = Step Therapy Applies to New Starts Only

Field Name	Field Type	Maximum Field Length	Field Description	Sample Field Value(s)
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 number that will be accepted is "99." 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.	3
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 Rx CUI, each Group Description must be unique. Note: For each Step Therapy Group Description, there must be a Rx CUI with a Step Therapy Value equal to 1.	Step_Therapy_Group_Desc = "CHF Therapy" Step_Therapy_Group_Desc = "Angina Therapy" Step_Therapy_Group_Desc = "CVD Therapy"

Field Name	Field Type	Maximum Field Length	Field Description	Sample Field Value(s)
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_Type = 0 (No), then leave this field blank. The range of valid accepted values is 1 to 99. Note: For each Step Therapy Group Description, there must be a Rx CUI with a Step Therapy Value equal to 1.	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)

Table 5: CY 2023 Free First Fill File Record Layout

Field Name	Field Type	Maximum Field Length	Field Description	Sample Field Value(s)
RxCUI	NUMBER Always Required	Maximum of 8 digits	RxCUI concept unique identifier from the active Formulary Reference File.	210597

Table 6: CY 2023 Partial Gap Coverage File Record Layout

Field Name	Field Type	Maximum Field Length	Field Description	Sample Field Value(s)
RxCUI	NUMBER Always Required	Maximum of 8 digits	RxCUI concept unique identifier from the active Formulary Reference File. **Note: Partial Gap Coverage file must not include ALL the drugs from the partial gap tier(s). In addition, drugs from fully covered tiers or tiers without additional gap coverage must not be submitted on the Partial Gap Coverage file.**	210597

Table 7: CY 2023 Home Infusion File Record Layout

Field Name	Field Type	Maximum Field Length	Field Description	Sample Field Value(s)
RxCUI	NUMBER Always Required	Maximum of 8 digits	RxCUI concept unique identifier from the active Formulary Reference File.	210597

Table 8: CY 2023 Excluded Drug File Record Layout

Field Name	Field Type	Maximum Field Length	Field Description	Sample Field Value(s)
RxCUI	Number Always Required	8	RxCUI concept unique identifier.	210597
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
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 Quantity_Limit_YN = 1 (Limits Apply), enter the quantity limit unit amount for a given prescription or time period. The units for this amount must be defined by a unit of measure e.g. number of tablets, milliliters, grams, etc. If the Quantity_Limit_YN = 0 (No Limits), leave this field blank. The maximum number of decimal points that will be accepted is 5., i.e., “9.99999.” The maximum number that will be accepted is “9999.99.”	9

Field Name	Field Type	Maximum Field Length	Field Description	Sample Field Value(s)
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.”	30 (e.g. 9 tablets every 30 days) (e.g. 9 mls every 30 days)
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	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. Note: The Capped_Benefit_Quantity must be greater than the Quantity_Limit_Amount for a given RxCUI. If the Capped_Benefit_YN field is 0 = No, then leave this field blank The maximum logical number that will be accepted is “9999.99.”	365
Capped_Benefit_Days	NUM Sometimes Required	3	Enter the number of days associated with the capped benefit limit. If the Capped_Benefit_YN field is 0 = No, then leave this field blank Note: The Capped_Benefit_Days must be greater than the Quantity_Llimit_Days for a given RxCUI. The maximum logical number that will be accepted is “999.”	365 (e.g., 180 tablets every 365 days)
Prior_Authorization_YN	CHAR Always Required	1	Is prior authorization required for the drug?	1 = Yes 0 = No

Field Name	Field Type	Maximum Field Length	Field Description	Sample Field Value(s)
Prior_Authorization_Criteria	CHAR Sometimes Required	1500	The description of the drug's prior authorization criteria. If response to Prior_Authorization_YN = 0 (No), then leave this field blank.	
Step_Therapy_YN	CHAR Always Required	1	Does step therapy apply to this drug?	1 = Yes 0 = No
Step_Therapy_Criteria	CHAR Sometimes Required	500	The description of step therapy protocol. If response to Step_Therapy_YN = 0 (No), then leave this field blank.	
Gap_Coverage_YN	NUM Always Required	1	Is this drug covered in the gap? Response should be 1 (Yes) regardless of whether this drug is on a tier that is fully or partially covered in the gap.	1 = Yes 0 = No

Table 9: CY 2023 Over The Counter File Record Layout

Field Name	Field Type	Maximum Field Length	Field Description	Sample Field Value(s)
RxCUI	CHAR Always Required	8	RxCUI concept unique identifier.	210597
UM_Type	CHAR Always Required	1	Indicate whether the RxCUI will be included as part of general drug utilization management program (0) or a formal step therapy protocol (1). The same RxCUI cannot be included in both a general drug utilization management program and a formal step therapy protocol.	0 = general UM program 1 = formal step therapy protocol

Field Name	Field Type	Maximum Field Length	Field Description	Sample Field Value(s)
Step_Therapy_Total_Groups	NUM Sometimes Required	2	Enter the total number of step therapy drug treatment groups or protocols in which the drug is included. If the response to UM_Type = 0 (No), then leave this field blank. The maximum logical number of groups is "25." 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.	2
Step_Therapy_Group_Desc	CHAR Sometimes Required	100	Description of step therapy drug treatment groups or protocol. This step therapy group description must match a description found in your Formulary text file. Field should be repeated in the record based upon number of groups declared in Step_Therapy_Total_Groups. If the response to UM_Type = 0 (No), then leave this field blank. Note: For a given RxCUI each step therapy group description must be unique.	Step_Therapy_Group_Desc = "Anti-Histamine Therapy"; Step_Therapy_Group_Desc = "GERD Therapy";

Field Name	Field Type	Maximum Field Length	Field Description	Sample Field Value(s)
Step_Therapy_Step_Value	NUM Sometimes Required	1	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 the response to UM_Type = 0 (No), then leave this field blank. If the response to UM_Type = 1 (Yes), then the only allowable value is 1.	Step_Therapy_Step_Value = 1 (e.g. Step 1 of 3); Step_Therapy_Step_Value = 1 (e.g. Step 1 of 2)

Table 10: CY 2023 Value-Based Insurance Design File Record Layout

Field Name	Field Type	Maximum Field Length	Field Description	Sample Field Value(s)
Contract ID	Alphanumeric Always Required	5	Contract Number	H0001
Plan ID	Number Always Required	3	Plan Number	001
RxCUI	Number Always Required	8	RxCUI – must exist on the related Formulary file	210597
Packages	Alphanumeric Always Required	50	Identify the packages defined in the PBP for the RxCUI	1,3,7

Table 11: CY 2023 Medicare-Medicaid Plan (MMP) Additional Demonstrational Drug (ADD) File Layout

Field Name	Field Type	Maximum Field Length	Field Description	Sample Field Value(s)
MMP_NDC	CHAR Always Required	11	11-Digit National Drug Code Do not include any spaces, hyphens or other special characters.	00012533460
MMP_Tier	CHAR Always Required	1	The cost-share tier level associated with the drug (assumes that the drug is assigned to only one tier value). Tier values 1-6 are consistent with the selection of tier level options available to data entry users in the Plan Benefit Package software. Tier values of 1 or 2 can only be selected for 2-tier Formulary designs.	1 = Tier Level 1 2 = Tier Level 2 3 = Tier Level 3 4 = Tier Level 4 5 = Tier Level 5 6 = Tier Level 6
MMP_QL_YN	CHAR Always Required	1	Does the drug have a quantity limit (MMP_QL_YN) restriction?	0 = No Quantity Limits 1 = Quantity Limits Apply
MMP_QL_Amt	NUM Sometimes Required	7	If the MMP_QL_YN is" 1" (meaning limits apply), enter the quantity limit amount (MMP_QL_Amt) for a given prescription or time period (typically 1 month). The units for this amount must be defined by a unit of measure e.g. number of tablets, milliliters, grams, etc. The maximum logical number that will be accepted is "9999.99." If the MMP_QL_YN field is "0" (No), then leave this field blank.	9 (e.g. 9 tablets)
MMP_QL_Days	NUM Sometimes Required	3	The number of days (MMP_QL_Days) associated with the quantity limit amount. The maximum logical number that will be accepted is "365." If the MMP_QL_YN field is "0" (No), then leave this field blank.	30 (e.g. 9 tablets every 30 days)
MMP_CapBen_YN	CHAR Always Required	1	Does the drug have a capped benefit (MMP_CapBen_YN) limit?	0 = No 1 = Yes

Field Name	Field Type	Maximum Field Length	Field Description	Sample Field Value(s)
MMP_CapBen_Amt	NUM Sometimes Required	7	If the MMP_CapBen_YN field is "1" (meaning limits apply), enter the capped benefit limit amount (MMP_CapBen_Amt) for a given prescription or time period. Plans may elect to have a capped benefit amount without a quantity limit. However if a quantity limit applies as well, the capped benefit amount must be greater than the quantity limit amount. The units for this amount must be defined by a unit measure e.g. number of tablets, number of milliliters, number of grams, etc. The maximum logical number that will be accepted is "9999.99." The capped benefit amount must be greater than the quantity limit amount. If the MMP_CapBen_YN field is "0" (No), then leave this field blank.	180 (e.g. 180 tablets)
MMP_CapBen_Days	NUM Sometimes Required	3	The number of days (MMP_CapBen_Days) associated with the capped benefit limit. The capped benefit days must be greater than the quantity limit days. The maximum logical number that will be accepted is "365." If the MMP_CapBen_YN field is "0" (No), then leave this field blank.	365 (e.g. 180 tablets every 365 days)
MMP_PA_YN	CHAR Always Required	1	Is prior authorization (MMP_PA_YN) required for the drug?	0 = No 1 = Yes
MMP_PA_Criteria	CHAR Sometimes Required	3000	The description of the prior authorization criteria (MMP_PA_criteria) for this drug. If the MMP_PA_YN field is "0" (No), then leave this field blank.	
MMP_ST_YN	CHAR Always Required	1	Does step therapy (MMP_ST_YN) apply to this drug?	0 = No 1 = Yes
MMP_ST_Criteria	CHAR Sometimes Required	1000	The description of the step therapy protocol (MMP_ST_Criteria) for this drug. If the MMP_ST_YN field is "0" (No) then leave this field blank.	

Table 12: CY 2023 UMGD Criteria Response File Layout

Field Name	Field Type	Maximum Field Length	Field Description	Sample Field Value(s)
Criteria ID	NUM Always Required	NA	Identifier for the UMGD criteria for which to submit response. Note: Criteria ID with open response requests can be found on the UMGD Criteria Detail Report under OJS Reports.	654321
Request for Formulary Gate Opening	CHAR Always Required	1	Valid values: Y or N. Indicates whether a new version of the formulary will be submitted to address the UMGD response.	N = No Y = Yes
Plan Response Option	NUM Always Required	1	Valid values for Plan Response Option field are: 1=Remove Entire UMGD 2=Remove PA Element 3=Revise UMGD Criteria 4=Submit Clinical Justification	1
Plan Clinical Justification/ Resubmission Comment	CHAR Sometimes Required	4000	Comments or clinical justification (this field is optional unless option 4 is chosen for the plan response option)	

UMGD Criteria Response File can be submitted from OJS - UMGD Criteria Response page.

Table 13: CY 2023 Outlier Justification Upload File Layout

Field Name	Field Type	Maximum Field Length	Field Description	Sample Field Value(s)
Outlier ID	NUM Always Required	10	Identifier for the outlier.	654321
Resubmission? (Y/N)	CHAR Always Required	1	Indicates whether a new version of the formulary will be submitted to address the outlier.	Y
Resubmission Comment/Justification	CHAR Always Required	2000	Resubmission Comment or Clinical Justification.	Comment/Justification

Outlier Justification Upload File can be submitted from OJS – Outlier Justification Upload page.

Table 14: CY 2023 PAST Criteria Change Request File Layout

Field Name	Field Type	Maximum Field Length	Field Description	Sample Field Value(s)
Formulary ID	CHAR Always Required	8	Formulary ID (with or without leading zeros) for which to request PA/ST edits.	00020005 Or 20005
Reason for UM Change	CHAR Always Required	1	Reason for the UM Criteria Change Request submitted. Reason Codes 1 to 6 and their descriptions: 1 - Removal of a restriction 2 - Addition of drug(s) to existing Criteria 3 - Addition of a new indication 4 - Restriction based on a new Boxed Warning/FDA Safety Communication 5 - Other extraordinary circumstance 6 - Revision of existing criteria to include a Part B drug (MAPDs only)	1
Current UM Type	CHAR Always Required	2	Current UM Type values: PA or ST	PA
Current UM Group Description	CHAR Always Required	100	Description of the prior authorization group as it appears on the submitted Formulary file. This field must exactly match the value entered in the Prior_Authorization_Group_Desc field on the Formulary File. Or Description of the step therapy group as it appears on the submitted Formulary file. This field must exactly match the value entered in the Step_Therapy_Group_Desc field on the Formulary File.	Antiemetics

Table 15: CY 2023 Part D Senior Savings Model File Layout

Field Name	Field Type	Maximum Field Length	Field Description	Sample Field Value(s)
RxCUI	Number Always Required	8	RxCUI concept unique identifier from the active Formulary Reference File.	210597

Cohort	Number Always Required	1	Defines the Cohort number (1,2,3,4 or 5) associated with the drug. The file must contain at least one RxCUI for each Cohort number defined in the Plan Benefit Package software, for selected Plan(s).	5

Please Note: The content of the Part D Senior Savings Model file shared between multiple Plans must be identical. As long as Plans that offer Part D Senior Savings Model with the exact same coverage (Drugs and Cohorts) and are able to share the same Part D Senior Savings file, then these plans can be selected to be associated with the same file.

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

APPENDIX B: FORMULARY UPLOAD FILE INSTRUCTIONS

Note: To download all upload file formats, click the **Submission File Layouts** link in the Documentation section of the Formulary Submission Start Page.

FORMULARY FILE INSTRUCTIONS

The Formulary file must be created in an ASCII File Tab delimited format and contain one proxy RxCUI record for each drug offered with an organization's benefit plans. The Appendix A: Formulary file Record Layout is provided for your reference. Please note that only proxy RxCUI provided in the CY 2023 Formulary Reference File may be uploaded. All other codes 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 "Required," "Optional," or "Conditional." The conditional fields should be populated if the condition is met as outlined below. When an optional 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.

Field 1 – Change_Type:
REQUIRED: During the initial submission period, the value should be "ADD" for all records. During review period, only changes to the Formulary file will be submitted. Each RxCUI submitted will need a change type field value of "ADD", "DEL", or "UPD." The HPMS system will perform a validation on RxCUIs that have the update flag to ensure that a change was made.

Field 2 – RxCUI:
REQUIRED: Each record should include up to 8-digit numeric RxCUI associated with the Formulary. The list of acceptable RxCUI can be found in the CY 20XX Formulary Reference RxCUI File. RxCUI should only be entered once in this Formulary file.

Field 3 – Tier_Level:
REQUIRED: Enter the cost-share tier level value associated with the drug. Include a value from 1-7 only for non-MMP formularies. MMP formularies can only have tiers 1-6. A number outside of this range will result in an upload error. If cost-share tier 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.
For Non-MMP formularies, if it includes an excluded drug only tier, no FRF drug should be entered on the Formulary record layout as having that tier number.
For MMP formularies, only Medicare tiers are included in the Formulary file.

Field 4 – Quantity_Limit_Type:
REQUIRED: This field should be set to a value of 0, 1, or 2, where 0 = No QL, 1 = Daily QL, and 2 = QL over Time. Set the value to 1 if the quantity limit is based on a maximum daily

amount provided over a month. Set the value to 2 if the quantity limit is not based on a maximum daily dose.

Field 5 - Quantity_Limit_Amount:
CONDITIONAL: If the **Quantity_Limit_Type** is 0, then leave this field blank by providing a tab delimiter. If the **Quantity_Limit_Type** is 1 or 2, include the quantity limit unit amount. The unit amount for this field refers to unit value 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 30 days, this field should indicate a value of 9.

Field 6 - Quantity_Limit_Days:
CONDITIONAL: If the **Quantity_Limit_Type** is 0, then leave this field blank by providing a tab delimiter. If the **Quantity_Limit_Type** is 1or 2, include the quantity limit day amount for this drug. For example, for a quantity limit that includes 9 tablets every 30 days, this field should indicate a value of 30.

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 B vs. Part D 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 RxCUI records must have a value of 1 or greater for this field. If these values are inconsistent, an upload error will result.

Field 8 – Prior_Authorization_Group_Desc:
CONDITIONAL: If Prior Authorization 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. RxCUIs should only be grouped together if the Prior Authorization criteria are the same for all RxCUIs 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 RxCUI 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.

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

- If RxCUI is equal to the 0003686 (OTC CUI), then the Step_Therapy_Type fields must be equal to 1 or 2.

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 Field15. 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 RxCUI 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

NOTE: If RxCUI is equal to the 0003686 (OTC CUI), then the Step_Therapy_Step_Value must always equal 1.

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 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, it must be represented by a tab delimiter.

For a given PA Group Description, a "1" must be entered for the **PA_Criteria_Change_Indicator** field if the criteria are different than the values on the CY 2022 Formulary version approved as of February 1, 2022. In addition, if PA is required for drugs that are on your CY 2023 Formulary that were either 1) not on the approved CY 2022 file, OR 2) did not previously require a PA for CY 2022, then a "1" must be entered. If the criteria are completely unchanged, a "0" must be entered.

Please Note: For those plans that have PA Type 3 only, you are not required to upload a blank PA file. You will still indicate on the Formulary questions page that the Formulary includes Type 3 PA, but there will be a check box on the Formulary upload page that allows you to complete your Formulary submission without uploading a PA file. The PA criteria document must be a tab delimited text file and a filename extension of "txt." Do not include a header record.

Required File Format = ASCII File - Tab Delimited
Do not include a header record
Filename extension should be ".txt"

Table 16: Prior Authorization File Instructions

Field Name	Field Type	Maximum Field Length	Field Description
PA_Change_Type	CHAR Always Required	3	Defines the type of change that is being made to the Prior Authorization File. During the initial Formulary submission period, all rows must be "ADD." ADD = Add Group Description to file UPD = Change fields for an existing Group 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 match the value entered in the Prior_Authorization_Group_Desc field on the Formulary File.
PA_Criteria_Change_Indicator	CHAR Always Required	1	If the PA criteria content did not change for this group description compared to CY 2022, please place a "0" in this field. If this group description is new, or the criteria content changed in any way (e.g. additional restrictions), please place a "1" in this field."
PA_Indication_Indicator	CHAR Always Required	1	This field must be populated with one of the values below. This field is used to describe the indications for which the PA will be approved. 1 = All FDA-approved Indications. This value cannot be used if the drug that requires PA is subject to Indication-Based Coverage (IBC). 2 = Some FDA-approved Indications Only. This value is to be submitted for drugs that are subject to IBC. 3 = All Medically-accepted Indications. Drugs for which the PA will be approved for all Part D medically-accepted indications (FDA-approved and compendia-supported) should be submitted with a 3. 4 = All FDA-approved Indications, Some Medically-accepted Indications. If the PA will only be approved for specific off-label uses, a 4 should be submitted. The additional off-label uses should be submitted in the subsequent Off-Label Uses field.
Off-label_Uses	CHAR Required only if a 4 is entered for PA_Indication_Indicator	3000	Enter the specific off-label uses for which the PA will be approved. This field must not contain any FDA-approved indications.

Field Name	Field Type	Maximum Field Length	Field Description
Exclusion_Criteria	CHAR If applicable	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 If applicable	2000	Enter laboratory, diagnostic, or other medical information required for initiation or continuation of the drug(s).
Age_Restrictions	CHAR If applicable	500	Enter age limitations or restrictions required for prior authorization approval.
Prescriber_Restrictions	CHAR If applicable	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.
Other_Criteria	CHAR If applicable	3000	Enter any other relevant criteria.
Part B Prerequisite	CHAR If applicable	1	If the PA criteria requires a Part B drug before a Part D drug then please enter “1” in this field, otherwise enter “0”. This field only applies to MAPD plans that are associated with this formulary ID.

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 (<), and 3) semi-colon (;).

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 ASCII Tab delimited text file format.

Required File Format = ASCII File - Tab Delimited
Do not include a header record
Filename extension should be ".txt"

Table 17: Step Therapy File Instructions

Field Name	Field Type	Field Length	Field Description	Sample Field Value(s)
ST_Change_Type	CHAR Always Required	3	Defines the type of change that is being made to the Step Therapy File. During the initial Formulary submission period, all rows must be "ADD."	ADD = Add Group Description to file UPD = Change fields for an existing Group Description
Step_Therapy_Group_Desc	CHAR Always 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 in the Formulary File submission upload. Description of the step therapy group as it appears on the submitted Formulary file. This field must exactly match the value entered in the Step_Therapy_Group_Desc field on the Formulary File. Note: For a given Rx CUI, each Group Description must be unique. Note: For each Step Therapy Group Description, there must be a RxCUI with a Step Therapy Value equal to 1.	Step_Therapy_Group_Desc = "CHF Therapy" Step_Therapy_Group_Desc = "Angina Therapy" Step_Therapy_Group_Desc = "CVD Therapy"
Step_Therapy_Criteria	CHAR Always Required	4000	Description of the criteria of the step therapy drug.	
ST_Criteria_Change_Indicator	CHAR Always Required	1	If the ST criteria content did not change for this group description compared to CY 2022, please place a "0" in this field. If this group description is new, or the criteria content changed in any way, please place a "1" in this field."	

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 (<), and 3) semi-colon (;).

INDICATION-BASED COVERAGE FILE INSTRUCTIONS

If a Formulary includes Indication-Based Coverage for one or more drugs, then the Formulary upload submission must include an attachment for Indication-Based Coverage file. The Indication-Based Coverage file should be provided in ASCII Tab delimited text file format.

Required File Format = ASCII File - Tab Delimited
Do not include a header record
Filename extension should be ".txt"

Table 18: CY 2023 Indication-Based Coverage (IBC) File Layout

Field Name	Field Type	Maximum Field Length	Field Description	Sample Field Value(s)
RxCUI	Number Always Required	8	RxCUI – must exist on the related Formulary file	210597
MeSH CUI (MUI/M#)	Alphanumeric Always Required	11	Condition Indication Code	M0010859

APPENDIX C: CY2023 FILE EDIT RULES

This section provides a listing of validation edits that are performed when Formulary files are uploaded and submitted to HPMS. This list is not all-inclusive but includes the majority of edit rules. These rules are included to assist you in troubleshooting your submissions should rejection errors occur.

There are two areas where the edit rules might take place:

a) On-line Upload
b) Formulary Validation Process

ON-LINE UPLOAD

The user CANNOT continue with the upload if any of the following edit checks fail:

1. The system searches for **HPMS restricted characters** (greater than >, less than < and, semi-colon ;) in the upload file and **rejects** submissions if the file contains one or more restricted characters.

FORMULARY VALIDATION PROCESS

An email is sent to the person who uploaded the Formulary, as well as the Formulary contact for each contract associated with the Formulary. This email notifies the user if the edit checks are successful and otherwise contain an error message for each edit check that did not pass. The edit checks are as follows:

An email is sent to the person who uploaded the Formulary, as well as the Formulary contact for each contract associated with the Formulary. This email notifies the user if the edit checks are successful and otherwise contain an error message for each edit check that did not pass. The edit checks are as follows:

1. The Formulary file must be **tab-delimited** and must **no**t contain **a header record.**
2. The **Change_Type, RxCUI, Tier_Level, Quantity_Limit_YN, Prior_Authorization_Type, Therapeutic_Category_Name, Therapeutic_Class_Name, Limited_Access_YN** and **Step_Therapy_Type** fields must be populated for submission.
3. **Change_Type** value must be ADD, UPD or DEL; the value cannot be null. Change_Type must be ADD in the initial submission.
4. While revising the Formulary:
    a. Change_Type must be ADD if the drug is not contained in the latest version of the Formulary that is in desk review, which is not denied or withdrawn.
    b. Change_Type must be UPD if the drug is contained in the latest version of the Formulary that is in desk review, which is not denied or withdrawn, and there is a change in the characteristics of the drug.
    c. Change_Type should be DEL if the drug is contained in the latest version of the Formulary that is in desk review which is not denied or withdrawn and you want to delete the drug from the revised version.

   d. If the Change_Type is UPD at least one value must be different from the current version of the Formulary that is in desk review which is not denied or withdrawn
5. The Formulary file's RxCUIs are compared against the RxCUI in the Formulary Reference File to determine the validity of the RxCUIs in the Formulary file.
6. Each **RxCUI** must be unique in the submission file.
7. For **non-MMP** formularies, the maximum value for the **Tier_Level** field in the Formulary file must be equal to the number of cost-share tiers entered during HPMS data entry.
8. For **non-MMP** formularies, the value of the **Tier_Level** field must be 1 to 7.
9. **Non-MMP** Formulary submission files must contain at least one row for every tier (other than the Excluded Drug only tier) identified on the **Formulary Tier Information** page.
10. **Non-MMP** Formulary submission files must NOT contain any rows with a **Tier_Level** field value equal to the tier number defined as the **Excluded Drugs Only** tier on the Formulary Tier Information page.
11. **MMP Formulary** submission file must contain at least one row for each tier defined as **Medicare Tier (**Generic Drugs, Brand Drugs, Preferred Brand Drugs, Non-Preferred Brand Drugs, $0 Drugs, Preferred Generic Drugs, and Non-Preferred Generic Drugs).
12. **MMP Formulary** submission files must NOT contain any rows with the **Tier_Level** field value equal to tier numbers defined as **Non-Medicare tiers**. Note: The tier model selected on the **Formulary Tier Information** page may include placeholder tiers for non-Part D drugs that are not included on the Formulary file.
13. In HPMS data entry, if the user selects **YES** on the **Limited Access question**, then one or more records in the Formulary file must have a **1 = YES** value for the **Limited_Access_YN** field in the Formulary file.
14. In HPMS data entry, if the user selects **NO** on the **Limited Access question**, then all records in the Formulary file must have a **0 = NO** value for the **Limited_Access_YN** field in the Formulary file.
15. The value of **Limited_Access_YN** field must be 0 or 1.
16. In HPMS data entry, if the user selects **YES** to the **Quantity Limits question**, then one or more records in the Formulary file must have a value of **1 or 2 (Quantity Limits Apply)** for the **Quantity_Limit_Type** field in the Formulary file.
17. In HPMS data entry, if the user selects **NO** to the **Quantity Limits question**, then ALL records must have a value of **0 (NO Quantity Limits)** for the **Quantity_Limit_Type** field in the Formulary file.
18. If the **Quantity_Limit_Type** is **0 (NO Quantity Limits)**, then the **Quantity_Limit_Amount** and **Quantity_Limit_Days** fields must be null.
19. If the **Quantity_Limit_Type** is **1 or 2 (Quantity Limits Apply)**, then the **Quantity_Limit_Amount** field must be a numeric value greater than 0 and less than 10,000 (.00001 to 9999.99). The field can have up to five decimal places (9.99999). The floor for entry is 0.00001. Possible entries include 9.99999 -> 99.9999 -> 999.999 -> 9999.99.
20. If the **Quantity_Limit_Type** is **1 (Daily Quantity Limits)**, the **Quantity_Limit_Days** field must be numeric and must be a value of 1 - 999.
21. If the **Quantity_Limit_Type** is **2** (**Quantity Limits Overtime)**, the **Quantity_Limit_Days** field must be numeric and must be a value of 2 - 999.
22. The **Prior_Authorization_Type** field must be a value of 0 to 3.

23. In HPMS data entry, if the user selects **YES** to the **Prior Authorization question,** then one or more records in the Formulary file must have a value of 1 or greater for the **Prior_Authorization_Type** field in the Formulary file.
24. In HPMS data entry, if the user selects **NO** to the **Prior Authorization question,** then ALL records must have a value of **0 = NO Prior Authorization** applies for the **Prior_Authorization_Type** field in the Formulary file.
25. If the **Prior_Authorization_Type** field is **greater than 0,** then the **Prior_Authorization_Group_Desc** must be populated.
26. If the **Prior_Authorization_Type** field is equal to 0, then the **Prior_Authorization_Group_Desc** must be null.
27. For each **RxCUI** in the Formulary file with a **Prior_Authorization_Type = 1 or 2,** the **Prior_Authorization_Group_Desc** must exist in the Prior Authorization submission file.
28. The **PA Group Description** must match the current version (latest version in desk review that is not denied or withdrawn) when the **PA Type is > 0.**
29. In HPMS data entry, if the user selects **YES** to the **Step Therapy question**, then one or more records in the Formulary file must have a value **greater than 0** for the **Step_Therapy_Type** field in the Formulary file.
30. In HPMS data entry, if the user selects **NO** to the **Step Therapy question**, then ALL records must have a value of **0 = No Step Therapy Applies** for the **Step_Therapy_Type** field in the Formulary file.
31. If the **Step_Therapy_Type** is **greater than 0**, then the **Step_Therapy_Total_Groups, Step_Therapy_Group_Desc** and **Step_Therapy_Step_Value** fields must be populated.
32. If the **Step_Therapy_Type** is equal to **0**, then the **Step_Therapy_Total_Groups** field must be null.
33. The **Step_Therapy_Type** field must be a value of 0 to 2.
34. If the **Step_Therapy_Total_Groups** field is populated, it must be numeric, greater than 0 and less than 100 (1 to 99; whole numbers only).
35. If the **Step_Therapy_Step_Value** field is populated, it must be numeric, greater than 0 and less than 100 (1 to 99; whole numbers only).
36. If **Step_Therapy_Total_Groups** is populated, then the number of **pairs** of **Step_Therapy_Group_Desc** and **Step_Therapy_Step_Value** must equal the number indicated in **Step_Therapy_Total_Groups**.
37. If **Step_Therapy_Total_Groups** is null, then **Step_Therapy_Group_Desc and Step_Therapy_Step_Value** fields must be null.
38. If **Step_Therapy_Total_Groups** is populated, then **Step_Therapy_Step_Value and Step_Therapy_Group_Desc**, fields must be populated.
39. For each **RxCUI**, the same **Step_Therapy_Group_Desc** must not occur more than once in the step therapy trailer.
40. For each **Step_Therapy_Group_Desc**, there must be at least one **RxCUI** with an associated **Step_Therapy_Step_Value** equal to 1 for that description and at least one **Step_Therapy_Step_Value** greater than 1 for that description.
41. If the **Step_Therapy_Group_Desc** field is populated, ensure that the **Step_Therapy_Group_Desc** field is not greater than 100 characters in length.
42. The **maximum number** of errors that are allowed before processing of the Formulary file stops is **200**.
43. The **Formulary and dependent files** (Prior Authorization and/or Step Therapy files), if submitted, are **rejected** if the validation does not meet these rules.

44. If all contracts associated with the Formulary are **bid approved**, the system validates that a drug may **Not** be moved from a tier that is **fully** or **partially** covered in the gap to a tier that has **No** gap coverage in the PBP.
45. The system automatically removes leading and trailing asterisks **(*)** from the **Therapeutic_Category_Name** field.
46. The system automatically removes leading and trailing asterisks **(*)** from the **Therapeutic_Class_Name** field

Prior Authorization File:

1. The file must be in a **tab-delimited text** (.txt) format and must not contain a **header record.**
2. For the Prior Authorization File, check that all occurrences of the **Prior_Authorization_Group_Desc** field provided are unique and exist in the **Prior_Authorization_Group_Desc** field in the Formulary file. Both the Formulary and Prior Authorization files are rejected if the validation does not pass.
3. For the Prior Authorization File, the system ensures that the **Change_Type, Prior_Authorization_Group_Desc, PA_Criteria_Change_Indicator, PA_Indication_Indicator, Off-label_Uses,** and **Coverage_Duration** fields are not null.
4. **Change_Type** value must be ADD or UPD; the value cannot be null. Change_Type must be ADD in the initial submission.
5. The system searches for **HPMS restricted characters** (greater than >, less than < and semi-colon ;) in the upload file and rejects submissions if the file contains one or more restricted characters.
6. The system ensures that there is an open edit request for the Group Description with **UPD Change_Type.**
7. The system ensures that at least one field value is different from the current version (most recent version in desk review that is not denied or withdrawn) for the Group Description with an **UPD Change_Type.**

   Note: The system automatically deletes the Group Descriptions from the Prior Authorization file when they are deleted from the Formulary File.

Step Therapy File:

1. The file must be in a **tab-delimited text** (.txt) format and must not contain a header record.
2. For the Step Therapy file, check that all occurrences of the **Step_Therapy_Group_Desc** field provided in the Step Therapy file are unique and exist in the **Step_Therapy_Group_Desc** field in the submitted Formulary.
3. For the Step Therapy File, the system validates that the **Change_Type, Step_Therapy_Group_Desc** and the **Step_Therapy_Criteria** fields are populated.
4. **Change_Type** value must be ADD or UPD; the value cannot be null. Change_Type must be ADD in the initial submission.
5. The system searches for **HPMS restricted characters** (greater than >, less than < and semi-colon ;) in the upload file and rejects submissions if the file contains one or more restricted characters.
6. The system ensures that there is an open edit request for the Group Description with **UPD Change_Type.**

7. The system ensures that at least one field value is different from the current version (most recent version in desk review that is not denied or withdrawn) for the Group Description with an **UPD Change_Type.**

   Note: The system automatically deletes the Group Descriptions from the Step Therapy file when they are deleted from the Formulary File.

Indication-Based Coverage File:

1. The file must be in a **tab-delimited text** (.txt) format and must not contain a header record.
2. IBC file can be submitted along with Formulary, PA and ST files.
3. IBC files can only be submitted if selected 'Yes' to the question about Indication-Based Coverage on the Formulary Information page.
4. At given time, only full IBC files are accepted.
5. The **IBC** submissions must contain a RxCUI that exists in the Formulary submission file.
6. **Strip leading zeroes** from the **RxCUI field** in the IBC submission files.
7. The system searches for **HPMS restricted characters** (greater than >, less than <, and semi-colon ;) in the upload file and will reject submissions if the file contains one or more restricted characters.
8. Each row must contain a **unique combination of RxCUI and MeSH CUI (MUI/M#)** in the IBC file.
9. The validity of the RxCUIs and MeSH CUI (MUI/M#) submitted on the IBC file will be evaluated against the IBC Reference file data.

   Note: The system automatically deletes the RxCUIs and corresponding MeSH CUIs from the Indication-Based Coverage file when they are deleted from the Formulary File.

SUPPLEMENTAL AND OTHER FILE VALIDATIONS

Partial Gap Coverage/Free First Fill/Home Infusion:

1. The file must be in a **tab-delimited text** (.txt) format and must not contain a header record.
2. The **PGC, FFF and HI** submissions must contain an RxCUI that exists in the Formulary submission file.
3. Supplemental files can only be submitted if **at least one plan** associated with the current version of the Formulary has a validated bid submission.
4. Each **RxCUI** must be **unique** in the PGC, FFF and HI submission files.
5. All RxCUIs included in the file must apply to all plans associated with the file. Plans that require different versions of a particular file based on the number of RxCUIs or the specific drugs covered cannot share the same supplemental file and therefore cannot be linked to the same Formulary ID.
6. **Strip leading zeroes** from the **RxCUI field** in the PGC, FFF and HI submission files.
7. The system creates a flag to indicate if the current **PGC, FFF, or HI** submission is identical to the previous successfully submitted file.

8. The system searches for **HPMS restricted characters** (greater than >, less than <, and semi-colon ;) in the upload file and will reject submissions if the file contains one or more restricted characters.
9. At least one plan associated with the Formulary must have a **PBP tier** designation of partial gap coverage for each RxCUI in the partial gap coverage supplemental file.
10. The partial gap coverage file must not include **all** of the RxCUIs that are on a Formulary tier indicated as being only partially covered in the gap.
11. The partial gap coverage file must not include **any** of the RXCUIs that are on fully covered Formulary tiers in the coverage gap or on tiers with no additional gap coverage.
12. If all contracts associated with the Formulary are **bid approved**, the system validates that any RxCUIs that are moved from **full gap** tier to **partial gap** tier must be included in the **Partial Gap Coverage** file.
13. If all contracts associated with the Formulary are **bid approved**, the system validates an **RxCUI may not be removed from the Partial Gap Coverage (PGC)** file, unless it is also removed from the revised Formulary or the RxCUI is moved from a partially covered tier to a fully covered tier. Any drug removed from the Formulary or moved to a fully covered tier must be removed from the PGC file. RxCUIs will not be allowed to move from a partially covered tier to a tier with no additional gap coverage.
14. If all contracts associated with the Formulary are **bid approved**, the system validates that an **RxCUI may not be removed from the FFF and HI file,** unless it is also removed from the revised Formulary.
15. Until all the contracts associated with the Formulary are bid approved, the system will send a reminder to add HI eligible drugs to the HI file when HI eligible drugs are added to the Formulary and are not added to HI file.
16. If all contracts associated with the Formulary are bid approved, the system validates that an **RXCUI may be added to the HI file if the drug is HI eligible** and is **not on the last approved version of the Formulary**.

Over-the-Counter (OTC):

1. The file must be in a **text (.txt)** format and must not contain a header record.
2. Each **RxCUI** must be **unique** in the submitted file, populated, and up to maximum of **8 characters** in length.
3. All RxCUIs included in the file must apply to all plans associated with the file. Plans that require different versions of a particular file based on the number of RxCUIs or the specific drugs covered cannot share the same OTC supplemental file and therefore cannot be linked to the same Formulary ID.
4. The **UM_Type** field must be populated and **must be equal to 0 or 1.**
5. If the **UM_Type field is equal to 1**, the **Step_Therapy_Total_Groups, Step_Therapy_Group_Desc, and Step_Therapy_Step_Value** fields must be populated.
6. If the **UM_Type field is equal to 0, the Step_Therapy_Total_Groups, Step_Therapy_Group_Desc, and Step_Therapy_Step_Value** fields must be null.
7. If the **Step_Therapy_Total_Groups** is required, the value **must be a value between and including 1-25.**
8. If the **Step_Therapy_Step_Value** is required, the **value must be equal to 1.**

9. If **Yes** is selected for the question, "Do you cover OTCs as a part of a Step Therapy Protocol submitted for review and approval by CMS?" on the Formulary Information page, then 1 must be entered for the **UM_Type** field for at least one row in the OTC file.
10. If **No** is selected for the question, "Do you cover OTCs as a part of a Step Therapy Protocol submitted for review and approval by CMS?" on the Formulary Information page, then "1" cannot be entered for the **UM_Type** field in the OTC file; **UM_Type must equal 0** for all records.
11. If Yes is selected for the question, "Do you cover OTCs as a part of a Step Therapy Protocol submitted for review and approval by CMS?" on the Formulary Information page, then all **unique** occurrences of the **Step_Therapy_Group_Desc** on the **OTC RxCUI** within the Formulary file must exist in the **Step_Therapy_Group_Desc** field in the OTC file. This step therapy group description validation only occurs when processing the OTC file; validation does not occur when unloading the Formulary file.
12. The validity of the RxCUIs submitted on the OTC supplemental file will be evaluated. This check is performed for all initial submissions and resubmissions. If the RxCUIs do not match, the submission is rejected.
13. The **extension checking** method must be consistent with the identified HPMS standard for such checks for the OTC submission file.
14. The system stores the **time and date** when the submission was made (when the "Submit" button is clicked).
15. The system searches for **HPMS restricted characters** (greater than >, less than <, and semi-colon ;) in the upload file and rejects submissions if the file contains one or more restricted characters.

Excluded Drug:

1. The file must be in a **tab-delimited text** (.txt) format and must not contain a header record.
2. The system validates the **lengths and values** for all fields (file layout).
3. The Tier field must be a number between **1 and 7**.
4. Each **RXCUI** must be **unique** in the submitted file, **populated**, and up to **8 characters in length.**
5. All **RXCUIs** included in the file must apply to all plans associated with the file. Plans that require different versions of a particular file based on the number of **RXCUIs** or the specific drugs covered cannot share the same Excluded Drug supplemental file and therefore cannot be linked to the same Formulary ID.
6. Check the Excluded Drug file to ensure that the following fields **are not null**: **RXCUI, Tier, Quantity_Limits_YN, Capped_Benefit_YN, Prior_Authorization_YN, Step_Therapy_YN, and Gap_Coverage_YN.**
7. For the **Excluded Drug** file, **if 0 = No** is entered for **Quantity_Limits_YN**, then the **Quantity_Limit_Amount** and **Quantity_Limit_Days** fields must be null.
8. For the **Excluded Drug File, if 1 = YES** is entered for **Quantity_Limits_YN**, then the **Quantity_Limit_Amount** and **Quantity_Limit_Days** fields must be populated.
9. If the value is 1 for the **Quantity_Limits_YN** field, then the **Quantity_Limit_Amount** field must contain a numeric value of 1 thru 9999.99.
10. If the value is 1 for the **Quantity_Limits_YN** field, then the **Quantity_Limit_Days** field must contain a numeric value of 1 thru 999.

11. For the **Excluded Drug File, if 0 = NO** is entered for **Capped_Benefit_YN**, then **Capped_Benefit_Quantity and Capped_Benefit_Days** must be null.
12. For the **Excluded Drug File, if 1 = YES** is entered for **Capped_Benefit_YN**, then **Capped_Benefit_Quantity** and **Capped_Benefit_Days** must be populated.
13. If the value is 1 for the **Capped_Benefit_YN** field, then the **Capped_Benefit_Quantity** field must contain a numeric value of 1 thru 9999.99.
14. If the value is 1 for the **Capped_Benefit_YN** field, then the **Capped_Benefit_Days** field must contain a numeric value of 1 thru 999.
15. For the **Excluded Drug file, the Capped_Benefit_Quantity** must **be greater than the Quantity_Limit_Amount** for a given **RXCUI** if both Capped_Benefit_Quantity and Quantity_Limit_Amount are non-blank.
16. The **CapBen_Days** field must be greater than the **QL_Days** field for a given **RXCUI** if both **CapBen_Days** and **QL_Days** are non-blank.
17. For the **Excluded Drug File, if 0 = NO** is entered for **Prior_Authorization_YN,** then **Prior_Authorization_Criteria** must be null.
18. For the **Excluded Drug File, if 1 = YES** is entered for **Prior_Authorization_YN,** then **Prior_Authorization_Criteria** must be populated.
19. For the **Excluded Drug File, if 0 = NO** is entered for **Step_Therapy_YN**, then **Step_Therapy_Criteria** must be null.
20. For the **Excluded Drug File, if 1 = YES** is entered for **Step_Therapy_YN**, then **Step_Therapy_Criteria** must be populated.
21. The plans offering excluded drug coverage that are associated with the same Formulary ID, must have identical drugs and tiers in order for the plans to share an **Excluded Drug file**.
22. At least one drug must be in the **Excluded Drug file** for tiers in the PBP that have excluded drugs (either alone or in combination with Part D drugs).
23. If the tier is partially covered in the gap, then at least one drug in that tier must be populated with a "1" in the **Gap_Coverage_YN** field.
24. If the tier is fully covered in the gap, then all drugs in that tier must be populated with a "1" in the **Gap_Coverage_YN** field.
25. If the tier is not covered in the gap, then all drugs in that tier must be populated with a "0" in the **Gap_Coverage_YN** field.
26. The file extension checking method must be consistent with the identified HPMS standard for such checks for the Excluded Drug submission file.
27. The validity of the **RXCUIs** submitted on the Excluded Drug supplemental file will be evaluated. This check is performed for all initial submissions and resubmissions. If the **RXCUIs** do not match, the submission is rejected.
28. The system stores the time and date when the submission was made (when the "Submit" button is clicked).
29. The system searches for **HPMS restricted characters** (greater than >, less than <, and semi-colon ;) in the upload file and rejects submissions if the file contains one or more restricted characters.

Value-Based Insurance Design:

1. The file must be in a **tab-delimited text** (.txt) format and must not contain a header record.

2. The **VBID** submissions must contain an RxCUI that exists in the Formulary submission file.
3. VBID files can only be submitted if **at least one plan** associated with the current version of the Formulary has a validated bid submission.
4. **Strip leading zeroes** from the **RxCUI field** in the VBID submission files.
5. The system searches for **HPMS restricted characters** (greater than >, less than <, and semi-colon ;) in the upload file and will reject submissions if the file contains one or more restricted characters.
6. Each row must contain a **unique combination of Contract-Plan-RxCUI** in the **VBID** file.

Additional Demonstration Drug (ADD):

1. The file must be in a **tab-delimited text** (.txt) format and must not contain a header record.
2. The system validates the **lengths and values** for all fields (file layout).
3. Each **MMP_NDC** must be unique in the submitted file, populated, and 11 characters in length.
4. **MMP_Tier** must not contain a value greater than the maximum tier number indicated in PBP.
5. **MMP_Tier** must not contain a tier number that is flagged as **'Part D Drug Only Tier'** in the PBP.
6. The **MMP_Tier** field must contain a value of 1 through 6 and cannot be blank. For tier models that only include 2 tiers, the **MMP_Tier** field must only include a value of 1 through 2. For tier models that include 3 or more tiers, the **MMP_Tier** field must only include a value of 3 through 6.
7. The ADD file must contain at least one NDC in each tier defined as a **combo tier** or **Non-Medicare tier** in the PBP.
8. The **MMP_QL_YN** field must be non-blank and contain a value of 0 or 1.
9. If the value is 1 for the **MMP_QL_YN** field, then the **MMP_QL_Amt** and **MMP_QL_Days** fields must be non-blank.
10. If the value is 1 for the **MMP_QL_YN** field, then the **MMP_QL_Amt** field must contain a numeric value of 1 thru 9999.99.
11. If the value is 1 for the **MMP_QL_YN** field, then the **MMP_QL_Days** field must contain a numeric value of 1 thru 365.
12. If the value is 0 for the **MMP_QL_YN** field, then the **MMP_QL_Amt** and **MMP_QL_Days** fields must be null.
13. The **MMP_CapBen_YN** field must be non-blank and contain a value of 0 or 1.
14. If the value is 1 for the **MMP_CapBen_YN** field, then the **MMP_CapBen_Amt** and **MMP_CapBen_Days** fields must be non-blank.
15. If the value is 1 for the **MMP_CapBen_YN** field, then the **MMP_CapBen_Amt** field must contain a numeric value of 1 thru 9999.99.
16. If the value is 1 for the **MMP_CapBen_YN** field, then the **MMP_CapBen_Days** field must contain a numeric value of 1 thru 365.
17. If the value is 0 for the **MMP_CapBen_YN** field, then **MMP1_CapBen_Amt** and **MMP_CapBen_Days** must be null.
18. The **MMP_CapBen_Amt** must be greater than the **MMP_QL_Amt** for a given **MMP_NDC** if both **MMP_CapBen_Amt** and **MMP_QL_Amt** are non-blank.

19. The **MMP_CapBen_Days** field must be greater than the **MMP_QL_Days** field for a given **MMP_NDC** if both **MMP_CapBen_Days** and **MMP_QL_Days** are non-blank.
20. The **MMP_PA_YN** field must be non-blank and contain a value of 0 or 1.
21. If the **MMP_PA_Criteria** field is not null, then the field must not be greater than 3000 characters in length.
22. **MMP_PA_Criteria** must be non-blank if the value is 1 for the **MMP_PA_YN** field.
23. **MMP_PA_Criteria** must be null if the value is 0 for the **MMP_PA_YN** field.
24. The **MMP_ST_YN** field must be non-blank and contain a value of 0 or 1.
25. If the **MMP_ST_Criteria** field is not null, then the field must not be greater than 1000 characters in length.
26. **MMP_ST_Criteria** must be non-blank if the value is 1 for the **MMP_ST_YN** field.
27. **MMP_ST_Criteria** must be null if the value is 0 for the **MMP_ST_YN** field.
28. Each **MMP_NDC** must be unique in the submitted file.
29. **MMP_NDC, MMP_Tier, MMP_QL_YN, MMP_CapBen_YN, MMP_PA_YN,** and **MMP_ST_YN** must be non-blank.
30. The file extension checking method must be consistent with the identified HPMS standard for such checks for the ADD file.
31. The validity of the NDCs submitted on the ADD file will be evaluated. This check is performed for all initial submissions and resubmissions. If the NDCs do not match, the submission is rejected.
32. The system searches for **HPMS restricted characters** (greater than >, less than <, and semi-colon ;) in the upload file and rejects submissions if the file contains one or more restricted characters.

Part D Senior Savings Model:

1. Plan Sponsors can select one or multiple plans at a time and submit a single Part D Senior Savings Model file.
   Note: The content of the Part D Senior Savings Model file shared between multiple Plans must be identical. As long as Plans that offer Part D Senior Savings Model with the exact same coverage (Drugs and Cohorts) and are able to share the same Part D Senior Savings file, then these plans can be selected to be associated with the same file.
2. The file must be in a **tab-delimited text** (.txt) format and must not contain a header record.
3. The **Part D Senior Savings Model** submissions must contain an RxCUI that exists in the Formulary submission file and Part D Senior Savings Model reference data.
4. Part D Senior Savings Model file can be submitted for a plan that has a validated bid submission and has Part D Senior Savings Model applicability.
5. Each **RxCUI** must be **unique** in the Part D Senior Savings Model submission file.
6. **Strip leading zeroes** from the **RxCUI field** in the Part D Senior Savings Model submission files.
7. The system searches for **HPMS restricted characters** (greater than >, less than <, and semi-colon ;) in the upload file and will reject submissions if the file contains one or more restricted characters.
8. The **Cohort** field must contain a value of 1 through 5 and cannot be blank.
9. **Cohort** must not contain a value greater than the maximum Cohort number indicated in PBP.

10. For cohort number identified in PBP is 2, the **Cohort** field must only include a value of 1 through 2. For Cohort number identified in PBP is 3, the Cohort field must only include a value of 1 through 3.
11. The Part D Senior Savings Model file must contain **at least one RxCUI in each cohort** based on the Cohort number in the PBP.
12. The tier and cohort of a RxCUI in the Part D Senior Savings Model supplemental file must be same as the tier associated to the cohort in the PBP.

PA/ST Criteria Change Request File Validations:

1. The file must be in a tab-delimited text (.txt) format and must not contain a header record.
2. Check that all occurrences of the UM Group Descriptions on the PA/ST Criteria Change Request file exists in the Prior_Authorization_Group_Desc field or Step_Therapy_Group_Desc field in the Formulary file. The PA/ST Criteria Change Request file is rejected if the validation does not pass.
3. The system ensures that the FID, Reason for UM Change, Current UM Type and Current UM Group Description on the PA/ST Criteria Change Request file are not null.
4. The system searches for HPMS restricted characters (greater than >, less than < and semi-colon ;) in the upload file and rejects submissions if the file contains one or more restricted characters.
5. The system ensures that the FID entered is valid.
6. Formulary ID, Reason for UM Change, Current UM Group Description values must be unique within a PA/ST Criteria Change Request file.

APPENDIX D: CONTACT INFORMATION

Contact	Name	Phone Number	Email Address
HPMS Technical Help Desk	N/A	1-800-220-2028	hpms@cms.hhs.gov
HPMS	Sara Walters Julia Heeter	410-786-3330 410-786-6198	sara.walters@cms.hhs.gov julia.heeter@cms.hhs.gov
Formulary Content & Review Guidelines	Part D Formularies Mailbox	N/A	PartDFormularies@cms.hhs.gov
Supplemental File Content	Part D Benefits Mailbox	N/A	PartDBenefits@cms.hhs.gov
Supplemental Submissions and Reports	HPMS Help Desk	1-800-220-2028	hpms@cms.hhs.gov
Indication-Based Coverage File Submissions	Part D Formularies Mailbox	N/A	PartDFormularies@cms.hhs.gov