OFFICE of the INSURANCE COMMISSIONER WASHINGTON STATE

Electronic Formulary Review Tools for Plan Year 2020

User Manual

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How to use this User Manual

This User Manual is meant to be used electronically. The Table of Contents, above, has links to each section for easy reference. This Manual is meant to be used as a reference, to find answers to questions you run into as you review Electronic Review Tool results. The user would just click on the topic they need to know about. Another reason this Manual is best used electronically is that you will need to enlarge the screen shots in each section to see all of the details discussed.

You can also use it as a tutorial to learn how to review Electronic Drug Tool results. If you do that, ideally, you should have real versions of the Tool results in front of you as you go through the tutorial, so that you can familiarize yourself with manipulating the Tools to display the information you need. The best way to learn these Tools would be to obtain the plan data so that you can practice running the Tools yourself when you get to those sections, and then use the Tool results you've run to explore those results as they are described.

For this User Guide, we frequently used dummy data in templates so that we could illustrate certain results. Although based upon real templates submitted by real carriers, the templates used for screen shots have, in many cases, been altered for this reason and do not reflect the actual data submitted.

If you want to use a printed copy of the User Manual, you may want to copy the screenshots and paste them into a separate Word document, making them as large as possible.

What's a Formulary?

When we are talking about a formulary, we are talking about the prescription drugs covered under a health plan. Unfortunately, there are two schools of thought about what a "formulary" includes. Sometimes the word "formulary" is used to mean a list of prescription drugs covered by a plan, and nothing else. That is how the Category & Class Drug Count Review Tool uses the word. That tool really only analyzes which drugs are on each Drug List. It does not analyze cost sharing or utilization management criteria (such as a requirement for prior authorization or step therapy).

Alternatively, "formulary" is sometimes used to mean the combination of the list of covered drugs and the particular plan's cost sharing and utilization management criteria for those drugs. This is how the Non-Discrimination Formulary Outlier Tool and Non-Discrimination Clinical Appropriateness Tool use this word. When you have completed your study of what aspect of the formulary each of the Tools analyzes, this will make more sense.

The Formulary ID in a binder refers to this second definition: the Drug List plus the coverage criteria.

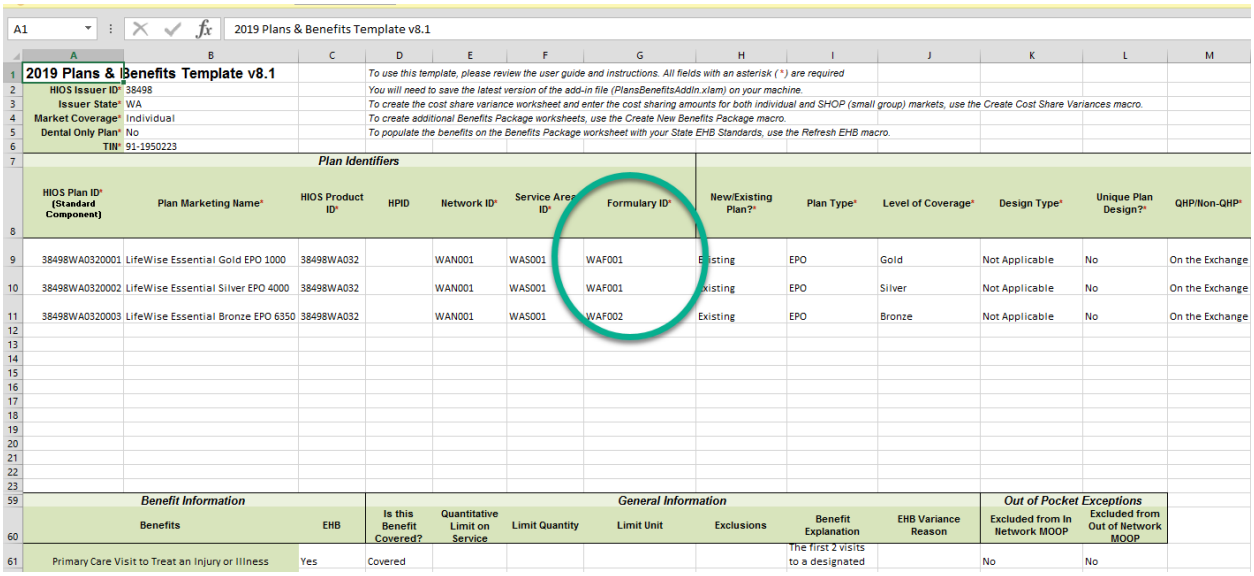
OIC requires that all formularies used by individual and small group plans that have a binder be filed quarterly. These quarterly formularies are filed using the Prescription Drug Formulary Template created by CMS (Rx Drug Template). 1st Quarter formularies have been filed in this way since binders were first introduced in 2014 but, in the past, there was no requirement that subsequent quarterly formularies be filed in any particular format. As a result, the 2nd, 3rd, and 4th quarter formulary filings were not machine-readable and were not very user friendly. The requirement to use the Rx Drug Template allows research using all 4 quarterly formularies, because they are machine-readable, and also aligns with the requirement that the Washington HeatlhPlanFinder (Washington's Health Benefit Exchange) has instituted for formulary filings.

Finally, it allows carriers to run the Electronic Review Tools on all 4 quarterly formularies, demonstrating that the 2nd, 3rd, and 4th quarter formularies meet the EHB.

What's a Formulary ID?

The details about what prescription drugs a plan covers, and how those drugs are covered, are reflected on the Plans & Benefits Template and the Prescription Drug Formulary Template (RX Drug Template). This information is collectively captured as the "Formulary ID". The Formulary ID begins with the state abbreviation, followed by an "F" (for "Formulary"), then a number to indicate a specific set of cost sharing and utilization management criteria. For example, WAF001, WAF002, WAF003...

Let's look at exactly what information is included in a Formulary ID. Below is a screen shot of the Benefits Package Tab of a carrier's Plans & Benefits Template. It shows three plans. Two of those plans use the same Formulary, which is indicated by the Formulary IDs: these two plans use WAF001. (Green circle.) The third plan uses WAF002.



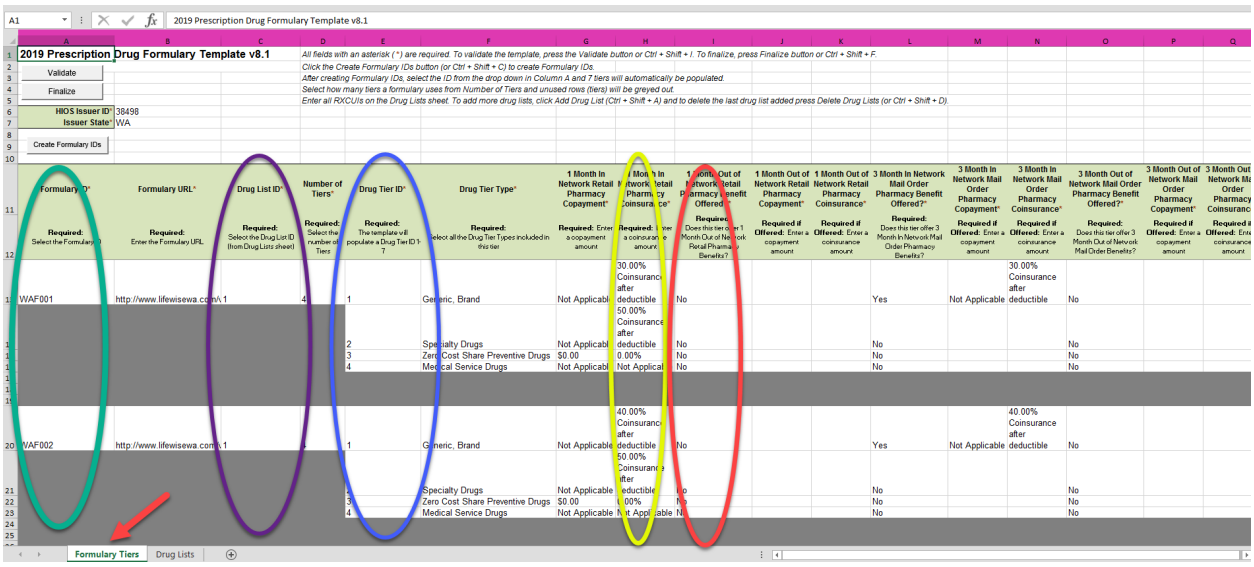
A1 | 2019 Plans & Benefits Template v8.1

	A	B	C	D	E	F	G	H	I	J	K	L	M
1	2019 Plans & Benefits Template v8.1			To use this template, please review the user guide and instructions. All fields with an asterisk (*) are required									
2	HIOS Issuer ID*	38498		You will need to save the latest version of the add-in file (PlansBenefitsAddIn.xlam) on your machine.									
3	Issuer State*	WA		To create the cost share variance worksheet and enter the cost sharing amounts for both individual and SHOP (small group) markets, use the Create Cost Share Variances macro.									
4	Market Coverage*	Individual		To create additional Benefits Package worksheets, use the Create New Benefits Package macro.									
5	Dental Only Plan*	No		To populate the benefits on the Benefits Package worksheet with your State EHB Standards, use the Refresh EHB macro.									
6	TIN*	91-1950223											
7				Plan Identifiers									
8	HIOS Plan ID* (Standard Component)	Plan Marketing Name*	HIOS Product ID*	HPID	Network ID*	Service Area ID*	Formulary ID*	New/Existing Plan?*	Plan Type*	Level of Coverage*	Design Type*	Unique Plan Design?*	QHP/Non-QHP*
9	38498WA0320001	LifeWise Essential Gold EPO 1000	38498WA032		WAN001	WAS001	WAF001	Existing	EPO	Gold	Not Applicable	No	On the Exchange
10	38498WA0320002	LifeWise Essential Silver EPO 4000	38498WA032		WAN001	WAS001	WAF001	Existing	EPO	Silver	Not Applicable	No	On the Exchange
11	38498WA0320003	LifeWise Essential Bronze EPO 6350	38498WA032		WAN001	WAS001	WAF002	Existing	EPO	Bronze	Not Applicable	No	On the Exchange
12													
13													
14													
15													
16													
17													
18													
19													
20													
21													
22													
23													
59	Benefit Information			General Information							Out of Pocket Exceptions		
60	Benefits	EHB		Is this Benefit Covered?	Quantitative Limit on Service	Limit Quantity	Limit Unit	Exclusions	Benefit Explanation	EHB Variance Reason	Excluded from In Network MOOP	Excluded from Out of Network MOOP	
61	Primary Care Visit to Treat an Injury or Illness	Yes		Covered					The first 2 visits to a designated		No	No	

The first two plans use the same formulary, which means that coverage of prescription drugs is identical for these two plans. The third plan uses a different formulary (different Formulary ID), which means that this plan covers prescription drugs differently from the other two plans. To determine how each plan covers prescription drugs, we look at the Rx Drug Template.

The Rx Drug Template includes all the information about each Formulary ID. This template is made up of two tabs. Take a look at the screen shot below. The "Formulary Tiers" tab (red arrow) shows the information by Formulary ID (green circle). This information includes the Drug List associated with each Formulary ID (purple circle), and how those drugs are tiered (blue

circle). It also includes the cost sharing information and where the enrollee can obtain covered prescription drugs (in network, out of network, retail pharmacy, mail order). This information is located in columns G through Q. (Columns are lettered at the top of the spreadsheet – see pink highlighted row.)

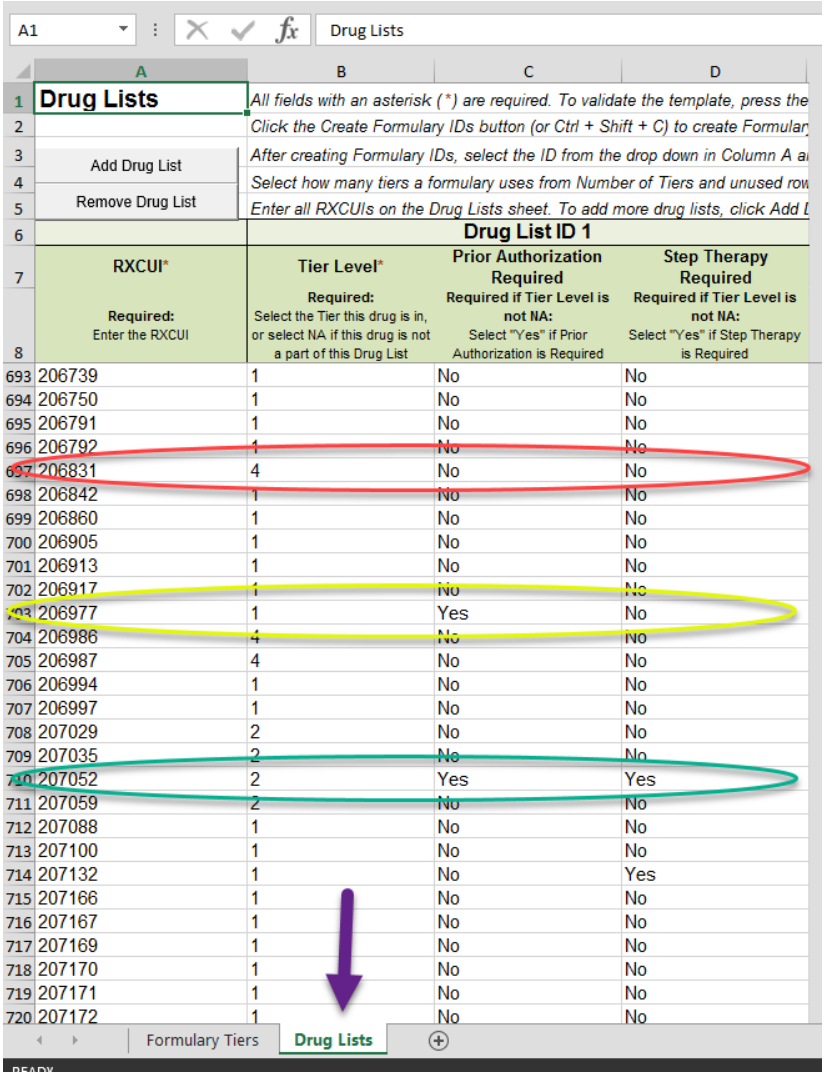


Going back to our example, we see that the first plan on the PBT above uses Formulary ID WAF001 (green circle in screen shot on Pg. 4). The Formulary Tiers tab of the RX Drug Template (screen shot above) tells us a lot about the Formulary IDs. For example, we can see that Formulary ID WAF001 uses Drug List 1 (purple circle), covered drugs are separated into 4 tiers (blue circle), each tier has a different coinsurance (yellow circle), and there is no coverage for drugs purchased from out of network pharmacies (red circle).

Now click on the "Drug Lists" tab of the Rx Drug Template (purple arrow in screen shot below). The Drug Lists tab shows the rest of the information about the Formulary IDs (screen shot below). It lists the exact drugs covered. (The drugs are identified by RxCUI number. For a definition of RxCUI, click here.). For each drug, the tab shows the tier upon which the drug is placed, and whether coverage of the drug requires preauthorization or step therapy. ("Step therapy" means a requirement that a less expensive drug be prescribed first, and only if that drug does not work will a more expensive drug be covered for that condition.) In the screen shot below, we see that most drugs on Drug List 1 have neither of these criteria. But you can see that some of the drugs do have one or both of these criteria.

For example, the screen shot below shows that drug 206831 is on tier 4, and requires neither prior authorization nor step therapy (red circle). We know this because the drug list says "4" in the "Tier Level" column, and "No" in both the "Prior Authorization Required" and "Step Therapy Required" columns. Drug 206977 is on tier 1, and requires prior authorization, but not step

therapy (yellow circle). Drug 207052 is on tier 2, and requires both prior authorization and step therapy (green circle).



	A	B	C	D
1	Drug Lists	All fields with an asterisk (*) are required. To validate the template, press the		
2		Click the Create Formulary IDs button (or Ctrl + Shift + C) to create Formular		
3	Add Drug List	After creating Formulary IDs, select the ID from the drop down in Column A a		
4		Select how many tiers a formulary uses from Number of Tiers and unused row		
5	Remove Drug List	Enter all RXCUIs on the Drug Lists sheet. To add more drug lists, click Add L		
6		Drug List ID 1		
7	RXCUI*	Tier Level*	Prior Authorization Required	Step Therapy Required
8	Required: Enter the RXCUI	Required: Select the Tier this drug is in, or select NA if this drug is not a part of this Drug List	Required if Tier Level is not NA: Select "Yes" if Prior Authorization is Required	Required if Tier Level is not NA: Select "Yes" if Step Therapy is Required
693	206739	1	No	No
694	206750	1	No	No
695	206791	1	No	No
696	206792	1	No	No
697	206831	4	No	No
698	206842	1	No	No
699	206860	1	No	No
700	206905	1	No	No
701	206913	1	No	No
702	206917	1	No	No
703	206977	1	Yes	No
704	206986	4	No	No
705	206987	4	No	No
706	206994	1	No	No
707	206997	1	No	No
708	207029	2	No	No
709	207035	2	No	No
710	207052	2	Yes	Yes
711	207059	2	No	No
712	207088	1	No	No
713	207100	1	No	No
714	207132	1	No	Yes
715	207166	1	No	No
716	207167	1	No	No
717	207169	1	No	No
718	207170	1	No	No
719	207171	1	No	No
720	207172	1	No	No

Formulary Tiers | Drug Lists

All of the above information, collectively, is represented by a particular Formulary ID. So you can see that a Formulary ID is a shorthand way of saying a LOT. In fact, it tells us more than we've discussed here – you'll learn more as we learn about RxCUIs and Categories and Classes of drugs.

Medical Service Drugs

"Medical service drugs" are drugs that must be administered in a clinical setting, such as certain IV chemotherapy and hemophilia drugs.

A carrier reports which medical service drugs are included in its formulary (or formularies) by listing the covered medical service drugs by RxCUI in its Rx Drug Template. (The Rx Drug Template requires that drugs be identified by RxCUI, and will not validate if they are not.) However, some medical service drugs do not have RxCUIs and therefore cannot be included in the Rx Drug Template. The carrier must attach a list of those covered medical service drugs that do not have RxCUIs on the Supporting Documentation tab in its binder(s), and identify these drugs by "J-code". The lists are provided in a separate Excel template attached on the Supporting Documentation tab in the binder.

What's a J-code?

A J-code is a number that identifies a particular medical service drug and dosage. Clinical providers use the J-codes to bill for medical service drugs administered to their patients. All carriers have access to the list of J-codes. Therefore, when a particular medical service drug doesn't have an RxCUI, carriers can report to OIC that they cover that drug by listing it by its J-code.

J-codes are not assigned for ordinary drugs that can be administered at home. Those drugs are identified by their RxCUIs. So J-codes and RxCUIs serve the same purpose, but for different groups of drugs. J-codes are generally identifiers for medical service drugs and RxCUIs are generally identifiers for all other drugs.

Category & Class Drug Count Review Tool

Under the Affordable Care Act (ACA), all non-grandfathered individual and small group health plans must cover prescription drugs. In ACA language, prescription drug coverage is an Essential Health Benefit (EHB). In order to meet this requirement, each non-grandfathered individual and small group plan must cover prescription drugs "in a manner substantially equal to the base-benchmark plan."

The Category & Class Drug Count Review Tool ("Drug Count Tool") is an electronic Tool that analyzes two binder templates - the Plans & Benefits Template, in combination with the Prescription Drug Formulary Template ("Rx Drug Template") – to determine whether the plan formularies reviewed meet this ACA requirement.

What's a Category and Class?

In order to provide the prescription drug EHB, plans must cover prescription drugs "in a manner substantially equal to the base-benchmark plan." This requirement is easy to say. But what, exactly, does it mean? The United States Department of Health and Human Services (HHS) was tasked with defining it. They determined that "substantially equal" does not mean that each plan must cover the exact same drugs as the benchmark plan. The requirement is looser than that. It means, in essence, that each plan's drug coverage must be at least as comprehensive as the benchmark plan coverage.

HHS then had to figure out a way to measure that.

They started with the United States Pharmacopeia (USP), which separates drugs into groups of similar drugs called Categories and Classes, based upon the properties of the drugs. HHS then adopted the standard that, in order to provide the prescription drug EHB, each plan must cover as many drugs in each USP Category and Class as the benchmark plan covers.

That is what the Drug Count Tool measures.

It is important to pay attention to the USP Category Class designations (the names), not the numbers assigned to each Category and Class in the Tools. The Category and Class names have meaning, but the numbers assigned to them in the Tools are completely arbitrary numbers assigned by HHS based on where the name of the Category Class falls in the alphabet on that particular Tool. HHS made them up. You should know this simply because the Category Classes have *different numbers* in each of the Tools, which could be confusing.

For example, in the Drug Count Tool, the Category Class "blood glucose regulators; antidiabetic agents" is given Category Class ID 80. But in the Formulary Review Suite, which looks at far fewer Category Classes, that same group of drugs is given Category Class ID 23. But it's still the same group of drugs. Just pay attention to the name of the Category Class, not the number, and you won't get confused.

A "Category" is just that – a group of drugs that have a particular function, such as cardiovascular agents or genitourinary agents. Within each Category, there can be multiple Classes of drugs. A Class is a group of drugs that performs their function by affecting the body in a particular way. So a Category is the larger group, and a Class is a subgroup of the Category. Each combination of Category and Class is called a "Category Class", and has a different "Category Class ID".

Here's an example. The Category "Analgesics" (pain relievers) has 4 Classes. These are:

nonsteroidal anti-inflammatory drugs

opioid analgesics, long-acting

opioid analgesics, short acting; and

local anesthetics.

Each of these is a separate Category Class. The Drug Count Tool counts drugs at the Category Class level, which is why each Category Class has its own Category Class ID.

The Drug Count Tool happens to give these pain relievers Category Class IDs 1, 2, 3, and 4. Each of these Category Classes relieves pain by affecting the body in a particular way.

Category Class 1 is called "Analgesics; nonsteroidal anti-inflammatory drugs".

Category Class 2 is called "Analgesics; opioid analgesics, long-acting".

Category Class 3 is called "Analgesics; opioid analgesics, short-acting".

Category Class 4 is called "Analgesics, local anesthetics".

Be aware: one drug can be in multiple Category Classes, because drugs can have more than one effect on the body. To use a well-known example, aspirin is both a pain reliever and a blood thinner. So aspirin could be counted to satisfy both an EHB for pain relievers and an EHB for blood thinners. Lots of drugs are like that.

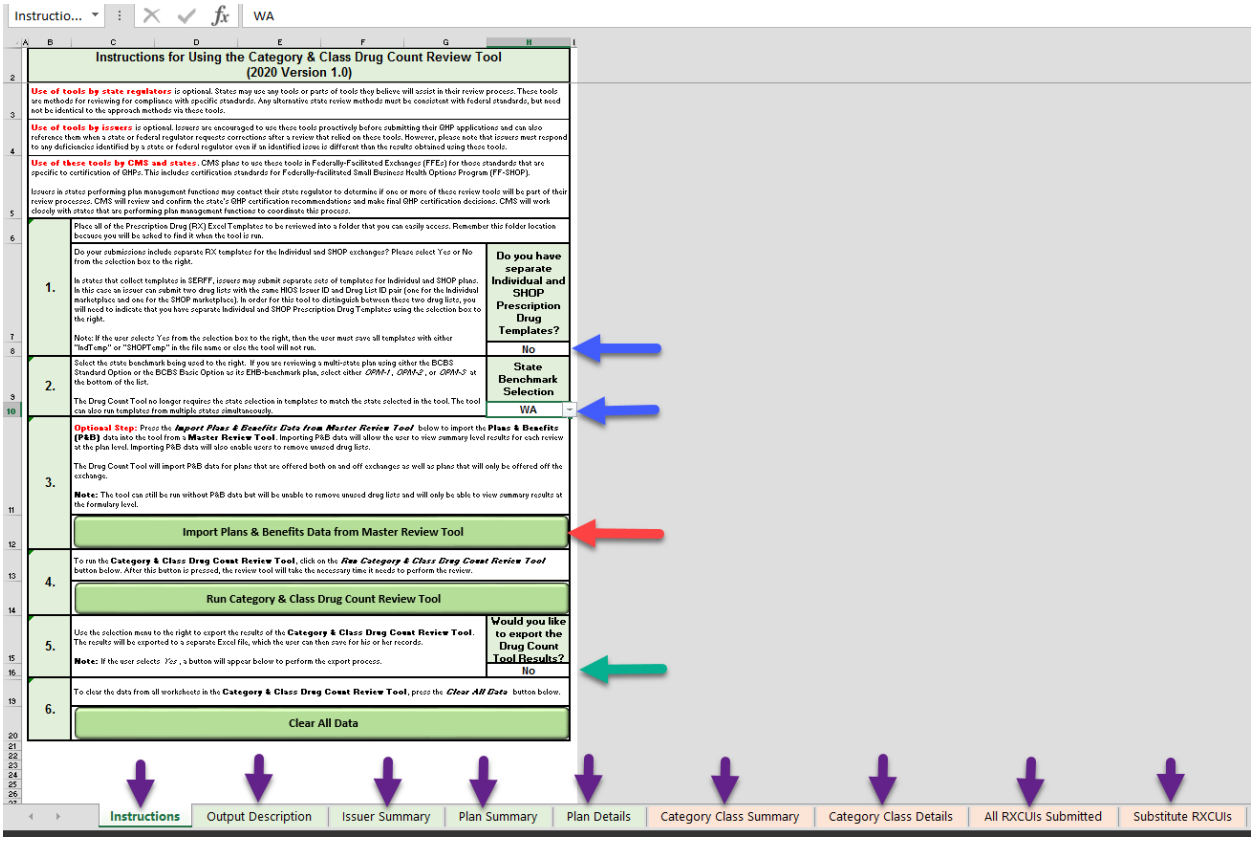
The Drug Count Tool counts the number of covered drugs in each Category Class, to determine whether the formularies being reviewed meet the benchmark. The information in the Formulary IDs is not analyzed by the Drug Count Tool. The only reason this tool requires the Formulary ID information is so that it can identify the results down to the plan level. As a result, you will see that every plan that uses the same drug list will have the same Drug Count Tool result, regardless of Formulary ID.

The results are presented in an Excel spreadsheet, with several tabs. (Indicated with purple arrows in the screen shot below.) When the Tool results show that a formulary does not meet the benchmark for a Category Class, the carrier must submit a justification as to why the formulary can be approved despite this result. OIC has state-specific Justification Forms for each Tool.

In the past, OIC required only the Category Class Summary tab to be submitted with the binder, along with any justifications needed. However, it is very helpful to understand what information is presented on each of the tabs, because this information can be used to assess a carrier's justification for not meeting the benchmark in a particular Category Class. The information can also help the OIC's Health Forms Compliance Analyst to give carriers guidance about how to resolve a particular failed result. For that reason, OIC now requires carriers to submit the entire Excel workbook of the Tool results.

The OIC Analyst's responsibility is to review the Tool results. If the results show a formulary has not met one or more Category Class, the Analyst is responsible for reviewing the justifications for each Category Class not met, and determining whether they are acceptable. Analysis of justifications will be addressed below, following a description of each tab in the results.

Instructions Tab



Above is a screenshot of the Instructions tab. This tab is used by the person running the Tool to input the data to be analyzed.

Note that the data that must be input includes information about whether the RX Drug Templates include separate individual and small group templates, and the state in which the plans are to be sold. (Blue arrows). If the data includes separate individual and small group RX Drug Templates, the Tool will display the results for each separately. (See "Category Class Summary" tab, below.) The state must be specified so that the Tool compares the formulary(ies) to the correct benchmark formulary. (Each state's benchmark formulary is different, and each state's benchmark formulary data is pre-loaded into the tool.) OIC does not use the "Would you like to export the Drug Count Tool results" box. (Green arrow.)

When the person running the Tool clicks on these boxes, a dropdown menu of choices appears. These boxes must be completed or the Tool will not run (a warning appears, reminding the user to input the data).

OIC requires the Plans and Benefits data to be imported into the Drug Count Tool from the Master Review Tool. (Red arrow.) This allows the Drug Count Tool to display results for each

plan, and also to remove any unused drug lists from the result. Because the Drug Count Tool only analyzes the drug lists, every plan that uses the same drug list will have the same result. Thus, data at the plan level really isn't necessary. But it is helpful to have unused drug lists removed so we don't bother with results that don't matter.

To load the data from the Master Review Tool, the user clicks on this green button (red arrow in screen shot above), and a dialog box opens asking the user to click on the folder containing the Master Review Tool data. The Tool then imports that data.

When the user clicks on the "Run Category & Class Drug Count Review Tool" button, a dialog box opens asking the user to click on the folder containing the RX Drug Template(s). A status bar then opens while the Tool runs. The Tool takes approximately 30 seconds to run on one carrier's formulary(ies), and approximately a minute and a half to run marketwide.

If you want to run the Drug Count Tool yourself:

To run the Drug Count Tool, you would need to have the Master Review Tool data saved on your computer somewhere.

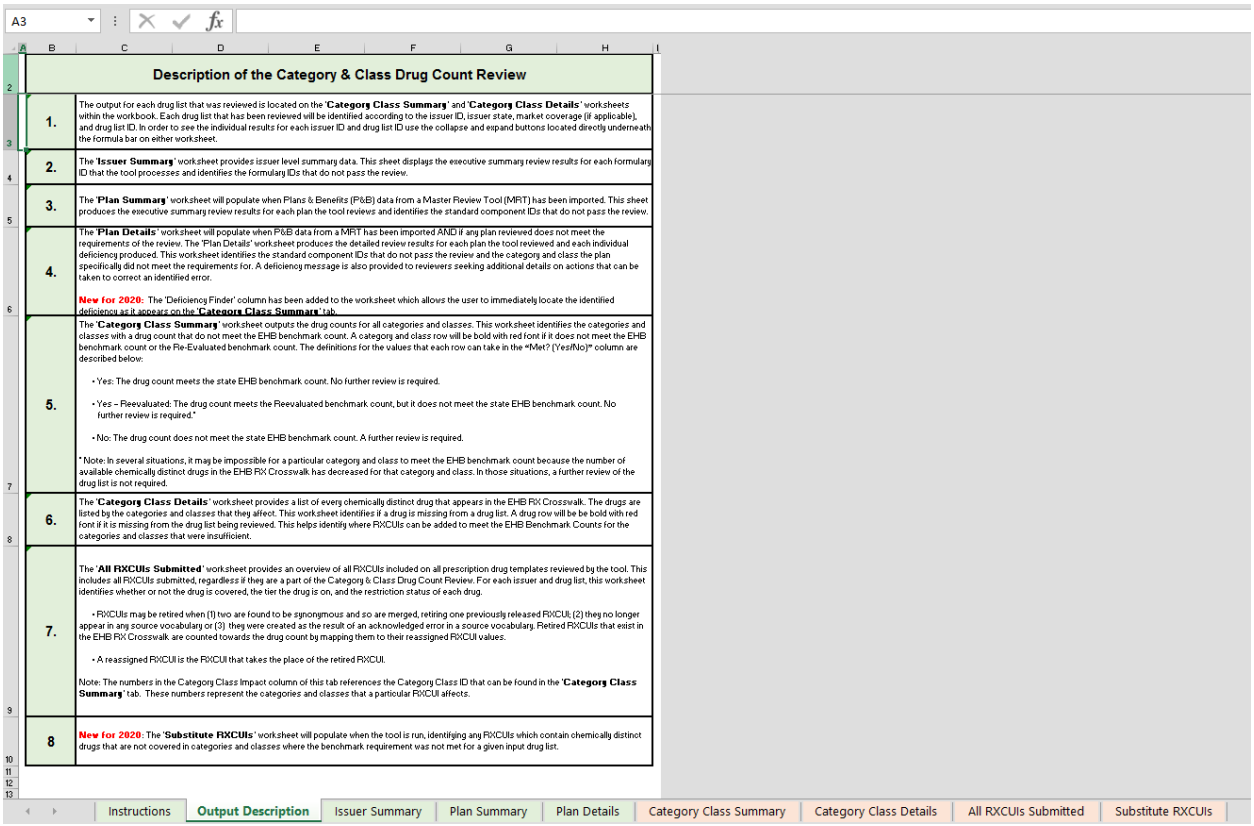
You can run the Master Review Tool yourself using the data on a carrier's binder. How to do that is a different lesson.

In addition to the Master Review Tool data, you will also need a folder with the carrier's RX Drug Template(s) stored in it.

If you load all the information, the tool will analyze all of a carrier's formularies, for both its Individual and Small Group plans, at the same time. In order to separate the results, however, the user must save the carrier's Plans & Benefits Templates and Rx Drug Templates using specific naming conventions so that the tool recognizes them as either Individual or Small Group. (See Instruction 1 on the Instructions tab of the Drug Count Tool.)

Output Description Tab

The Output description tab is just that: a description of what the Tool does, and what information is located on each tab. It also contains some information about what various results mean. This tab is a resource for the user and the Analyst to understand what the results mean and can be helpful in troubleshooting issues. Below is a screenshot of this tab.



Description of the Category & Class Drug Count Review

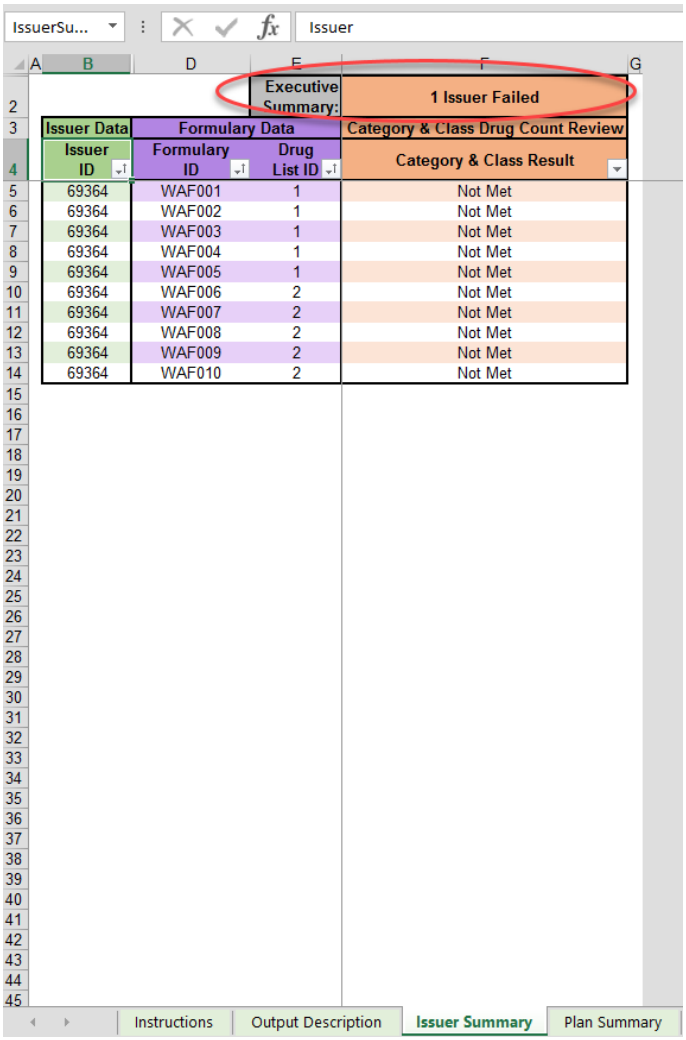
1.	The output for each drug list that was reviewed is located on the '**Category Class Summary**' and '**Category Class Details**' worksheets within the workbook. Each drug list that has been reviewed will be identified according to the issuer ID, issuer state, market coverage (if applicable), and drug list ID. In order to see the individual results for each issuer ID and drug list ID use the collapse and expand buttons located directly underneath the formula bar on either worksheet.
2.	The '**Issuer Summary**' worksheet provides issuer level summary data. This sheet displays the executive summary review results for each formulary ID that the tool processes and identifies the formulary IDs that do not pass the review.
3.	The '**Plan Summary**' worksheet will populate when Plans & Benefits (P&B) data from a Master Review Tool (MRT) has been imported. This sheet produces the executive summary review results for each plan the tool reviews and identifies the standard component IDs that do not pass the review.
4.	The '**Plan Details**' worksheet will populate when P&B data from a MRT has been imported AND if any plan reviewed does not meet the requirements of the review. The 'Plan Details' worksheet produces the detailed review results for each plan the tool reviewed and each individual deficiency produced. This worksheet identifies the standard component IDs that do not pass the review and the category and class the plan specifically did not meet the requirements for. A deficiency message is also provided to reviewers seeking additional details on actions that can be taken to correct an identified error. **New for 2020:** The 'Deficiency Finder' column has been added to the worksheet which allows the user to immediately locate the identified deficiency as it appears on the '**Category Class Summary**' tab.
5.	The '**Category Class Summary**' worksheet outputs the drug counts for all categories and classes. This worksheet identifies the categories and classes with a drug count that do not meet the EHB benchmark count. A category and class row will be bold with red font if it does not meet the EHB benchmark count or the Re-Evaluated benchmark count. The definitions for the values that each row can take in the "Met? (Yes/No)" column are described below: • Yes: The drug count meets the state EHB benchmark count. No further review is required. • Yes – Reevaluated: The drug count meets the Reevaluated benchmark count, but it does not meet the state EHB benchmark count. No further review is required.* • No: The drug count does not meet the state EHB benchmark count. A further review is required. * Note: In several situations, it may be impossible for a particular category and class to meet the EHB benchmark count because the number of available chemically distinct drugs in the EHB RX Crosswalk has decreased for that category and class. In those situations, a further review of the drug list is not required.
6.	The '**Category Class Details**' worksheet provides a list of every chemically distinct drug that appears in the EHB RX Crosswalk. The drugs are listed by the categories and classes that they affect. This worksheet identifies if a drug is missing from a drug list. A drug row will be be bold with red font if it is missing from the drug list being reviewed. This helps identify where RXCUIs can be added to meet the EHB Benchmark Counts for the categories and classes that were insufficient.
7.	The '**All RXCUIs Submitted**' worksheet provides an overview of all RXCUIs included on all prescription drug templates reviewed by the tool. This includes all RXCUIs submitted, regardless if they are a part of the Category & Class Drug Count Review. For each issuer and drug list, this worksheet identifies whether or not the drug is covered, the tier the drug is on, and the restriction status of each drug. • RXCUIs may be retired when (1) two are found to be synonymous and so are merged, retiring one previously released RXCUI; (2) they no longer appear in any source vocabulary or (3) they were created as the result of an acknowledged error in a source vocabulary. Retired RXCUIs that exist in the EHB RX Crosswalk are counted towards the drug count by mapping them to their reassigned RXCUI values. • A reassigned RXCUI is the RXCUI that takes the place of the retired RXCUI. Note: The numbers in the Category Class Impact column of this tab references the Category Class ID that can be found in the '**Category Class Summary**' tab. These numbers represent the categories and classes that a particular RXCUI affects.
8	**New for 2020:** The '**Substitute RXCUIs**' worksheet will populate when the tool is run, identifying any RXCUIs which contain chemically distinct drugs that are not covered in categories and classes where the benchmark requirement was not met for a given input drug list.

Instructions | Output Description | Issuer Summary | Plan Summary | Plan Details | Category Class Summary | Category Class Details | All RXCUIs Submitted | Substitute RXCUIs

Issuer Summary tab

The results are shown on the Issuer Summary tab at the product level (shows a result for each product).

Look at the screen shot below. In the green column furthest to the left, the carrier is identified by its HIOS Issuer ID ("Issuer ID" column). We ran this Tool on one carrier's formularies in one market (the Individual market). You can also run the Tool on multiple carriers' formularies and on both Individual and Small Group plans at the same time.



Executive Summary:	1 Issuer Failed

Issuer Data	Formulary Data		Category & Class Drug Count Review
Issuer ID	Formulary ID	Drug List ID	Category & Class Result
69364	WAF001	1	Not Met
69364	WAF002	1	Not Met
69364	WAF003	1	Not Met
69364	WAF004	1	Not Met
69364	WAF005	1	Not Met
69364	WAF006	2	Not Met
69364	WAF007	2	Not Met
69364	WAF008	2	Not Met
69364	WAF009	2	Not Met
69364	WAF010	2	Not Met

Instructions | Output Description | Issuer Summary | Plan Summary

Note the "Executive Summary" field at top right. (Red circle.) This field gives you a quick indication of whether any drug lists failed the Tool. When you run the Tool on only one carrier's formulary(ies), you will always see either a 1 or a 0 in this field, because either the carrier had one or more drug lists that failed to meet the benchmark, or it did not.

The next two columns, in purple, show the ID of the formulary analyzed ("Formulary ID" column) and the number of the drug list analyzed ("Drug List ID" column). As you can see, this carrier uses 2 drug lists.

The orange column shows the Category & Class result for each Formulary ID analyzed. So this tab tells you, at a glance, whether each Formulary ID met the benchmark, including which drug list it uses.

Issuers tend to have few drug lists. Remember what this particular Tool does; it reviews drug lists by counting the drugs in each Category Class. So each drug list will have the same result regardless of how many Formulary IDs and plans it is used with. In other words, you see in the

screen shot above that every formulary ID that uses drug list 1 has the same result. The same is true for every formulary ID that uses drug list 2.

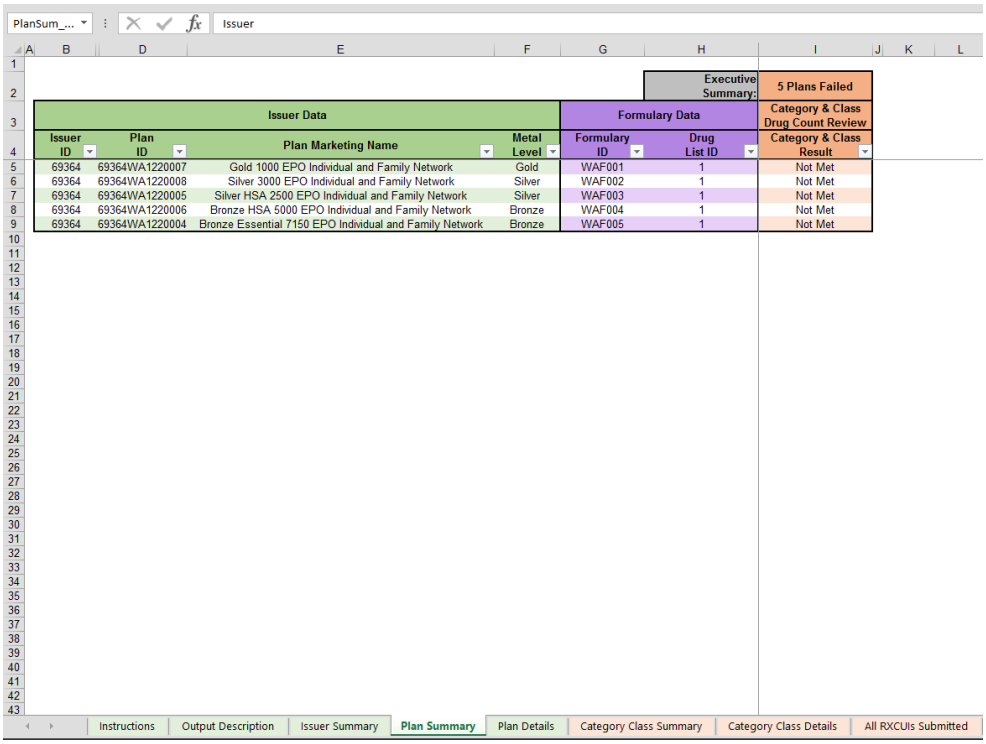
The Issuer Summary tab shows a high-level result. However, if the result showed in the "Executive Summary" field at the top that no formularies failed to meet the benchmark, you would not need any further information. Sometimes we speak in terms of a formulary "passing" or "failing" the Tool. That is simply another way to describe whether the Tool showed that the formulary met the benchmark (passed), or did not meet the benchmark (failed).

If any formularies failed to meet the benchmark, then you need more information. That is where the rest of the tabs come in.

Plan Summary Tab

The Plan Summary tab is the next level of detail after the Issuer Summary tab. This tab shows the results at the plan level (shows a result for each plan). The reason OIC requires carriers to import the information for this tool from the Master Review Tool is so that this plan-level information can be displayed.

Sample plan summary results are shown below. You will see that this tab contains the same information as the Issuer Summary tab, but broken down by each plan, rather than just each product.



Executive Summary:	5 Plans Failed

Issuer Data				Formulary Data		Category & Class Drug Count Review
Issuer ID	Plan ID	Plan Marketing Name	Metal Level	Formulary ID	Drug List ID	Category & Class Result
69364	69364WA1220007	Gold 1000 EPO Individual and Family Network	Gold	WAF001	1	Not Met
69364	69364WA1220008	Silver 3000 EPO Individual and Family Network	Silver	WAF002	1	Not Met
69364	69364WA1220005	Silver HSA 2500 EPO Individual and Family Network	Silver	WAF003	1	Not Met
69364	69364WA1220006	Bronze HSA 5000 EPO Individual and Family Network	Bronze	WAF004	1	Not Met
69364	69364WA1220004	Bronze Essential 7150 EPO Individual and Family Network	Bronze	WAF005	1	Not Met

Plan Details Tab

The Plan Details tab contains the same information as the Issuer Summary and Plan Summary tabs, plus additional detailed information about each "not met" result, and what to do about it.

This tab will only populate when the Plans & Benefits data has been imported into this Tool from a Master Review Tool, AND when one or more plans uses a drug list that does not meet the benchmark. That's because it displays information at the plan level, which requires data from the Master Review Tool, and because it only displays information about "not met" results.

This tab identifies plan(s) that use a drug list that does not meet the benchmark (green columns), and which Formulary ID(s) and drug list(s) are used by those plans (purple columns). The next column to the right (first blue column) identifies the specific Category Class(es) in which the Tool found deficiencies. To the right of that column (second blue column) is the number of covered drugs in that Category Class, followed by the benchmark count that needs to be met (for example, 9 out of 10). The next blue column to the right on the Plan Details tab provides detailed information about exactly what the deficiency is, and how the carrier can remedy it. Finally, the far right column is a link to the exact result. Clicking on this link will take you to the next tab, where the specific failed result will be shown in a black box. This tab is quite helpful in that it provides detailed identification of a failed result, explains the result, and provides a message stating what a carrier needs to do to make the drug list meet the benchmark.

M9 | Find Deficiency

	Issuer Data					Formulary Data		Deficiency Results: Category & Class Deficiencies: 60 — Detailed Deficiency Results			
	State	Issuer ID	Standard Component ID	Plan Marketing Name	Metal Level	Formulary ID	Drug List ID	Category; Class	Drug Count & Benchmark	Deficiency Message	Deficiency Finder
5	WA	69364	69364WA1220007	Gold 1000 EPO Individual and Family Network	Gold	WAF001	1	Antibacterials category; Macrolides class (ID: 14)	4 out of 5	The submitted plan does not cover a sufficient number of chemically distinct drugs in the Antibacterials category; Macrolides class. An issuer must cover at least the greater of (a) one drug or (b) the same number of prescription drugs as the EHB benchmark (5) plan to be considered compliant. Please modify the drug list associated with this plan to meet or exceed this requirement, or submit an appropriate justification.	Find Deficiency
6	WA	69364	69364WA1220007	Gold 1000 EPO Individual and Family Network	Gold	WAF001	1	Antiemetics category; Antiemetics, Other class (ID: 30)	9 out of 10	The submitted plan does not cover a sufficient number of chemically distinct drugs in the Antiemetics category; Antiemetics, Other class. An issuer must cover at least the greater of (a) one drug or (b) the same number of prescription drugs as the EHB benchmark (10) plan to be considered compliant. Please modify the drug list associated with this plan to meet or exceed this requirement, or submit an appropriate	Find Deficiency
7	WA	69364	69364WA1220007	Gold 1000 EPO Individual and Family Network	Gold	WAF001	1	Antiemetics category; Emetogenic Therapy Adjuncts class (ID: 31)	5 out of 6	The submitted plan does not cover a sufficient number of chemically distinct drugs in the Antiemetics category; Emetogenic Therapy Adjuncts class. An issuer must cover at least the greater of (a) one drug or (b) the same number of prescription drugs as the EHB benchmark (6) plan to be considered compliant. Please modify the drug list associated with this plan to meet or exceed this requirement, or submit an appropriate justification.	Find Deficiency
8	WA	69364	69364WA1220007	Gold 1000 EPO Individual and Family Network	Gold	WAF001	1	Antineoplastics category; Enzyme Inhibitors class (ID: 49)	1 out of 3	The submitted plan does not cover a sufficient number of chemically distinct drugs in the Antineoplastics category; Enzyme Inhibitors class. An issuer must cover at least the greater of (a) one drug or (b) the same number of prescription drugs as the EHB benchmark (3) plan to be considered compliant. Please modify the drug list associated with this plan to meet or exceed this requirement, or submit an appropriate	Find Deficiency
9	WA	69364	69364WA1220007	Gold 1000 EPO Individual and Family Network	Gold	WAF001	1	Antineoplastics category; Monoclonal Antibody/Antibody-Drug Conjugate class (ID: 51)	0 out of 1	The submitted plan does not cover a sufficient number of chemically distinct drugs in the Antineoplastics category; Monoclonal Antibody/Antibody-Drug Conjugate class. An issuer must cover at least the greater of (a) one drug or (b) the same number of prescription drugs as the EHB benchmark (1) plan to be considered compliant. Please modify the drug list associated with this plan to meet or exceed this requirement, or submit an appropriate justification.	Find Deficiency

Instructions | Output Description | Issuer Summary | Plan Summary | Plan Details | Category Class Summary | Category Class Details | All RXCUIs Submitted | Substitute RXCUIs

One important "heads up" about this tab. **It may not show all the deficiencies in a drug list.** This tab will not show when a drug list does not meet the Washington State Benchmark, but instead meets only the "Benchmark Reevaluation". As explained below, the "Benchmark Reevaluation" is not always a meaningful number. Therefore, although the Tool treats a "Yes – Reevaluated" result as passing the test, the OIC does not.

That means that each "Yes – Reevaluated" result on the next tab will need to be corrected. Unfortunately, however, this Plan Details tab will not flag these results or provide you with information about how to resolve them.

Category Class Summary Tab

This tab is packed with information. It looks like this:

F85 | 5

				Category Class Result:	2 Lists Not Met	12 Category Classes Not Met		142 Category Classes Not Met	
Category Class ID	Category	Class	Benchmark Count	Benchmark Reevaluation*	69364 Drug Lists	List 1 Count	List 1 Met? (Yes/No)	List 2 Count	List 2 Met? (Yes/No)
1	Analgesics	Nonsteroidal Anti-inflammatory Drugs	20	21		21	Yes	3	No
2	Analgesics	Opioid Analgesics, Long-acting	11	11		11	Yes	3	No
3	Analgesics	Opioid Analgesics, Short-acting	12	15		17	Yes	9	No
4	Anesthetics	Local Anesthetics	3	2		3	Yes	8	Yes
5	Anti-Addiction/ Substance Abuse Treatment Agents	Alcohol Deterrents/Anti-craving	3	3		3	Yes	1	No
6	Anti-Addiction/ Substance Abuse Treatment Agents	Opioid Dependence Treatments	2	4		4	Yes	3	Yes
7	Anti-Addiction/ Substance Abuse Treatment Agents	Opioid Reversal Agents	1	1		1	Yes	0	No
8	Anti-Addiction/ Substance Abuse Treatment Agents	Smoking Cessation Agents	3	3		3	[illegible]	0	No
9	Antibacterials	Aminoglycosides	5	2		3	Yes - Reevaluated	4	Yes - Reevaluated
10	Antibacterials	Antibacterials, Other	[illegible]	[illegible]		14	[illegible]	16	Yes - Reevaluated
11	Antibacterials	Beta-lactam, Cephalosporins	10	10		10	Yes	11	Yes
12	Antibacterials	Beta-lactam, Other	2	1		1	Yes - Reevaluated	7	Yes
13	Antibacterials	Beta-lactam, Penicillins	5	5		5	Yes	6	Yes
14	Antibacterials	Macrolides	5	5		4	No	2	No
15	Antibacterials	Quinolones	10	5		5	Yes - Reevaluated	4	No
16	Antibacterials	Sulfonamides	5	2		2	Yes - Reevaluated	1	No
17	Antibacterials	Tetracyclines	4	4		4	Yes	2	No
18	Anticonvulsants	Anticonvulsants, Other	4	3		4	Yes	2	No
19	Anticonvulsants	Calcium Channel Modifying Agents	4	4		4	Yes	0	No
20	Anticonvulsants	Gamma-aminobutyric Acid (GABA) Augmenting Agents	4	7		6	Yes	3	No
21	Anticonvulsants	Glutamate Reducing Agents	3	3		3	Yes	0	No
22	Anticonvulsants	Sodium Channel Agents	7	7		7	Yes	3	No
23	Antidementia Agents	Antidementia Agents, Other	1	1		1	Yes	0	No
24	Antidementia Agents	Cholinesterase Inhibitors	3	3		3	Yes	0	No
25	Antidementia Agents	N-methyl-D-aspartate (NMDA) Receptor Antagonist	1	1		1	Yes	0	No
26	Antidepressants	Antidepressants, Other	8	8		8	Yes	0	No
27	Antidepressants	Monoamine Oxidase Inhibitors	4	4		4	Yes	0	No
28	Antidepressants	SSRIs/SNRIs (Selective Serotonin Reuptake Inhibitors/ Serotonin and Norepinephrine Reuptake Inhibitors)	11	11		11	Yes	0	No
29	Antidepressants	Tricyclics	9	9		9	Yes	0	No
30	Antiemetics	Antiemetics, Other	10	10		9	No	9	No
31	Antiemetics	Emetogenic Therapy Adjuncts	6	6		5	No	5	No
32	Antifungals	No USP Class	21	21		23	Yes	9	No
33	Antigout Agents	No USP Class	6	6		7	Yes	0	No
34	Anti-inflammatory Agents	Glucocorticoids	26	6		7	Yes - Reevaluated	3	No
35	Anti-inflammatory Agents	Nonsteroidal Anti-inflammatory Drugs	20	21		21	Yes	3	No
36	Antimigraine Agents	Ergot Alkaloids	2	1		2	Yes	0	No
37	Antimigraine Agents	Prophylactic	3	4		4	Yes	1	No
38	Antimigraine Agents	Serotonin (5-HT) 1b/1d Receptor Agonists	7	7		7	Yes	0	No
39	Antimyasthenic Agents	Parasympathomimetics	3	2		2	Yes - Reevaluated	0	No
40	Antimycobacterials	Antimycobacterials, Other	2	2		2	Yes	0	No

Instructions | Output Description | Issuer Summary | Plan Summary | Plan Details | Category Class Summary | Category Class Details | All RXCUIs Submitted | Substitute RXCUIs

In the blue columns on the far left, the tab lists each Category Class of drugs. Note that you can sort this list by each of the columns. The default is for the list to be sorted by Category Class ID. But you can also sort by "List X Met" so that you have all the failed Category Classes together, allowing you to ignore the ones that are met.

The next column, the purple column, is called "Benchmark Count". This column shows how many drugs in that particular Category Class are covered by the state's benchmark plan. The plan being analyzed must cover at least that many drugs in that Category Class. If it does not,

then the plan's coverage of drugs is not as comprehensive as the benchmark formulary's coverage of drugs in that Category Class. As a result, the plan does not satisfy the prescription drug EHB.

Why would the Benchmark Count in a Category Class be zero?

Take a look at the yellow highlighted row in the screen shot below.

	Category Class ID	Category	Class	Benchmark Count	Benchmark Reevaluation	69364 Drug Lists	List 1 Count	List 1 Met? (Yes/No)	List 2 Count	List 2 Met? (Yes/No)
					Category Class Result:	2 Lists Not Met	12 Category Classes Not Met		142 Category Classes Not Met	
137	133	Hormonal Agents, Stimulant/ Replacement/ Modifying (Sex Hormones/ Modifiers)	Estrogens	8	15		15	Yes	1	No
138	134	Hormonal Agents, Stimulant/ Replacement/ Modifying (Sex Hormones/ Modifiers)	Progesterone Agonists/ Antagonists	0	1		1	Yes	0	No
139	135	Hormonal Agents, Stimulant/ Replacement/ Modifying (Sex Hormones/ Modifiers)	Progestins	7	15		18	Yes	4	No

Note that the Benchmark Count for Hormonal Agents, Stimulant/Replacement/Modifying (Sex hormones/ Modifiers) is zero (red circle). That means that this Category Class did not exist in 2014.

There are drugs available in this Category Class for Plan Year 2020 and, in fact, the benchmark plan's formulary covered one of them in 2014. (More on how this result tells us that in the next section.) But because the Category Class did not exist in 2014, no drugs were counted toward it, so the Benchmark Count is zero.

The "Benchmark Reevaluation" Column

The next column to the right is the "Benchmark Reevaluation" column (second purple column). This column requires a bit of explanation.

Remember that the numbers in the Benchmark Count column are the number of drugs that were covered in each Category Class on the state's benchmark plan. Remember also that the current benchmark plans are from Plan Year 2014. Many drugs have come onto, and gone off of, the market since the Plan Year 2014 benchmark formulary was filed.

The Drug Count Tool needs to have a database of all drugs available to satisfy the prescription drug EHB benchmark, in order to provide the information on the Category Class Details tab (see description below). It does. Actually, it has two. Here, we'll only talk about one of them: the HHS Essential Health Benefits Rx Crosswalk (see description below). Although it can't be kept entirely current, the EHB Rx Crosswalk is updated each year. As prescription drugs go on and off the market, sometimes the updated EHB Rx Crosswalk contains more or fewer drugs in a Category Class than there were in 2014 when the current benchmark plans were sold. Also, as new prescription drugs are approved that work in new ways, the updated EHB Rx Crosswalk sometimes includes new Category Classes of drugs. Enter the "Benchmark Reevaluation" column.

The Benchmark Reevaluation column is described by HHS as "the count of chemically distinct drugs in each of the categories and classes of drugs included in the category & class drug count review based on each state's original benchmark plan." In other words, the numbers in the Benchmark Reevaluation column are the number of drugs that were on the benchmark plan's formulary in 2014 AND are still on the market today. For Plan Year 2020 in Washington, there are 32 Category and Class IDs with reevaluated benchmarks lower than the initial benchmark.

You can think of the Benchmark Count, described above, as the intersection between the formulary for Washington's benchmark plan (which is a Plan Year 2014 plan), and the EHB Rx Crosswalk against which it was initially measured (which was the EHB Rx Crosswalk for Plan Year 2015). The numbers in the Benchmark Count column reflect the number of drugs in each Category Class on the benchmark plan that were listed on the PY 2015 EHB Rx Crosswalk. Because that's what those numbers represent, they don't change over time. They are the numbers that represent how "comprehensive" the prescription drug coverage in the benchmark plan was. As discussed above, this tool measures to ensure that the plan being tested has similarly "comprehensive" drug coverage in each Category Class. So it measures plan formularies to see that they still contain the same number of drugs in each Category Class as the benchmark plan.

The Benchmark Reevaluation measures the benchmark formulary against a different EHB Rx Crosswalk than the Benchmark Count. The Benchmark Reevaluation is the intersection between the benchmark formulary and the EHB Rx Crosswalk for the *upcoming* Plan Year. So, for example, the Drug Count Tool for Plan Year 2020 measures the benchmark formulary against the EHB Rx Crosswalk for Plan Year 2020. Since the benchmark plan formulary never changes, but EHB Rx Crosswalk changes each year based upon what drugs have become unavailable and newly available, the numbers in the Benchmark Reevaluation *can* change each year.

So the numbers of drugs in this column reflect a "reevaluated" number based on what has happened regarding the drugs in that Category Class since the benchmark plan was sold. With that understanding, here's why the numbers in the Benchmark Reevaluation might be different from the numbers in the Benchmark Count:

Why the "Benchmark Reevaluation" number may be **lower** than the "Benchmark Count."

The overall description above sums up why the Benchmark Reevaluation number would be lower than the Benchmark Count: because there are some drugs in a particular Category Class that were on the benchmark formulary but are no longer available.

Up to Plan Year 2019, OIC accepted a result that shows the formulary had met the drug count in the Benchmark Reevaluation column. But, for Plan Year 2020, this is no longer acceptable. Carriers are required to meet the higher of the Benchmark Count or the Benchmark Reevaluation wherever possible. That's because, in most categories, there are actually more

drugs in that Category Class (as shown on the Category Class Details tab) than the Benchmark Count or Benchmark Reevaluation, because new drugs have come on the market. That's why you sometimes see a result where the drug list count exceeds the Benchmark Reevaluation count. (Red circles, below.)

				Category Class Result:	2 Lists Not Met	12 Category Classes Not Met		142 Category Classes Not Met	
Category Class ID	Category	Class	Benchmark Count	Benchmark Reevaluation*	69364 Drug Lists	List 1 Count	List 1 Met? (Yes/No)	List 2 Count	List 2 Met? (Yes/No)
7	Anti-Addiction/ Substance Abuse Treatment Agents	Opioid Reversal Agents	1	1		1	Yes	0	No
8	Anti-Addiction/ Substance Abuse Treatment Agents	Smoking Cessation Agents	3	3		3	Yes	0	No
9	Antibacterials	Aminoglycosides	5	2		3	Yes - Reevaluated	4	Yes - Reevaluated
10	Antibacterials	Antibacterials, Other	17	13		14	Yes - Reevaluated	16	Yes - Reevaluated
11	Antibacterials	Beta-lactam, Cephalosporins	10	10		10	Yes	11	Yes

Of course, the benchmark plan, which was sold in 2014, could not have covered new drugs that have come out in subsequent years. However, current plans *can* cover them to meet the benchmark in that particular Category Class. So there is no reason to limit the benchmark requirement, and to do so would be inconsistent with the requirement to provide the full Prescription Drug EHB under federal and state law. To require plans to continue to meet the state benchmark if possible is also consistent with the statement on the Category Class Summary tab that says:

> The Benchmark Reevaluation column contains updated benchmark counts based on the current EHB Rx Crosswalk. This column is only for reference purposes since issuers are still required to meet or exceed the values in Benchmark Count column. In several situations, it may be impossible for a particular Category and Class to meet the EHB benchmark count because the number of available chemically distinct drugs in the EHB Rx Crosswalk has decreased for that Category and Class.

That last sentence from the statement above is what we've just been talking about. When there are fewer drugs left in a Category Class than the benchmark plan covered, it is no longer possible to meet the benchmark. In that case, the carrier must be allowed to meet the benchmark by covering as many drugs as remain available in that Category Class. The carrier must submit a justification that explains this. Since the number of available drugs is the same for every carrier, every carrier would submit the same justification for that Category Class.

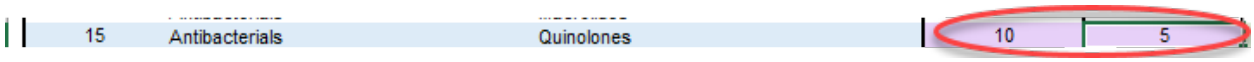
This is easier to understand with a simple example.

In 2014, the Benchmark Plan formulary covered 10 drugs in the Category Class "Antibacterials, Qhinolones". The Drug Count Tool contains a list of these 10 drugs by RxCUI. Remember: that list does not change.

We all know that old drugs go off the market and new drugs come on the market all the time. For that reason, the HHS Essential Health Benefit Rx Crosswalk is updated annually with the RxCUIs for all off-the-market drugs removed and the RxCUIs for all new drugs added. And in October, 2018, when the EHB Rx Crosswalk for Plan Year 2020 was created, there were only 6

drugs in this Category Class. As a result, although the benchmark number of drugs in this Category Class is 10, that benchmark cannot currently be met, because there are only 6 drugs available in this Category Class.

5 of the currently available drugs in this Category Class were covered in the benchmark plan. That's what the number in the Benchmark Reevaluation Column represents: of the 10 drugs covered by the benchmark plan in 2014, 5 of those drugs are still available. Therefore, the "Benchmark Reevaluation" reflects 5. See screen shot, below.



This is a good example of why we say that the Benchmark Reevaluation is not always a meaningful number. It doesn't matter how many of the specific drugs in this Category Class in 2014 are still available because, as discussed above, federal law does not require that a plan cover the same drugs as the benchmark plan to meet the EHB. Federal law requires that a carrier cover the same *number* of drugs in each Category Class as the benchmark plan. Since this is not possible in the "Antibacterials, Quinolones" Category Class, the carrier cannot meet that standard. But the carrier must still cover as many drugs as possible toward meeting the Benchmark Count. In this case, that means the carrier must cover all 6 drugs available in this Category Class. Covering the 5 drugs that were covered in 2014 that are still available (what the Benchmark Reevaluation measures) is not sufficient, because that is not the standard. If there are sufficient drugs available to meet the Benchmark Count in a particular Category Class, the carrier is required to meet that benchmark. If there are not sufficient drugs available to meet the Benchmark Count in a particular Category Class, the carrier is required to cover as many drugs as are available.

For Plan Year 2020, OIC is aware of 9 Category Classes of drugs in which there are no longer sufficient drugs available to meet the Benchmark Count:

Category	Class	Benchmark Count	Number that must be covered	Does the number that must be covered match the Benchmark Reevaluation?
Antibacterials	Quinolones	10	6	No
Antibacterials	Sulfonamides	5	2	Yes
Anti-Inflammatory Agents	Glucocorticoids	26	6	Yes
Antimigraine Agents	Ergot Alkaloids	2	2	No

Category	Class	Benchmark Count	Number that must be covered	Does the number that must be covered match the Benchmark Reevaluation?
Cardiovascular Agents	Diuretics, Carbonic Anhydrase Inhibitors	2	1	Yes
Hormonal Agents, Stimulant / Replacement / Modifying (Adrenal)	No USP Class	31	10	Yes
Hormonal Agents, Suppressant (Adrenal)	No USP Class	2	1	Yes
Ophthalmic Agents	Ophthalmic Anti-allergy Agents	10	9	Yes
Respiratory Tract / Pulmonary Agents	Phosphodiesterase Inhibitors, Airways Disease	6	3	No

How does OIC know that? We know because there is a "heads up" on the Category Class Summary tab of the Drug Count Tool. If you scroll to the bottom, you'll see a chart that looks like this:

*The Benchmark Reevaluation column contains updated benchmark counts based on the current EHB RX Crosswalk (excluding Illinois (IL), where re-evaluated benchmark counts were updated just prior to PY2020; meaning IL's re-evaluated benchmarks counts are based on the PY2019 EHB RX Crosswalk). This column is only for reference purposes since issuers are still required to meet or exceed the values in Benchmark Count column. In several situations, it may be impossible for a particular category and class to meet the EHB benchmark count because the number of available chemically distinct drugs in the EHB RX Crosswalk has decreased for that category and class.

In these situations, there will have a value of "Yes – Reevaluated" in the "Met? (Yes/No)" column and be in the following categories and classes for the corresponding states:

Category Class ID	Category	Class	States Affected
15	Antibacterials	Quinolones	AK; AL; AR; AZ; CT; DC; DE; FL; GA; HI; IA; ID; IL; IN; KS; KY; LA; MA; MD; ME; MI; MO; MS; MT; NC; ND; NE; NH; NJ; NM; NV; NY; OH; OK; OR; PA; RI; SC; SD; TN; TX; VA; VT; WA; WI; WV; WY; OPM - 1; OPM - 2; OPM - 3;
16	Antibacterials	Sulfonamides	AK; AL; AR; AZ; CA; CO; CT; DC; DE; FL; GA; HI; IA; ID; IL; IN; KS; KY; LA; MA; MD; ME; MI; MN; MO; MS; MT; NC; ND; NE; NH; NJ; NM; NV; NY; OH; OK; OR; PA; RI; SC; SD; TN; TX; UT; VA; VT; WA; WI; WV; WY; OPM - 1; OPM - 2; OPM - 3;
34	Anti-inflammatory Agents	Glucocorticoids	AK; AL; AR; AZ; CA; CO; CT; DC; DE; FL; GA; HI; IA; ID; IL; IN; KS; KY; LA; MA; MD; ME; MI; MN; MO; MS; MT; NC; ND; NE; NH; NJ; NM; NV; NY; OH; OK; OR; PA; RI; SC; SD; TN; TX; UT; VA; VT; WA; WI; WV; WY; OPM - 1; OPM - 2; OPM - 3;
36	Antimigraine Agents	Ergot Alkaloids	AK; AL; AR; AZ; CA; CO; CT; DC; DE; FL; GA; HI; IA; ID; IL; IN; KS; KY; LA; MA; MD; ME; MO; MT; NC; ND; NE; NJ; NM; NV; NY; OH; OK; OR; PA; RI; SC; SD; TN; TX; VA; VT; WA; WI; WV; WY; OPM - 1; OPM - 2; OPM - 3;
97	Cardiovascular Agents	Diuretics, Carbonic Anhydrase Inhibitors	AK; AL; AR; AZ; CA; CO; CT; DC; DE; FL; GA; HI; IA; IL; IN; KS; KY; LA; MA; MD; ME; MN; MO; MS; MT; NC; ND; NE; NH; NJ; NM; NV; NY; OH; OK; OR; PA; RI; SC; SD; TN; TX; UT; VA; VT; WA; WI; WV; WY; OPM - 1; OPM - 2; OPM - 3;
128	Hormonal Agents, Stimulant/ Replacement/ Modifying (Adrenal)	No USP Class	AK; AL; AR; AZ; CA; CO; CT; DC; DE; FL; GA; HI; IA; ID; IL; IN; KS; KY; LA; MA; MD; ME; MI; MN; MO; MS; MT; NC; ND; NE; NH; NJ; NM; NV; NY; OH; OK; OR; PA; RI; SC; SD; TN; TX; UT; VA; VT; WA; WI; WV; WY; OPM - 1; OPM - 2; OPM - 3;
138	Hormonal Agents, Suppressant (Adrenal)	No USP Class	AK; AL; AZ; FL; GA; IN; LA; MA; ME; MI; MN; NY; OH; RI; SC; VA; WA; WI; WY; OPM - 1; OPM - 2; OPM - 3;
150	Ophthalmic Agents	Ophthalmic Anti-allergy Agents	AZ; CT; DE; GA; HI; KY; MA; OR; PA; SC; TN; VT; WA; WV; OPM - 1; OPM - 2;
162	Respiratory Tract/ Pulmonary Agents	Phosphodiesterase Inhibitors, Airways Dis	AR; AZ; CT; DE; GA; HI; IN; KY; LA; MA; ME; MO; NH; NV; OH; PA; SC; TN; VA; VT; WA; WV; OPM - 1; OPM - 2;

This chart tells us that the number of drugs in a Category Class has dropped and it may no longer be possible to meet the Benchmark Count for Plan Year 2020. With that knowledge, we then look at the 2020 EHB Rx Crosswalk to determine how many unique drugs are available in that Category Class to meet the Benchmark Count. (Remember that this is a different number than the Benchmark Reevaluation, which only looks at which 2014 drugs are still available, not how many drugs total are currently available to meet the Benchmark Count. That's why we've included the column above showing that these numbers are often not the same, to illustrate for which drugs meeting the Benchmark Reevaluation is sufficient for Plan Year 2020, and for which drugs it is not.)

Why the "Benchmark Count" may be zero and the "Benchmark Reevaluation" number may be higher:

In a few instances, a particular Category Class may be new since 2014. That results in the Benchmark Count being zero, even if the benchmark formulary covered some drugs that are now counted toward that new Category Class. That's because, as stated before, the Benchmark Count is the comparison of the 2014 benchmark formulary with the Plan Year 2015 EHB Rx Crosswalk. The 2015 EHB Rx Crosswalk didn't have this Category Class, so it didn't count any drugs in this Category Class in the benchmark plan.

The Benchmark Reevaluation, however, is the comparison of the benchmark formulary with the *current* EHB Rx Crosswalk. In this case, the 2014 Washington benchmark plan formulary with the Plan Year 2020 EHB Rx Crosswalk. Any drug on the 2014 benchmark formulary that counts toward the new Category Class will be counted in the Benchmark Reevaluation.

Take a look at an example. The highlighted rows represent two Classes in the Antivirals Category.

				Category Class Result:	2 Lists Not Met	12 Category Classes Not Met		142 Category Classes Not Met	
Category Class ID	Category	Class	Benchmark Count	Benchmark Reevaluation*	69364 Drug Lists	List 1 Count	List 1 Met? (Yes/No)	List 2 Count	List 2 Met? (Yes/No)
67	Antivirals	Anti-hepatitis B (HBV) Agents	7	7		6	No	0	No
68	Antivirals	Anti-hepatitis C (HCV) Agents, Direct Acting	0	0		9	Yes	0	No
69	Antivirals	Anti-hepatitis C (HCV) Agents, Other	0	4		4	Yes	0	No
70	Antivirals	Antiherpetic Agents	5	5		5	Yes	1	No

Category Class 68 is "Antivirals, Anti-hepatitis C Agents, Direct Acting". This Category Class was not added to the United States Pharmacopeia (USP) until after 2014. In addition, none of the drugs in this Class, like Sovaldi and Harvoni, were approved for use at that time. So the Benchmark Count is zero (because this Class didn't exist so no drugs were counted toward it). The Benchmark Reevaluation count is also zero (because no drugs that would satisfy this Class were covered on the benchmark formulary).

Now look at the row below it, Category Class 69, "Anti-hepatitis C Agents, Other". Again, the Benchmark Count is zero (purple circle). Again, that's because this particular Class of drugs didn't exist, so no drugs were counted toward it in 2014. However, in this case, there were 4 drugs on the benchmark formulary that would have satisfied this Class, if it had existed. Therefore, now that it does exist, the Benchmark Reevaluation count in this class is 4. (Because the Benchmark Reevaluation count shown here is a comparison of the 2014 benchmark formulary with the Plan Year 2020 EHB Crosswalk.)

That's why, where the Benchmark Count is zero, but the Benchmark Reevaluation count is higher, a carrier must meet the higher Benchmark Reevaluation count. Otherwise, the formulary's coverage in that Category Class is not as comprehensive as the benchmark formulary's coverage and plans using that formulary do not provide the prescription drug EHB.

An important heads up about this requirement: The tool does not flag this deficiency. Where the Benchmark Count is zero, and the Benchmark Reevaluation is more than zero, the

logic of the tool does not recognize a failure to meet the Benchmark Reevaluation as a deficiency. See below.

D184 | Phosphodiesterase Inhibitors, Airways Disease

	Category Class ID	Category	Class	Benchmark Count	Benchmark Reevaluation*	69364 Drug Lists	List 1 Count	List 1 Met? (Yes/No)	List 2 Count	List 2 Met? (Yes/No)
3					Category Class Result:	2 Lists Not Met	12 Category Classes Not Met		142 Category Classes Not Met	
53	49	Antineoplastics	Enzyme Inhibitors	3	2		1	No	6	Yes
54	50	Antineoplastics	Molecular Target Inhibitors	15	17		22	Yes	12	No
55	51	Antineoplastics	Monoclonal Antibody/Antibody-Drug Conjugate	1	0		0	No	18	Yes
56	52	Antineoplastics	Retinoids	3	2		3	Yes	0	No
57	53	Antineoplastics	Treatment Adjuncts	0	8		7	Yes	13	Yes
58	54	Antiparasitics	Anthelmintics	4	3		4	Yes	0	No
59	55	Antiparasitics	Antiprotozoals	11	11		11	Yes	1	No
60	56	Antiparasitics	Pediculicides/Scabicides	6	7		6	Yes	0	No
61	57	Antiparkinson Agents	Anticholinergics	3	3		2	No	2	No
62	58	Antiparkinson Agents	Antiparkinson Agents, Other	3	3		3	Yes	0	No
63	59	Antiparkinson Agents	Dopamine Agonists	4	5		5	Yes	0	No
64	60	Antiparkinson Agents	Dopamine Precursors/ L-Amino Acid Decarboxylase Inhibitors	2	2		2	Yes	0	No
65	61	Antiparkinson Agents	Monoamine Oxidase B (MAO-B) Inhibitors	2	2		2	Yes	0	No
66	62	Antipsychotics	1st Generation/Typical	10	10		10	Yes	4	No
67	63	Antipsychotics	2nd Generation/Atypical	9	9		10	Yes	6	No
68	64	Antipsychotics	Treatment-Resistant	1	1		1	Yes	0	No
69	65	Antispasticity Agents	No USP Class	4	3		3	Yes - Reevaluated	4	Yes
70	66	Antivirals	Anti-cytomegalovirus (CMV) Agents	2	2		2	Yes	2	Yes
71	67	Antivirals	Anti-hepatitis B (HBV) Agents	7	7		6	No	0	No
72	68	Antivirals	Anti-hepatitis C (HCV) Agents, Direct Acting	0	0		9	Yes	0	No
73	69	Antivirals	Anti-hepatitis C (HCV) Agents, Other	0	4		4	Yes	0	No
74	70	Antivirals	Antiherpetic Agents	5	5		5	Yes	1	No
75	71	Antivirals	Anti-HIV Agents, Integrase Inhibitors (INSTI)	2	2		5	Yes	0	No
76	72	Antivirals	Anti-HIV Agents, Non-nucleoside Reverse Transcriptase Inhibitors (NNRTI)	5	7		8	Yes	0	No
77	73	Antivirals	Anti-HIV Agents, Nucleoside and Nucleotide Reverse Transcriptase Inhibitors (NRTI)	12	14		18	Yes	1	No
78	74	Antivirals	Anti-HIV Agents, Other	3	3		6	Yes	0	No
79	75	Antivirals	Anti-HIV Agents, Protease Inhibitors	9	9		11	Yes	0	No
80	76	Antivirals	Anti-influenza Agents	4	4		4	Yes	0	No
81	77	Anxiolytics	Anxiolytics, Other	4	5		4	Yes	1	No
82	78	Anxiolytics	Benzodiazepines	0	8		6	Yes	3	Yes
83	79	Anxiolytics	SSRIs/SNRIs (Selective Serotonin Reuptake Inhibitors/ Serotonin and Norepinephrine Reuptake Inhibitors)	5	5		5	Yes	0	No
84	80	Bipolar Agents	Bipolar Agents, Other	7	8		9	Yes	5	No
85	81	Bipolar Agents	Mood Stabilizers	5	5		5	Yes	0	No
86	82	Blood Glucose Regulators	Antidiabetic Agents	21	21		35	Yes	0	No
87	83	Blood Glucose Regulators	Glycemic Agents	1	1		1	Yes	0	No
88	84	Blood Glucose Regulators	Insulins	10	10		12	Yes	0	No
89	85	Blood Products/ Modifiers/ Volume Expanders	Anticoagulants	8	7		8	Yes	2	No
90	86	Blood Products/ Modifiers/ Volume Expanders	Blood Formation Modifiers	6	7		6	Yes	5	No
91	87	Blood Products/ Modifiers/ Volume Expanders	Hemostasis Agents	0	2		2	Yes	16	Yes

Instructions | Output Description | Issuer Summary | Plan Summary | Plan Details | Category Class Summary | Category Class Details | All RXCUIs Submitted

Note that, in each of the highlighted rows, the Benchmark Count is lower than the Benchmark Reevaluation count. However, although the drug list being evaluated does not meet the higher Benchmark Reevaluation count, in each case this deficiency is not flagged.

As a result, carriers and OIC Analysts need to know the Category Classes in which this situation exists, so that they can hand-check the drug counts. For Plan Year 2020, those Category Classes are:

Category Class ID*	Category	Class	Benchmark Reevaluation count that must be met
53	Antineoplastics	Treatment Adjuncts	8
69	Antivirals	Anti-Hepatitis C (HCV) Agents, Other	4
78	Anxiolytics	Benzodiazepines	8

Category Class ID*	Category	Class	Benchmark Reevaluation count that must be met
87	Blood Products / Modifiers / Volume Expanders	Hemostasis Agents	2
113	Electrolytes / Minerals / Metals / Vitamins	Electrolyte / Mineral Replacements	5
114	Electrolytes / Minerals / Metals / Vitamins	Electrolyte / Mineral / Metal Modifiers	6
115	Electrolytes / Minerals / Metals / Vitamins	Phosphate Binders	3
116	Electrolytes / Minerals / Metals / Vitamins	Vitamins	1
124	Genetic or Enzyme Disorder: Replacement, Modifiers Treatment	No USP Class	7
134	Hormonal Agents, Stimulant / Replacement / Modifying (Sex Hormones / Modifiers)	Progesterone Agonists / Antagonists	1

* Normally, we recommend ignoring the Category Class ID, because these change from tool to tool and that can be confusing. However, they're included here for ease of reference because there are so many Category Classes in this Tool that need to be hand checked.

Why the "benchmark count" may be one or more, and the "benchmark reevaluation" number may be higher

A state's benchmark plan formulary may contain drugs that, in Plan Year 2015, either were not on the EHB Rx Crosswalk at all, or were not being counted toward a particular Category Class on that EHB Rx Crosswalk. Since the Plan Year 2015 EHB Rx Crosswalk, drugs have been added to subsequent years' EHB-Rx Crosswalks, and new drugs that were previously not counted toward a Particular Category Class have also begun to be counted toward that Category Class. This would happen, for example, when a particular drug has been found, since 2014, to be effective for a new use.

Let's say a particular drug was covered in the benchmark formulary, and was not counted toward Category Class X when the Benchmark Count was calculated for Plan Year 2015 (remember the Benchmark Count doesn't change because it's the comparison of the 2014 formulary with the Plan Year 2015 EHB Rx Crosswalk). But the drug was subsequently found to be effective for use in Category Class X. Therefore, in 2018, the FDA approved that drug for use in Category Class X. The Plan Year 2020 EHB Rx Template will show the drug as now counting toward Category Class X, so when the benchmark formulary is compared to the Plan Year 2020 EHB Rx Crosswalk (which is how the Benchmark Reevaluation is calculated), those drugs will now count so the result will show a higher number of covered drugs in that Category Class in the benchmark plan.

As CCIIO explained in an E-mail to OIC, "We try our best to follow United States Pharmacopeia's (USP) drug classification system, but we may need to expand, edit, or update the system to be better aligned with the Marketplace population (USP's Medicare Model Guideline was created specifically for the Medicare Part D program)."

Category Class ID	Category	Class	Benchmark Count	Benchmark Reevaluation*	49831 Drug Lists	List 1 Count	List 1 Met? (Yes/No)	List 2 Count	List 2 Met? (Yes/No)
78	Anxiolytics	Benzodiazepines	0	9		8	Yes	8	Yes
79	Anxiolytics	SSRIs/SNRIs (Selective Serotonin Reuptake Inhibitors/ Serotonin and Norepinephrine Reuptake Inhibitors)	5	5		5	Yes	5	Yes
80	Bipolar Agents	Bipolar Agents, Other	7	9		10	Yes	10	Yes
81	Bipolar Agents	Mood Stabilizers	5	5		5	Yes	5	Yes
82	Blood Glucose Regulators	Antidiabetic Agents	21	21		27	Yes	27	Yes
83	Blood Glucose Regulators	Glycemic Agents	1	1		1	Yes	1	Yes
84	Blood Glucose Regulators	Insulins	10	10		11	Yes	11	Yes
85	Blood Products/ Modifiers/ Volume Expanders	Anticoagulants	8	8		8	Yes	8	Yes
86	Blood Products/ Modifiers/ Volume Expanders	Blood Formation Modifiers	6	7		8	Yes	8	Yes
87	Blood Products/ Modifiers/ Volume Expanders	Hemostasis Agents	0	2		2	Yes	2	Yes
88	Blood Products/ Modifiers/ Volume Expanders	Platelet Modifying Agents	8	8		8	Yes	8	Yes
89	Cardiovascular Agents	Alpha-adrenergic Agonists	4	4		4	Yes	4	Yes
90	Cardiovascular Agents	Alpha-adrenergic Blocking Agents	4	4		4	Yes	4	Yes
91	Cardiovascular Agents	Angiotensin II Receptor Antagonists	8	8		8	Yes	8	Yes
92	Cardiovascular Agents	Angiotensin-converting Enzyme (ACE) Inhibitors	10	10		10	Yes	10	Yes
93	Cardiovascular Agents	Antiarrhythmics	10	10		10	Yes	10	Yes
94	Cardiovascular Agents	Beta-adrenergic Blocking Agents	13	13		13	Yes	13	Yes
95	Cardiovascular Agents	Calcium Channel Blocking Agents	9	9		9	Yes	9	Yes
96	Cardiovascular Agents	Cardiovascular Agents, Other	4	5		6	Yes	6	Yes

Where there are no drugs in a Category Class:

For Plan Year 2018, there was one Category Class in which there were currently no FDA-approved drugs. Category Class 51: Antineoplastics, Monoclonal Antibodies showed "Not Met" for every carrier that year. (See highlighted row in screen shot, below.) OIC accepted a justification that there are no FDA-approved drugs to meet this Category Class.

				Category Class Result:	1 List Not Met	1 Category Class Not Met	
Category Class ID	Category	Class	Benchmark Count	Benchmark Reevaluation*	23371 Drug Lists	List 1 Count	List 1 Met? (Yes/No)
49	Antineoplastics	Enzyme Inhibitors	3	3		10	Yes
50	Antineoplastics	Molecular Target Inhibitors	15	15		24	Yes
51	Antineoplastics	Monoclonal Antibodies	1	0		0	No

For Plan Year 2019, there were no Category Classes in which there are no drugs available. The same is true for Plan Year 2020.

Now let's move on in the description of the Category Class Details tab. The next columns to the right of the Benchmark Reevaluation column are green columns. They are the results for the drug lists being tested.

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3					Category Class Result:	2 Lists Not Met	12 Category Classes Not Met		142 Category Classes Not Met	
4	Category Class ID	Category	Class	Benchmark Count	Benchmark Reevaluation*	69364 Drug Lists	List 1 Count	List 1 Met? (Yes/No)	List 2 Count	List 2 Met? (Yes/No)
5	1	Analgesics	Nonsteroidal Anti-inflammatory Drugs	20	21		21	Yes	3	No
6	2	Analgesics	Opioid Analgesics, Long-acting	11	11		11	Yes	3	No
7	3	Analgesics	Opioid Analgesics, Short-acting	12	15		17	Yes	9	No
8	4	Anesthetics	Local Anesthetics	3	2		3	Yes	8	Yes
9	5	Anti-Addiction/ Substance Abuse Treatment Agents	Alcohol Deterrents/Anti-craving	3	3		3	Yes	1	No
10	6	Anti-Addiction/ Substance Abuse Treatment Agents	Opioid Dependence Treatments	2	4		4	Yes	3	Yes
11	7	Anti-Addiction/ Substance Abuse Treatment Agents	Opioid Reversal Agents	1	1		1	Yes	0	No
12	8	Anti-Addiction/ Substance Abuse Treatment Agents	Smoking Cessation Agents	3	3		3	Yes	0	No
13	9	Antibacterials	Aminoglycosides	5	2		3	Yes - Reevaluated	4	Yes - Reevaluated
14	10	Antibacterials	Antibacterials, Other	17	13		14	Yes - Reevaluated	16	Yes - Reevaluated
15	11	Antibacterials	Beta-lactam, Cephalosporins	10	10		10	Yes	11	Yes
16	12	Antibacterials	Beta-lactam, Other	2	1		1	Yes - Reevaluated	7	Yes
17	13	Antibacterials	Beta-lactam, Penicillins	5	5		5	Yes	6	Yes
18	14	Antibacterials	Macrolides	5	5		4	No	2	No
19	15	Antibacterials	Quinolones	10	5		5	Yes - Reevaluated	4	No
20	16	Antibacterials	Sulfonamides	5	2		2	Yes - Reevaluated	1	No
21	17	Antibacterials	Tetracyclines	4	4		4	Yes	2	No
22	18	Anticonvulsants	Anticonvulsants, Other	4	3		4	Yes	2	No
23	19	Anticonvulsants	Calcium Channel Modifying Agents	4	4		4	Yes	0	No
24	20	Anticonvulsants	Gamma-aminobutyric Acid (GABA) Augmenting Agents	4	7		6	Yes	3	No
25	21	Anticonvulsants	Glutamate Reducing Agents	3	3		3	Yes	0	No
26	22	Anticonvulsants	Sodium Channel Agents	7	7		7	Yes	3	No
27	23	Antidementia Agents	Antidementia Agents, Other	1	1		1	Yes	0	No
28	24	Antidementia Agents	Cholinesterase Inhibitors	3	3		3	Yes	0	No
29	25	Antidementia Agents	N-methyl-D-aspartate (NMDA) Receptor Antagonist	1	1		1	Yes	0	No
30	26	Antidepressants	Antidepressants, Other	8	8		8	Yes	0	No
31	27	Antidepressants	Monoamine Oxidase Inhibitors	4	4		4	Yes	0	No
32	28	Antidepressants	SSRIs/SNRIs (Selective Serotonin Reuptake Inhibitors/ Serotonin and Norepinephrine Reuptake Inhibitors)	11	11		11	Yes	0	No
33	29	Antidepressants	Tricyclics	9	9		9	Yes	0	No
34	30	Antiemetics	Antiemetics, Other	10	10		9	No	9	No
35	31	Antiemetics	Emetogenic Therapy Adjuncts	6	6		5	No	5	No
36	32	Antifungals	No USP Class	21	21		23	Yes	9	No
37	33	Antigout Agents	No USP Class	6	6		7	Yes	0	No
38	34	Anti-inflammatory Agents	Glucocorticoids	26	6		7	Yes - Reevaluated	3	No
39	35	Anti-inflammatory Agents	Nonsteroidal Anti-inflammatory Drugs	20	21		21	Yes	3	No
40	36	Antimigraine Agents	Ergot Alkaloids	2	1		2	Yes	0	No
41	37	Antimigraine Agents	Prophylactic	3	4		4	Yes	1	No
42	38	Antimigraine Agents	Serotonin (5-HT) 1b/1d Receptor Agonists	7	7		7	Yes	0	No
43	39	Antimyasthenic Agents	Parasympathomimetics	3	2		2	Yes - Reevaluated	0	No
44	40	Antimycobacterials	Antimycobacterials, Other	2	2		2	Yes	0	No

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Note that, in the example above, the carrier has two Drug Lists. The results for List 2 appear to the right of the results for List 1.

The red arrows in the screen shots above point to the overview of the results at the top of the column. If this overview says that all Category Classes are met, that is all you need to know. You do not need any more information.

If, as in the case of the screenshot above, this overview indicates that there are unmet Category Classes, then you look at the information below the overview.

The first column in this green set of columns simply gives the HIOS ID of the carrier so that you know whose results they are. The second column, "List 1 count", tells you how many drugs are covered in each Category Class on that drug list. The column to the right of that, "List 1 met?

(Yes/No)" tells you whether the number of covered drugs in that Category Class meets or exceeds the Benchmark Count or Benchmark Reevaluation count. If there is more than one drug list, as there are in the screen shot above, there will be a "List X Count" and a "List X Met? (Yes/No)" column for each Drug List.

Let's look at some of the results in these columns. The second row shows a "Met" result (red circle). There are 20 drugs in the "Analgesics, Opioid Analgesics, Long-acting" Category Class in the benchmark plan, the Benchmark Reevaluation shows that there are still at least 11 drugs in that Category Class, and drug list 1 covers 11 drugs in this Category Class. Therefore, the "List 1 Met? (Yes/No)" column says Yes, and the result is in regular font. Drug list 2, however, shows a "failed" result for this Category Class. Drug list 2 covers only 3 drugs in this Category Class. This does not meet or exceed the Benchmark Count, so the "List 2 Met? (Yes/No)" column says "No". Both the result and the count are in bold, red font.

The purple circle shows a similar result. There are 21 drugs in the "Antifungals, No USP Class" Category Class in the benchmark plan, the Benchmark Reevaluation shows there are still at least 21 drugs in this Category Class, and the "List 1 Count" column shows that the list being tested has 13 covered drugs in this Category Class. Therefore, the List 1 Met? (Yes/No)" column says "Yes" in regular font. The List 2 count, however, is only 9. This does not meet the benchmark, so again the "List 2 Met? (Yes/No)" column says "No", and both the count and the result are shown in bold, red font.

The yellow circle shows a failed result for the Category Class "Antiemetics, Antiemetics, Other". The Benchmark Count is 10 drugs in this Category Class, and the Benchmark Reevaluation shows the same 10 drugs are still available in this Category Class. However, both drug lists cover only 9. This carrier will need to either cover an additional drug in this Category Class on each drug list, or submit a justification to show why this plan can be approved despite not meeting the benchmark.

The green circle shows a situation that illustrates several of the concepts discussed previously in this User Guide. The Benchmark Count for the "Antibacterials, Aminoglycosides" Category Class is 5. The Benchmark Reevaluation column shows that, of the 5 drugs in this Category Class covered under the benchmark plan in 2014, 2 of those same drugs are still available. Drug list 1 covers 3 drugs in this Category Class, and drug list 2 covers 4. Since those meet or exceed the Benchmark Reevaluation, the results columns show "Yes – Reevaluated". However, although the drug lists meet the Benchmark Reevaluation, we know that that number is often not meaningful. The carrier is required to meet the Benchmark Count if there are sufficient available drugs in this Category Class to do so. A check of the EHB Rx Crosswalk shows that there are 7 drugs available in this Category Class. Therefore, the carrier will need to add 2 drugs to drug list 1 and one drug to drug list 2 in this Category Class, because it is possible to meet the Benchmark Count.

The Category Class Summary tab tells you all you need to know in most cases. But there may be situations in which you want or need to look deeper to answer a question or solve a problem with a drug list. The last two tabs can help with this. That is one reason OIC requires carriers to submit their entire Excel workbook results.

Category Class Details tab

This tab is based on the HHS Essential Health Benefits Rx Crosswalk, described above. It lists each of the chemically distinct drugs on that crosswalk. "Chemically distinct" simply means that, although two drugs may be in the same Category Class, they are not the same substance. Just as each drug Category is made up of one or more drug Class, each drug Class is made up of one or more chemically distinct drugs. The benchmark tells us how many of those chemically distinct drugs must be covered in each Category Class.

The default is for the list to be sorted by Category Class ID, but like the other tabs in the Drug Count Tool results, it can be sorted by the information in any of the columns. For example, if you wanted to see whether a particular drug was included in a particular Category Class, or which drugs in a particular Category Class are covered, the default sort makes sense. But if you want to see whether a particular drug is covered, or which Category(ies) or Class(es) a particular drug falls into, sorting by Chemically Distinct Drug name would work much better. (Remember, one drug can fall into more than one Category Class, because drugs sometimes have multiple effects.)

Let's see how else we might use the Category Class Details tab. Suppose the carrier gets the result below, showing that its small group plan does not meet the benchmark in the "Genitourinary Agents, Genitourinary Agents, Other" Category Class. The benchmark count is 7 drugs in this Category Class, but the Small Group plan covers only 6. (See highlighted row, below.)

				Marketplace Type:	Individual			SHOP (Small Group)		
				Category Class Result:	*1 List Not Met*	*1 Category Class Not Met*		*1 List Not Met*	*4 Category Classes Not Met*	
Category Class ID	Category	Class	Benchmark Count	Benchmark Reevaluation*	80473 Drug Lists	List 1 Count	List 1 Met? (Yes/No)	80473 Drug Lists	List 1 Count	List 1 Met? (Yes/No)
121	Genitourinary Agents	Genitourinary Agents, Other	7	7		7	Yes		*6*	*No*
122	Genitourinary Agents	Phosphate Binders	3	3		4	Yes		4	Yes

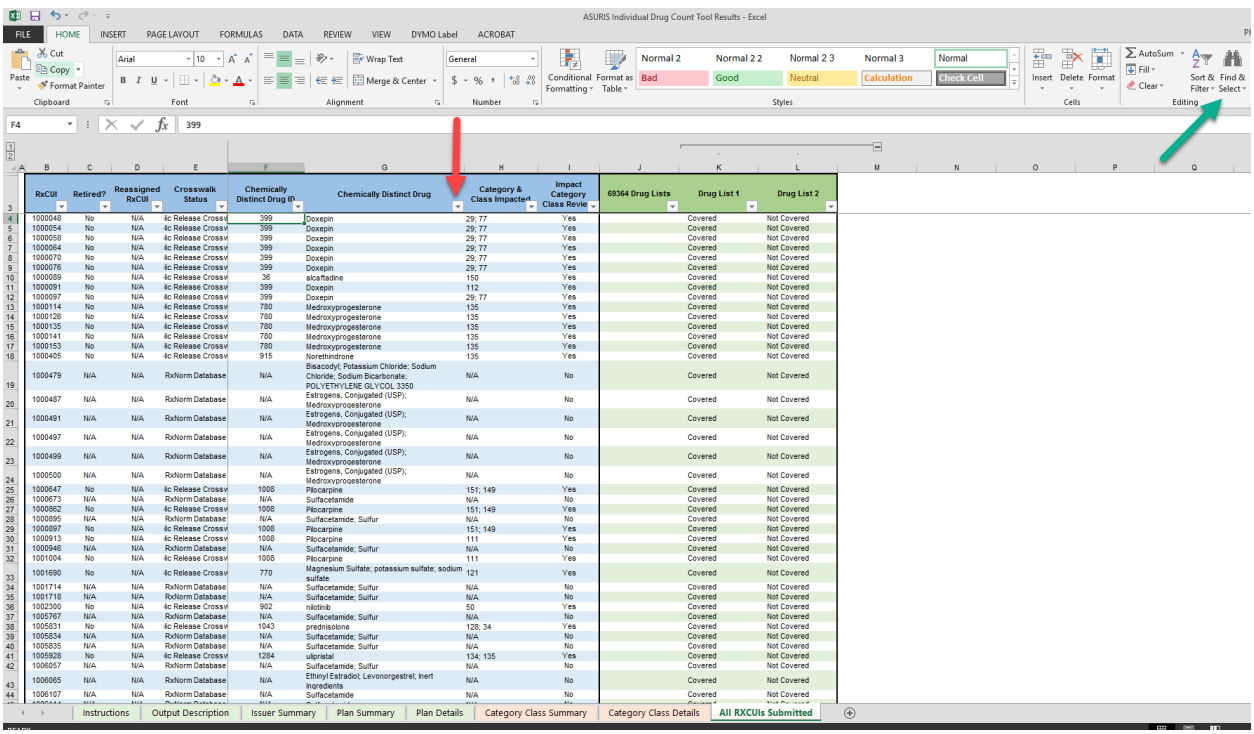
To determine what the carrier needs to do to meet the benchmark for this Category Class, we can look at the Category Class Details tab and see which drugs are included in this Category Class. There are 8 such drugs. (See highlighted area, below.) We also see which of these drugs are covered on the carrier's Drug List, and which are not. (See red circle, below.) Using this information, we know that the carrier can add either flibanserin or sildenafil to its formulary to meet this Category Class, because each of these drugs is listed as "missing" from the list. (See green circles, below.) By comparing the Individual Drug List result to the Small Group Drug List

result, we can also see that flibanserin is covered on the carrier's Individual formulary (red arrow, below) while sildenafil is not (blue arrow).

					Marketplace Type:	Individual		SHOP (Small Group)	
3	Chemically Distinct Drug ID	Chemically Distinct Drug	Category Class ID	Category	Class	80473 Drug Lists	List 1 Missing?	80473 Drug Lists	List 1 Missing?
911	846	Terazosin	120	Genitourinary Agents	Benign Prostatic Hypertrophy Agents		No		No
912	97	Bethanechol	121	Genitourinary Agents	Genitourinary Agents, Other		No		No
913	211	Cysteamine	121	Genitourinary Agents	Genitourinary Agents, Other		No		No
914	355	flibanserin	121	Genitourinary Agents	Genitourinary Agents, Other		No		Yes
915	624	Nitroglycerin	121	Genitourinary Agents	Genitourinary Agents, Other		No		No
916	674	Penicillamine	121	Genitourinary Agents	Genitourinary Agents, Other		No		No
917	677	Pentosan Polysulfate	121	Genitourinary Agents	Genitourinary Agents, Other		No		No
918	793	sildenafil	121	Genitourinary Agents	Genitourinary Agents, Other		Yes		Yes
919	832	tadalafil	121	Genitourinary Agents	Genitourinary Agents, Other		No		No
920	125	calcium acetate	122	Genitourinary Agents	Phosphate Binders		No		No

All RxCUIs Submitted tab

The All RxCUIs Submitted tab is just what the name implies. This is the list of all drugs on the drug list(s) being analyzed. It looks like this:



	RxCUI	Retired?	Reassigned RxCUI	Crosswalk Status	Chemically Distinct Drug ID	Chemically Distinct Drug	Category & Class Impacted	Impact Category Class Revie	69364 Drug Lists	Drug List 1	Drug List 2
4	1000048	No	N/A	lic Release Crossv	399	Doxepin	29; 77	Yes		Covered	Not Covered
5	1000054	No	N/A	lic Release Crossv	399	Doxepin	29; 77	Yes		Covered	Not Covered
6	1000058	No	N/A	lic Release Crossv	399	Doxepin	29; 77	Yes		Covered	Not Covered
7	1000064	No	N/A	lic Release Crossv	399	Doxepin	29; 77	Yes		Covered	Not Covered
8	1000070	No	N/A	lic Release Crossv	399	Doxepin	29; 77	Yes		Covered	Not Covered
9	1000076	No	N/A	lic Release Crossv	399	Doxepin	29; 77	Yes		Covered	Not Covered
10	1000089	No	N/A	lic Release Crossv	36	alcaftadine	150	Yes		Covered	Not Covered
11	1000091	No	N/A	lic Release Crossv	399	Doxepin	112	Yes		Covered	Not Covered
12	1000097	No	N/A	lic Release Crossv	399	Doxepin	29; 77	Yes		Covered	Not Covered
13	1000114	No	N/A	lic Release Crossv	780	Medroxyprogesterone	135	Yes		Covered	Not Covered
14	1000126	No	N/A	lic Release Crossv	780	Medroxyprogesterone	135	Yes		Covered	Not Covered
15	1000135	No	N/A	lic Release Crossv	780	Medroxyprogesterone	135	Yes		Covered	Not Covered
16	1000141	No	N/A	lic Release Crossv	780	Medroxyprogesterone	135	Yes		Covered	Not Covered
17	1000153	No	N/A	lic Release Crossv	780	Medroxyprogesterone	135	Yes		Covered	Not Covered
18	1000405	No	N/A	lic Release Crossv	915	Norethindrone	135	Yes		Covered	Not Covered
19	1000479	N/A	N/A	RxNorm Database	N/A	Bisacodyl; Potassium Chloride; Sodium Chloride; Sodium Bicarbonate; POLYETHYLENE GLYCOL 3350	N/A	No		Covered	Not Covered
20	1000487	N/A	N/A	RxNorm Database	N/A	Estrogens, Conjugated (USP); Medroxyprogesterone	N/A	No		Covered	Not Covered
21	1000491	N/A	N/A	RxNorm Database	N/A	Estrogens, Conjugated (USP); Medroxyprogesterone	N/A	No		Covered	Not Covered
22	1000497	N/A	N/A	RxNorm Database	N/A	Estrogens, Conjugated (USP); Medroxyprogesterone	N/A	No		Covered	Not Covered
23	1000499	N/A	N/A	RxNorm Database	N/A	Estrogens, Conjugated (USP); Medroxyprogesterone	N/A	No		Covered	Not Covered
24	1000500	N/A	N/A	RxNorm Database	N/A	Estrogens, Conjugated (USP); Medroxyprogesterone	N/A	No		Covered	Not Covered
25	1000647	No	N/A	lic Release Crossv	1008	Pilocarpine	151; 149	Yes		Covered	Not Covered
26	1000673	N/A	N/A	RxNorm Database	N/A	Sulfacetamide	N/A	No		Covered	Not Covered
27	1000862	No	N/A	lic Release Crossv	1008	Pilocarpine	151; 149	Yes		Covered	Not Covered
28	1000895	N/A	N/A	RxNorm Database	N/A	Sulfacetamide; Sulfur	N/A	No		Covered	Not Covered
29	1000897	No	N/A	lic Release Crossv	1008	Pilocarpine	151; 149	Yes		Covered	Not Covered
30	1000913	No	N/A	lic Release Crossv	1008	Pilocarpine	111	Yes		Covered	Not Covered
31	1000946	N/A	N/A	RxNorm Database	N/A	Sulfacetamide; Sulfur	N/A	No		Covered	Not Covered
32	1001004	No	N/A	lic Release Crossv	1008	Pilocarpine	111	Yes		Covered	Not Covered
33	1001690	No	N/A	lic Release Crossv	770	Magnesium Sulfate; potassium sulfate; sodium sulfate	121	Yes		Covered	Not Covered
34	1001714	N/A	N/A	RxNorm Database	N/A	Sulfacetamide; Sulfur	N/A	No		Covered	Not Covered
35	1001718	N/A	N/A	RxNorm Database	N/A	Sulfacetamide; Sulfur	N/A	No		Covered	Not Covered
36	1002300	No	N/A	lic Release Crossv	902	nilotinib	50	Yes		Covered	Not Covered
37	1005767	N/A	N/A	RxNorm Database	N/A	Sulfacetamide; Sulfur	N/A	No		Covered	Not Covered
38	1005831	No	N/A	lic Release Crossv	1043	prednisolone	128; 34	Yes		Covered	Not Covered
39	1005834	N/A	N/A	RxNorm Database	N/A	Sulfacetamide; Sulfur	N/A	No		Covered	Not Covered
40	1005835	N/A	N/A	RxNorm Database	N/A	Sulfacetamide; Sulfur	N/A	No		Covered	Not Covered
41	1005928	No	N/A	lic Release Crossv	1284	ulipristal	134; 135	Yes		Covered	Not Covered
42	1006057	N/A	N/A	RxNorm Database	N/A	Sulfacetamide; Sulfur	N/A	No		Covered	Not Covered
43	1006065	N/A	N/A	RxNorm Database	N/A	Ethinyl Estradiol; Levonorgestrel; Inert Ingredients	N/A	No		Covered	Not Covered
44	1006107	N/A	N/A	RxNorm Database	N/A	Sulfacetamide	N/A	No		Covered	Not Covered

On the drug list tab of their Rx Drug Templates, a carrier can indicate that a drug list does not cover a particular drug in one of two ways. The carrier can either list the RxCUI and say "Not Covered", or can simply not list the RxCUI.

There are several ways we can sort this tab. Probably the main thing someone would use this tab for is to determine whether a drug is covered. The default is for this tab to show the information sorted numerically by RxCUI. This is a good way to sort if you are looking to see whether a particular drug is covered and you know the RxCUI. More likely, you're going to want to search by the name of the drug. So you would sort the Chemically Distinct Drug column alphabetically. That way, you could just scroll to it (or show that it was not on the list). To sort

the drug list by chemically distinct drug, go to that column, click on the arrow (red arrow) and choose one of the first 2 choices (alphabetically A-Z, or alphabetically Z-A).

You can also search this tab using the "Find & Select" tool, in the upper right hand corner (green arrow in screen shot above). This works just like the one in Word. It can save you a lot of time, because you won't have to scroll through thousands of lines.

This tab used to list drugs that affect more than one Category Class separately from drugs that affect only one. However, that was problematic, and we were happy to see that this is no longer the case. Thank you, CCIIO!

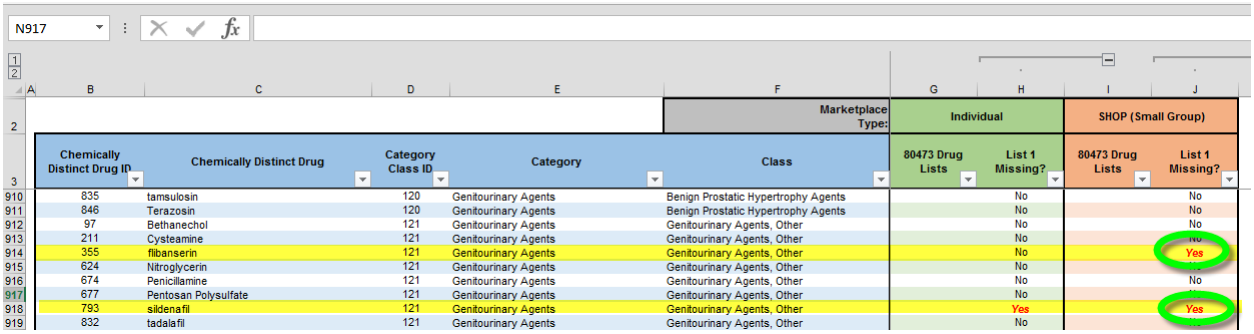
It is helpful to understand what information is on each tab, and how it is presented. Then, you can consider how you should sort in order to answer the particular question you are trying to answer.

One last bit of information about the Drug Count Tool and these last two tabs, the Category Class Details and the All RxCUIs Submitted tabs. The difference between Category Classes and RxCUIs can matter.

Remember that Category Classes are groups of drugs, and that RxCUIs are much more specific – a specific drug in a specific dose and specific route of administration (oral, IV, topical). It is the nature of drugs that certain doses and preparations of a drug, but not others, are effective for certain conditions. Carriers sometimes cover a particular drug, but only in certain doses and preparations. That's why they have to list the drug by RxCUI. That means that covering a certain drug may count toward satisfying *some* of the Category Classes it affects, but not others. In these cases, you have to look closer.

Here's an example (it's an old example, but it illustrates the point).

A carrier's Small Group plan fails Category Class 121: Genitourinary Agents, Other. They have looked at the Category Class Details tab, sorted by Category Class ID, to see which drugs they can use to complete this Category Class. They saw this:



						Marketplace Type:	Individual		SHOP (Small Group)	
	Chemically Distinct Drug ID	Chemically Distinct Drug	Category Class ID	Category	Class		80473 Drug Lists	List 1 Missing?	80473 Drug Lists	List 1 Missing?
910	835	tamsulosin	120	Genitourinary Agents	Benign Prostatic Hypertrophy Agents			No		No
911	846	Terazosin	120	Genitourinary Agents	Benign Prostatic Hypertrophy Agents			No		No
912	97	Bethanechol	121	Genitourinary Agents	Genitourinary Agents, Other			No		No
913	211	Cysteamine	121	Genitourinary Agents	Genitourinary Agents, Other			No		No
914	355	flibanserin	121	Genitourinary Agents	Genitourinary Agents, Other			No		Yes
915	624	Nitroglycerin	121	Genitourinary Agents	Genitourinary Agents, Other			No		
916	674	Penicillamine	121	Genitourinary Agents	Genitourinary Agents, Other			No		No
917	677	Pentosan Polysulfate	121	Genitourinary Agents	Genitourinary Agents, Other			No		
918	793	sildenafil	121	Genitourinary Agents	Genitourinary Agents, Other			Yes		Yes
919	832	tadalafil	121	Genitourinary Agents	Genitourinary Agents, Other			No		

Looking at the results, they saw that they could cover either Flibanserin or Sildenafil in order to meet the benchmark coverage of this Category Class, because those are the two drugs that are

missing from their Drug List in this Category Class. (See green circles.) But the carrier is confused because the Drug List for their small group plans *does* include Sildenafil.

You re-sort the Category Class Details tab by chemically distinct drug, to find Sildenafil, and you see this:

				Marketplace Type:	Individual		SHOP (Small Group)	
Chemically Distinct Drug ID	Chemically Distinct Drug	Category Class ID	Category	Class	80473 Drug Lists	List 1 Missing?	80473 Drug Lists	List 1 Missing?
793	sildenafil	121	Genitourinary Agents	Genitourinary Agents, Other		Yes		Yes
793	sildenafil	158	Respiratory Tract/ Pulmonary Agents	Phosphodiesterase Inhibitors, Airways Disease		No		No
793	sildenafil	159	Respiratory Tract/ Pulmonary Agents	Pulmonary Antihypertensives		No		No
794	silodosin	120	Genitourinary Agents	Benign Prostatic Hypertrophy Agents		No		No
795	silver sulfadiazine	16	Antibacterials	Sulfonamides		No		No

Huh? It's all Chemically Distinct Drug ID 793, Sildenafil, but it says it's covered for Category Classes 158 and 159 (Respiratory / Pulmonary Agents) and *not* for Category Class 121. How can the same drug be covered and counted toward one Category Class, and not another? The answer is dosage and route of administration, represented by RxCUIs.

Look at the "All RxCUIs Submitted" tab. This is all the RxCUIs the carrier covers. We want to know about Sildenafil, so we sort by Chemically Distinct Drug. We see this.

								Marketplace Type:	Individual		SHOP (Small Group)	
RxCUI	Retired?	Reassigned RxCU	Crosswalk Status	EHB-Rx Classification	Chemically Distinct Drug ID	Chemically Distinct Drug	Category & Class Impacted	Impact Category Class Revie	80473 Drug Lists	Drug List 1	80473 Drug Lists	Drug List 1
1307431	No	N/A	EHB Rx Crosswalk	N/A	793	sildenafil	158; 159	Yes		Covered		Covered
581645	No	N/A	EHB Rx Crosswalk	N/A	793	sildenafil	158; 159	Yes		Covered		Covered
577033	No	N/A	EHB Rx Crosswalk	N/A	793	sildenafil	158; 159	Yes		Covered		Covered

The carrier has listed 3 different RxCUIs for Sildenafil on its Rx Drug Template: 1307431, 581645, and 577033. We know what RxCUIs are, so we know that this means the carrier covers three different dosages and routes of administration of Sildenafil. But we're not clinicians, so we don't know what doses and routes of administration are used for what conditions. Fortunately, Google does.

When we Google these RxCUIs, we see that they are for Sildenafil in the 10 Mg/Ml oral suspension, the 10 Mg. oral tablet, and the 20 Mg. oral tablet. (The Google searches used were simply "RxCUI 1307431", then "RxCUI 581645", and "RxCUI 577033".) If we Google the drug Sildenafil (that Google search was simply "sildenafil"), we see that these dosages are for pulmonary hypertension, which is not a surprise because we know that these drugs satisfy two of the Respiratory / Pulmonary Agents Category Classes.

What *is* a surprise is to discover that Sildenafil is also used for erectile dysfunction under the trade name Viagra. But the dosage is much higher (25 to 100 mg. per dose) when used for this indication.

Mystery solved. Erectile dysfunction would fit with the Category Class "Genitourinary Agents, Other", but the dosages of Sildenafil that would be used for this indication are not covered. Sildenafil in the 25, 50, or 100 mg. tablet, which are used for erectile dysfunction, have the

RxCUIs 213269, 213270, 213271. None of those RxCUIs are covered on the Small Group Drug List for our carrier. We can determine that by either sorting by RxCUI and seeing that those numbers are not there, or we can use the Find & Select button to search for them and see that they are not there.

This information is useful simply to familiarize you with the information available in the Drug Count Tool results, and how it can be used. It's also specifically useful to carriers because they can use it to understand and resolve "failed" drug tool results. Finally, it's specifically useful to give OIC Analysts insight into a particular justification that they may see for a failed result, and why is not legitimate.

Bottom line:

When you first see that a drug is covered, but is not being counted toward a particular Category Class which it seemingly should satisfy, the natural conclusion is that there is a bug in the Drug Count Tool. Instead, think RxCUI. One of two things is probably going on: either the drug is too new to be on the Rx Crosswalk, or else the appropriate RxCUIs are not listed on the carrier's Rx Drug Template.

Troubleshooting begins by looking at the Category Class Details tab. If the drug is listed there, that means it is on the Rx Crosswalk. So the problem isn't that the drug is too new. If the drug is on the Rx Crosswalk, but isn't being counted toward a particular Category Class, the problem is probably that the applicable RxCUI was not listed as covered on the Rx Drug Template. In other words, the drug is not covered in the correct dosage and route of administration to satisfy that Category Class.

Substitute RxCUIs Tab

The final tab on the Category & Class Drug Count Tool results is the "Substitute RXCUIs" tab. The "Substitute RXCUIs" tab identifies any RxCUIs on the EHB Rx Crosswalk that contain chemically distinct drugs that are NOT covered on a drug list being tested. We discussed how you can use the Category Class Details tab to identify drugs that can be added to a formulary when the Tool shows it does not meet the benchmark requirements. The Substitute RxCUIs tab is a new tab added for Plan Year 2020 that can also be used for this same purpose.

Formulary Review Suite

The Formulary Review Suite is another electronic Tool for reviewing a carrier's formularies. It contains two Tools: the Non-Discrimination Formulary Outlier Review Tool and the Non-Discrimination Clinical Appropriateness Tool. Carriers must run the Non-Discrimination Clinical Appropriateness Tool and provide results to OIC. They are not required to run the Formulary Outlier Review Tool, because it will not return meaningful results when run on only one carrier's formularies. (This will be explained below in the description of this Tool.)

Both Tools analyze formularies to determine whether the particular drugs covered, and the restrictions placed upon those drugs, appear to have a discriminatory effect on people with particular health conditions. Each Tool analyzes this in a different way.

In the case of these tools, "formulary" means the combination of a drug list with two coverage criteria: preauthorization and step therapy requirements. Preauthorization and step therapy requirements are the "restrictions" the Tool analyzes.

Like the Drug Count Tool, the Formulary Review Suite uses Plans and Benefits Template data pulled from the Master Review tool, and the Rx Drug Template. That allows it to report results at the plan level. But also like the Drug Count tool, the Formulary Review Suite's results are based on particular drug lists, so every plan that uses a particular Drug List will have the same results. That's because the restrictions applied to each drug are part of the drug list. These restrictions do not differ by plan.

Here's an example of a carrier's drug list (part of the Rx Drug Template) that we looked at regarding the Drug Count tool:

A1 | Drug Lists

	A	B	C	D
1	Drug Lists	All fields with an asterisk (*) are required. To validate the template, press the		
2		Click the Create Formulary IDs button (or Ctrl + Shift + C) to create Formular		
3	Add Drug List	After creating Formulary IDs, select the ID from the drop down in Column A a		
4		Select how many tiers a formulary uses from Number of Tiers and unused row		
5	Remove Drug List	Enter all RXCUIs on the Drug Lists sheet. To add more drug lists, click Add L		
6		Drug List ID 1		
7	RXCUI*	Tier Level*	Prior Authorization Required	Step Therapy Required
8	Required: Enter the RXCUI	Required: Select the Tier this drug is in, or select NA if this drug is not a part of this Drug List	Required if Tier Level is not NA: Select "Yes" if Prior Authorization is Required	Required if Tier Level is not NA: Select "Yes" if Step Therapy is Required
693	206739	1	No	No
694	206750	1	No	No
695	206791	1	No	No
696	206792	1	No	No
697	206831	4	No	No
698	206842	1	No	No
699	206860	1	No	No
700	206905	1	No	No
701	206913	1	No	No
702	206917	1	No	No
703	206977	1	Yes	No
704	206986	4	No	No
705	206987	4	No	No
706	206994	1	No	No
707	206997	1	No	No
708	207029	2	No	No
709	207035	2	No	No
710	207052	2	Yes	Yes
711	207059	2	No	No
712	207088	1	No	No
713	207100	1	No	No
714	207132	1	No	Yes
715	207166	1	No	No
716	207167	1	No	No
717	207169	1	No	No
718	207170	1	No	No
719	207171	1	No	No
720	207172	1	No	No

Formulary Tiers | Drug Lists

For each drug, the carrier identifies on the drug list whether that drug has a preauthorization requirement, and whether it has a step therapy requirement. Here, you can see that drug 206977 requires prior authorization, but not step therapy (yellow circle). Drug 207052 requires both prior authorization and step therapy (green circle).

Non-Discrimination Clinical Appropriateness Tool

The Non-Discrimination Clinical Appropriateness Tool ("Clinical Appropriateness Tool") analyzes formularies to determine whether they are designed in a way that discourages those with certain health conditions from enrolling in plans using that formulary. The ACA prohibits discrimination on the basis of health status.

The Clinical Appropriateness Tool analyzes formularies in a different way than the Formulary Outlier Tool. The Clinical Appropriateness Tool is programmed to look at the coverage of drugs used to treat 10 different chronic diseases, each of which can result in large claims under a plan.

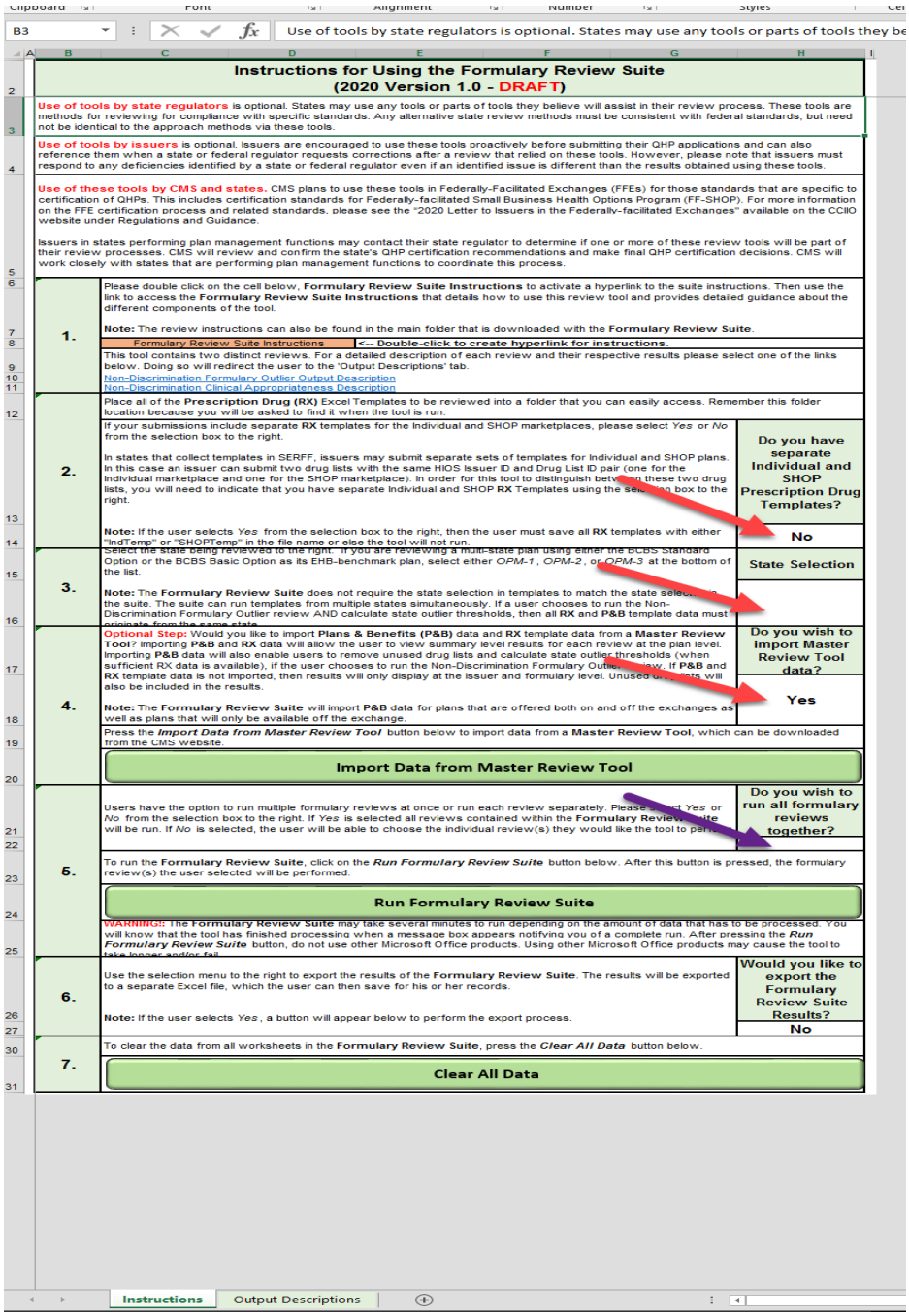
For Plan Year 2020, those diseases are: bipolar disorder, breast cancer, diabetes, hepatitis C, HIV, multiple sclerosis, opioid use disorder, prostate cancer, rheumatoid arthritis, and schizophrenia.

For each disease, HHS clinicians have determined a threshold number of drugs in each applicable class that a formulary would need to cover in order to be found not to discriminate against people with that disease. For example, the clinicians determined that a formulary would not discriminate against those with bipolar disorder if it covers at least 4 antidepressants, 4 mood stabilizers, and 7 second-generation antipsychotic drugs.

Because it measures formularies against preset clinical thresholds, you can run this Tool on a single Drug List, or a single carrier's portfolio of plans, and obtain meaningful results.

Instructions Tab

The Instructions tab guides the user of the Formulary Review Suite to input the data to be analyzed. It is a great deal like the Instructions tab of the Drug Count Tool. Like that Tool, the Formulary Review Suite has data boxes that must be completed. (See red arrows in the screen shot below.)



B3 | Use of tools by state regulators is optional. States may use any tools or parts of tools they be

Instructions for Using the Formulary Review Suite
(2020 Version 1.0 - DRAFT)

Use of tools by state regulators is optional. States may use any tools or parts of tools they believe will assist in their review process. These tools are methods for reviewing for compliance with specific standards. Any alternative state review methods must be consistent with federal standards, but need not be identical to the approach methods via these tools.

Use of tools by issuers is optional. Issuers are encouraged to use these tools proactively before submitting their QHP applications and can also reference them when a state or federal regulator requests corrections after a review that relied on these tools. However, please note that issuers must respond to any deficiencies identified by a state or federal regulator even if an identified issue is different than the results obtained using these tools.

Use of these tools by CMS and states. CMS plans to use these tools in Federally-Facilitated Exchanges (FFEs) for those standards that are specific to certification of QHPs. This includes certification standards for Federally-facilitated Small Business Health Options Program (FF-SHOP). For more information on the FFE certification process and related standards, please see the "2020 Letter to Issuers in the Federally-facilitated Exchanges" available on the CCIIO website under Regulations and Guidance.

Issuers in states performing plan management functions may contact their state regulator to determine if one or more of these review tools will be part of their review processes. CMS will review and confirm the state's QHP certification recommendations and make final QHP certification decisions. CMS will work closely with states that are performing plan management functions to coordinate this process.

1. Please double click on the cell below, **Formulary Review Suite Instructions** to activate a hyperlink to the suite instructions. Then use the link to access the **Formulary Review Suite Instructions** that details how to use this review tool and provides detailed guidance about the different components of the tool.

Note: The review instructions can also be found in the main folder that is downloaded with the **Formulary Review Suite**.

Formulary Review Suite Instructions <-- **Double-click to create hyperlink for instructions.**

This tool contains two distinct reviews. For a detailed description of each review and their respective results please select one of the links below. Doing so will redirect the user to the 'Output Descriptions' tab.

Non-Discrimination Formulary Outlier Output Description
Non-Discrimination Clinical Appropriateness Description

2. Place all of the **Prescription Drug (RX)** Excel Templates to be reviewed into a folder that you can easily access. Remember this folder location because you will be asked to find it when the tool is run.

If your submissions include separate **RX** templates for the Individual and SHOP marketplaces, please select *Yes* or *No* from the selection box to the right.

In states that collect templates in SERFF, issuers may submit separate sets of templates for Individual and SHOP plans. In this case an issuer can submit two drug lists with the same HIOS Issuer ID and Drug List ID pair (one for the Individual marketplace and one for the SHOP marketplace). In order for this tool to distinguish between these two drug lists, you will need to indicate that you have separate Individual and SHOP **RX** Templates using the selection box to the right.

Do you have separate Individual and SHOP Prescription Drug Templates?

No

Note: If the user selects *Yes* from the selection box to the right, then the user must save all **RX** templates with either "IndTemp" or "SHOPTemp" in the file name or else the tool will not run.

3. Select the state being reviewed to the right. If you are reviewing a multi-state plan using either the BCBS Standard Option or the BCBS Basic Option as its EHB-benchmark plan, select either *OPM-1*, *OPM-2*, or *OPM-3* at the bottom of the list.

State Selection

Note: The **Formulary Review Suite** does not require the state selection in templates to match the state selected in the suite. The suite can run templates from multiple states simultaneously. If a user chooses to run the Non-Discrimination Formulary Outlier review AND calculate state outlier thresholds, then all **RX** and **P&B** template data must originate from the same state.

4. **Optional Step:** Would you like to import **Plans & Benefits (P&B)** data and **RX** template data from a **Master Review Tool**? Importing **P&B** and **RX** data will allow the user to view summary level results for each review at the plan level. Importing **P&B** data will also enable users to remove unused drug lists and calculate state outlier thresholds (when sufficient RX data is available), if the user chooses to run the Non-Discrimination Formulary Outlier review. If **P&B** and **RX** template data is not imported, then results will only display at the issuer and formulary level. Unused drug lists will also be included in the results.

Do you wish to import Master Review Tool data?

Yes

Note: The **Formulary Review Suite** will import **P&B** data for plans that are offered both on and off the exchanges as well as plans that will only be available off the exchange.

Press the ***Import Data from Master Review Tool*** button below to import data from a **Master Review Tool**, which can be downloaded from the CMS website.

Import Data from Master Review Tool

5. Users have the option to run multiple formulary reviews at once or run each review separately. Please select *Yes* or *No* from the selection box to the right. If *Yes* is selected all reviews contained within the **Formulary Review Suite** will be run. If *No* is selected, the user will be able to choose the individual review(s) they would like the tool to perform.

Do you wish to run all formulary reviews together?

To run the **Formulary Review Suite**, click on the ***Run Formulary Review Suite*** button below. After this button is pressed, the formulary review(s) the user selected will be performed.

Run Formulary Review Suite

WARNING!: The **Formulary Review Suite** may take several minutes to run depending on the amount of data that has to be processed. You will know that the tool has finished processing when a message box appears notifying you of a complete run. After pressing the ***Run Formulary Review Suite*** button, do not use other Microsoft Office products. Using other Microsoft Office products may cause the tool to take longer and/or fail.

6. Use the selection menu to the right to export the results of the **Formulary Review Suite**. The results will be exported to a separate Excel file, which the user can then save for his or her records.

Note: If the user selects *Yes*, a button will appear below to perform the export process.

Would you like to export the Formulary Review Suite Results?

No

7. To clear the data from all worksheets in the **Formulary Review Suite**, press the ***Clear All Data*** button below.

Clear All Data

Instructions | Output Descriptions

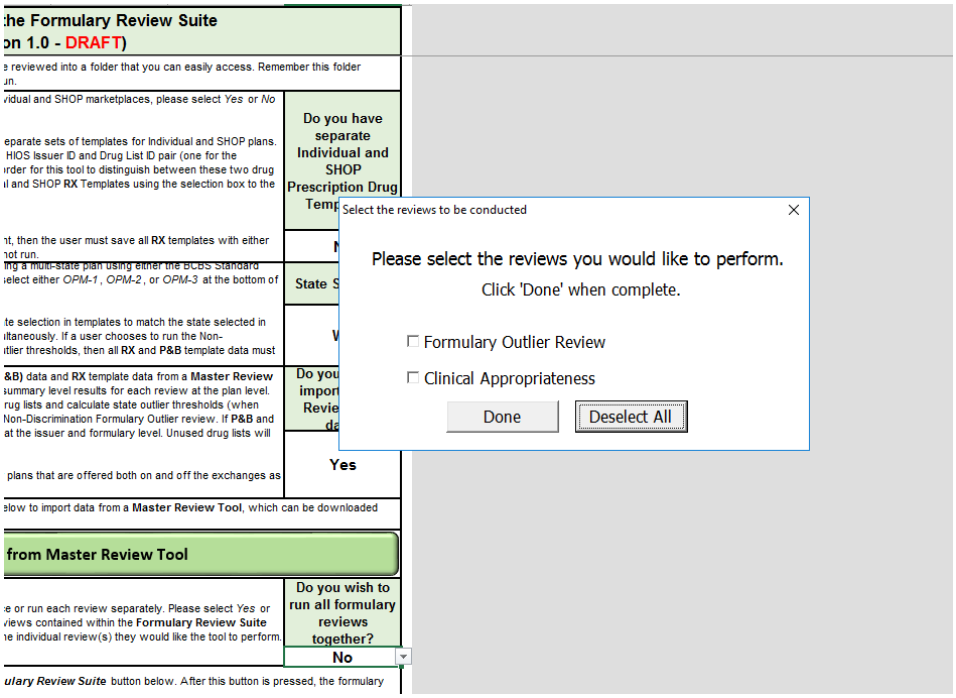
The data that must be input includes information about whether the RX Drug Templates include separate individual and small group templates, and the state in which the plans are to be sold. If the data includes separate individual and small group RX Drug Templates, the Tool will display the results for each separately. The state must be specified so that the Tool uses the correct thresholds. (Washington has traditionally used the default thresholds pre-loaded into the Tool.)

Although OIC does not use this feature, the Tool is able to run the review against multiple state thresholds at once. OIC does not use the "Would you like to export the Formulary Review Suite results" box.

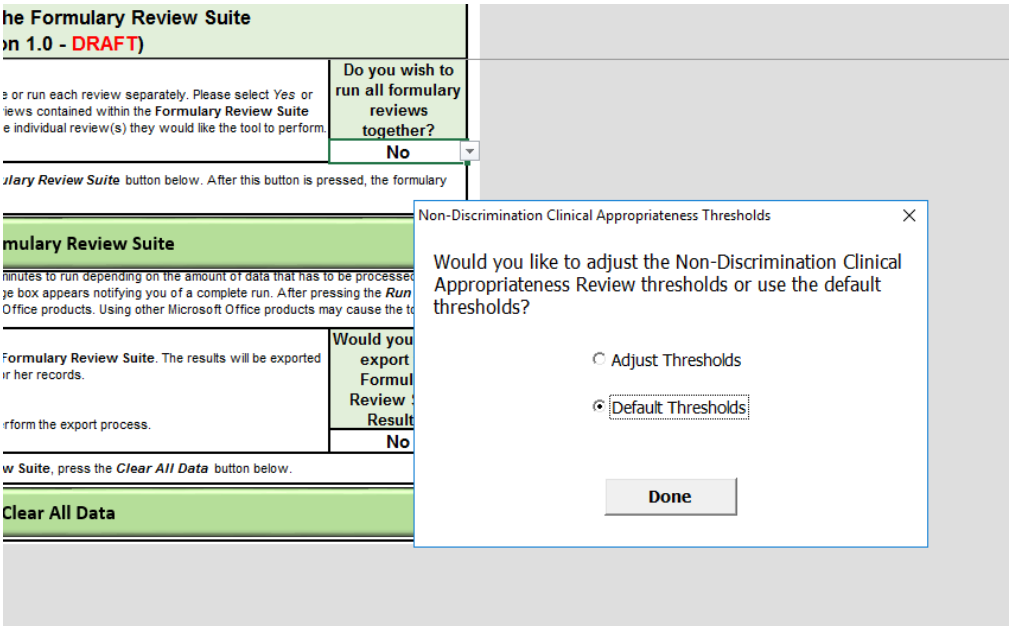
When the person running the Tool clicks on these boxes, a dropdown menu of choices appears. These boxes must be completed or the Tool will not run (a warning appears, reminding the user to input the data).

The Plans and Benefits data must be imported into the Drug Count Tool from the Master Review Tool by clicking on the big green "Import Data from Master Review Tool" button. This allows the Tools to display results for each plan, and also to remove any unused drug lists from the result. The user clicks on the button, and a dialog box opens asking the user to click on the folder containing the Master Review Tool data. The Tool then imports that data.

The third dialog box on the Instructions tab asks, "Do you wish to run all formulary reviews together?" (See purple arrow in screen shot, above). Carriers should answer "No" to this question, because the Formulary Outlier Review Tool will not return meaningful results when run on only one carrier's formularies. When the user clicks "No", a dialog box appears (see screen shot, below). Carriers should click the radio button next to "Clinical Appropriateness."



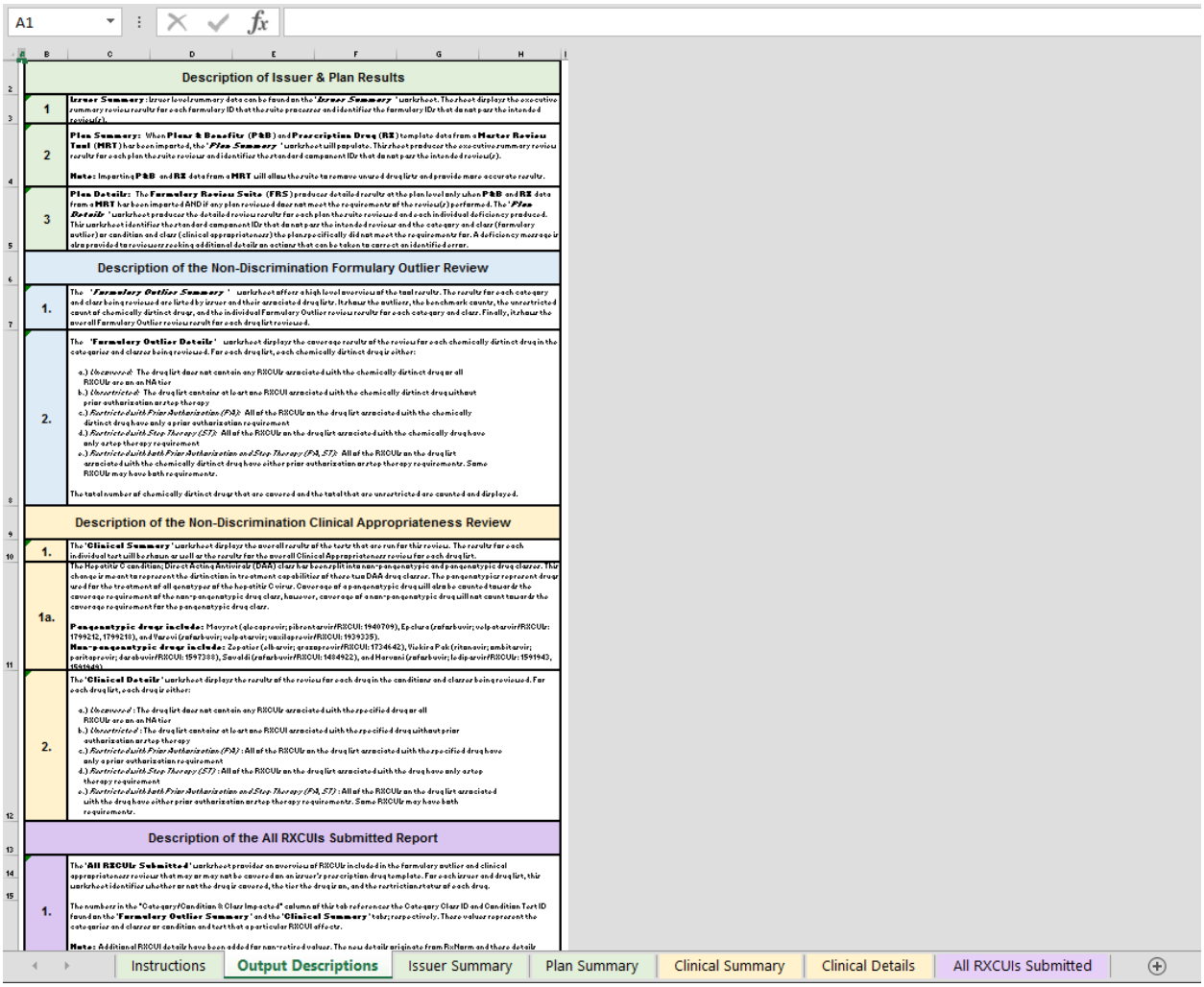
Next, the user clicks on the "Run Formulary Review Suite" button. A dialog box opens asking the user whether they want to adjust the thresholds or use the default thresholds. OIC asks carriers to click on "Default Thresholds".



The Tool then prompts the user to select the folder in which the Prescription Drug Templates are stored. Once that is done, the Tool runs. When run on only one carrier's data, the Tool takes about 15 seconds to run. The results will automatically be shown when the Tool has completed, taking the user to the "Plan Summary" tab. But we will discuss the tabs in order.

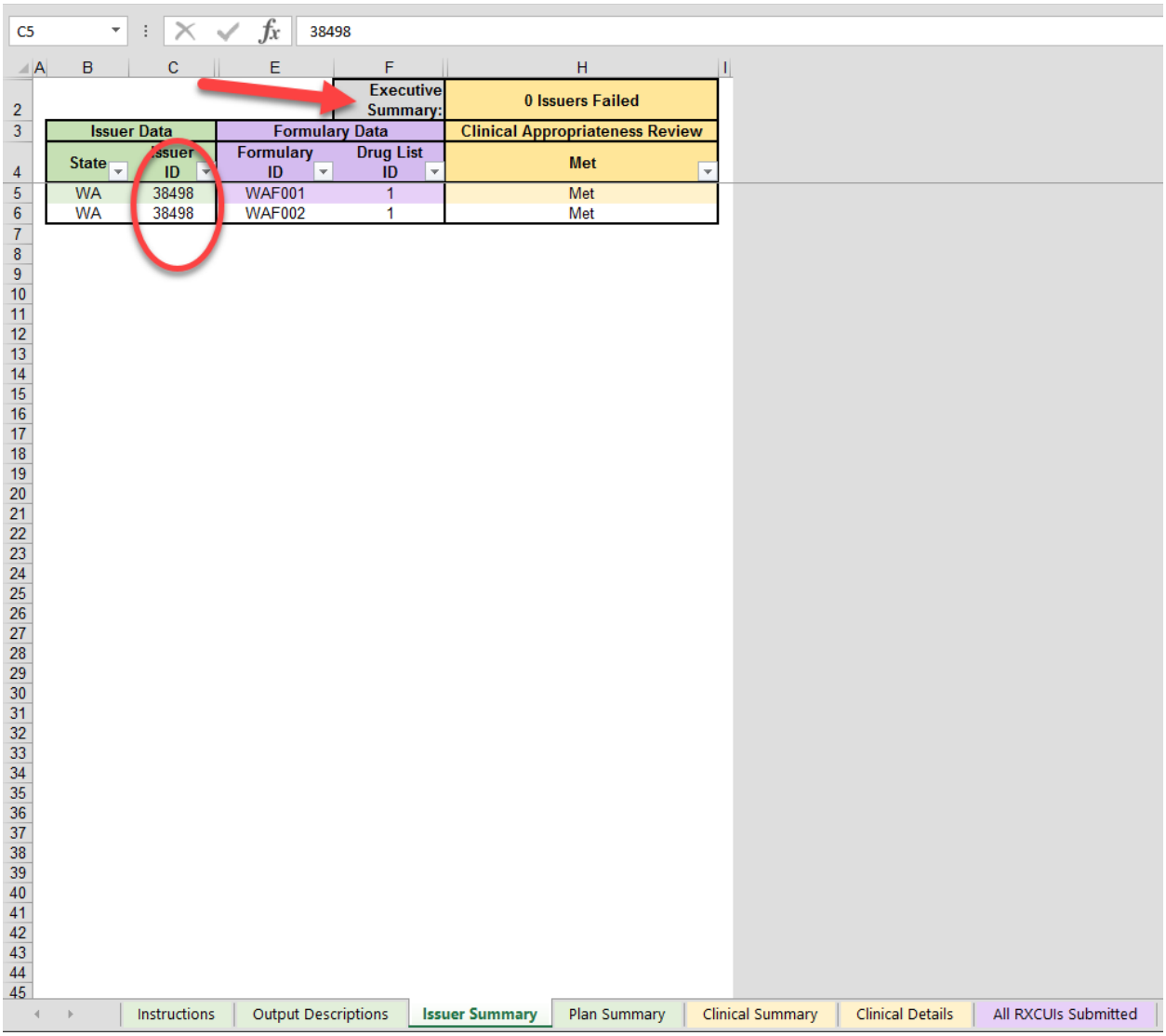
Output Descriptions Tab

The Output Descriptions tab describes what each tool does, and gives a brief description of the information found on the results tabs. This tab is a resource for the user to understand what the results mean and can be helpful in troubleshooting issues.



Issuer Summary Tab

The Issuer Summary tab is a high-level results tab. It shows the results for both Tools within the Formulary Review Suite (when both Tools are run). At the top, it has an Executive Summary field where it shows how many issuers had drug lists that failed the reviews. (See red arrow in screen shot below.) To "fail" the Clinical Appropriateness review means that a carrier has a drug list that covers fewer than the threshold number of drugs for one of the conditions analyzed. There is more information about both of these results in the discussions of each particular test, below.



Executive Summary:	0 Issuers Failed

Issuer Data		Formulary Data		Clinical Appropriateness Review
State	Issuer ID	Formulary ID	Drug List ID	Met
WA	38498	WAF001	1	Met
WA	38498	WAF002	1	Met

Since carriers to run this Tool themselves on their own formularies, the results you will usually see will be those for only one carrier's formularies. That means that the results in this field will be only a "0" or a "1". Either the carrier had one or more drug lists that failed the review, or it did not. The screen shot above shows results for the Suite run on one issuer. Only if the Suite is run on multiple issuers will the numbers be different.

The green "Issuer Data" columns on the left show which issuer's formularies are being analyzed. The carrier is represented by its HIOS Issuer ID (red circle). The results are provided on this tab for each formulary analyzed, and the tab shows which drug list each formulary uses (purple columns).

Note that the Executive Summary in the screen shot above shows that this carrier's formularies passed the Clinical Appropriateness Tool (red arrow). If the results on this high-level tab show

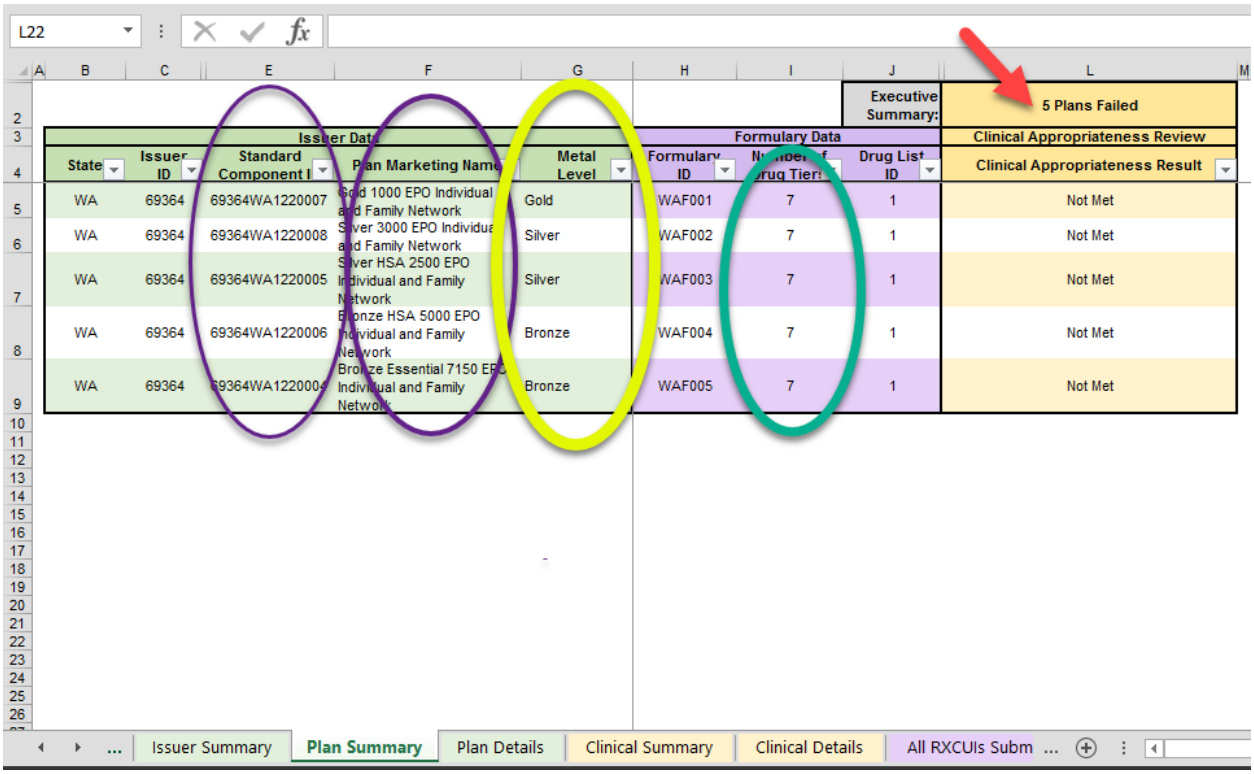
that all of the carrier's formularies passed the Tool, that is all you need to know. However, if the results show that one or more formularies failed the Tools, you need more information.

Like the Drug Count Tool, all plans that use the same drug list will have the same result on the Clinical Appropriateness Tool. That's because the data reviewed by this Tool is all contained in the drug list. That data is: drug name, drug tier, and whether the drug is subject to prior authorization or step therapy requirements.

The yellow column to the far right shows the results of the Non-Discrimination Clinical Appropriateness Tool. "Not Met" in this column means that a particular formulary does not meet the threshold for coverage of drugs for one or more of the diseases tested.

Plan Summary Tab

The Plan Summary tab is very similar to the Issuer Summary tab, but provides additional information.



Executive Summary:	5 Plans Failed

Issuer Data					Formulary Data			Clinical Appropriateness Review
State	Issuer ID	Standard Component I	Plan Marketing Name	Metal Level	Formulary ID	Number of Drug Tiers	Drug List ID	Clinical Appropriateness Result
WA	69364	69364WA1220007	Gold 1000 EPO Individual and Family Network	Gold	WAF001	7	1	Not Met
WA	69364	69364WA1220008	Silver 3000 EPO Individual and Family Network	Silver	WAF002	7	1	Not Met
WA	69364	69364WA1220005	Silver HSA 2500 EPO Individual and Family Network	Silver	WAF003	7	1	Not Met
WA	69364	69364WA1220006	Bronze HSA 5000 EPO Individual and Family Network	Bronze	WAF004	7	1	Not Met
WA	69364	69364WA1220004	Bronze Essential 7150 EPO Individual and Family Network	Bronze	WAF005	7	1	Not Met

On this tab, the green "Issuer Data" columns include everything in those columns on the Issuer Summary tab. In addition, these columns on the Plan Summary tab show the Standard Component ID (also called a SCID, or HIOS plan ID) (red circle) and plan marketing name (purple circle) of each plan. These columns also include the metal level of each plan (yellow circle).

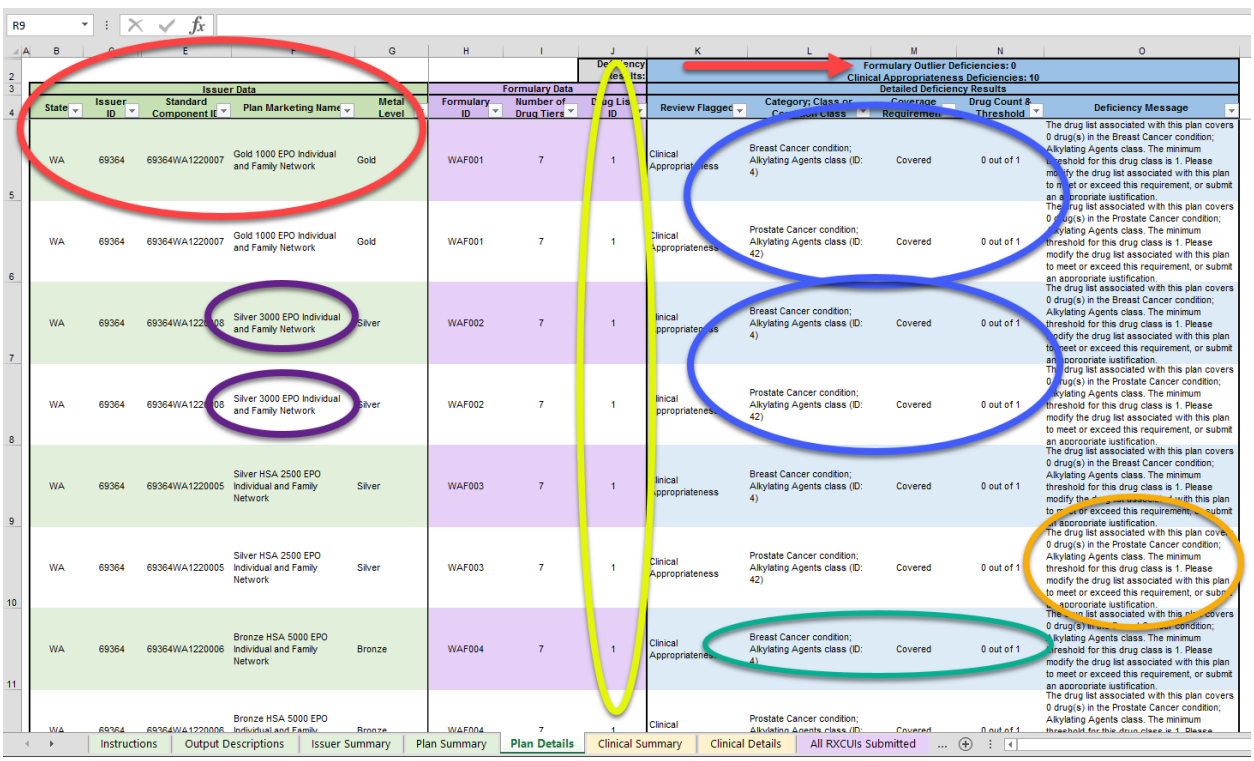
The purple "Formulary Data" columns also contain the same information as those columns on the Issuer Summary tab. But in addition, these columns on the Plan Summary tab also include the number of drug tiers for each plan's formulary (green circle).

Like the Issuer Summary tab, this tab tells you everything you need to know when, as with the result above, every plan has passed both tools. But if any plans failed, then we need more information.

In the screen shot above, the Executive Summary shows that this carrier's drug list failed the Clinical Appropriateness Tool (red arrow). That means we need to do further review.

Plan Details Tab

The Plan Details tab includes detailed information about each deficiency flagged by the Tool. It begins with 5 green columns giving details about the plan where the deficiency occurs (red circle). The details are: state, issuer ID, Standard Component ID (HIOS plan ID), plan marketing name, and metal level. If a plan shows more than one deficiency, each deficiency found in that plan will be listed on a separate row because detailed information is given about each deficiency. That means you may see the same plan listed on more than one row (purple circles).



Next, the tab includes 3 purple columns which provide information about the formulary for that plan, including the Formulary ID, number of drug tiers, and drug list ID (green circle). The drug list ID is important because the information analyzed by this Tool is all contained on the drug list being analyzed. That means that the results for each drug list will be the same. Therefore, if a

carrier uses only one drug list, the deficiencies for each plan will be the same. For example, our sample result in the screen shot shows plans that all use drug list 1 (yellow circle). Therefore, you will notice that the same two deficiencies are shown for each plan (blue circles).

The blue columns show the results of the Tool's analysis of the formularies. At the top is an executive summary (red arrow) which will show the overall results of the Review Suite Tools that were run. The first blue column tells which Tool showed the particular result. (In the sample results, we did not run the Formulary Outlier Tool.) The next blue column to the right lists the particular tested condition, and the Category Class of drugs the Tool shows is deficient. The third blue column shows the requirement to cover drugs in that particular Category Class. (If there is a requirement to cover drugs in this Category Class without restriction, this column will read "Covered, unrestricted".)

The next column to the right shows the number of deficiencies in the formulary being analyzed, by listing the number of covered drugs, and the threshold requirement. In this sample, we see that the threshold for coverage of drugs in the "Alkylating Agents" Class for treatment of breast cancer is 1. However, the formulary being tested does not cover any drugs in this Class (green circle).

The far right column, "Deficiency Message", contains information that specifically explains the deficiency, and tells the carrier what to do to address the deficiency. For example, the formulary for the "Silver HSA 2500 EPO Individual and Family Network" plan, WAF003, does not contain a drug in the "Alkylating Agents" class for treatment of prostate cancer, but the threshold to pass the Tool is one drug in this Class for this disease. So the deficiency message instructs the carrier to either add a drug in this Class to meet the requirement, or submit a justification explaining why the formulary is not discriminatory to those with prostate cancer, despite not meeting the requirement (orange circle).

Each of the tabs reviewed so far pertain to both Tools in the Formulary Review Suite. The next tabs discussed apply to only one of the two Tools. We will first look at the tabs that apply only to the Clinical Appropriateness Tool, since that is the Tool carriers will run on their formularies. The final tab, the "All RxCUIs Submitted" tab, again applies to both Tools and will be discussed, as relevant, in the sections for both Tools.

Clinical Summary Tab

The Clinical Summary tab includes an executive summary at the top showing the overall results (red arrow in screen shot below). The results are labeled by the Tool used. The first result shows how many drug lists failed one or more tests (blue arrow), and the second result shows how many tests were not met (green arrow).

F5

			Clinical Appropriateness Result:	1 List Not Met	30 Tests Not Met	
Condition	Test Description	Condition Test ID	Threshold Selected	69364 Drug Lists	List 1 Test Count	List 1 Result
Bipolar Disorder	Coverage of drugs in the Antidepressants class.	1	4		0	Not Met
	Coverage of drugs in the Mood Stabilizers class.	2	4		1	Not Met
	Coverage of drugs in the Second Generation Antipsychotics class.	3	7		1	Not Met
Breast Cancer	Coverage of drugs in the Alkylating Agents	4	1		0	Not Met
	Coverage of drugs in the Antimetabolites class.	5	1		0	Not Met
	Coverage of drugs in the Aromatase Inhibitors class.	6	1		0	Not Met
	Coverage of drugs in the Folic Acid Metabolites class.	7	1		0	Not Met
	Coverage of drugs in the Miscellaneous class.	8	1		1	Met
	Coverage of drugs in the Selective Estrogen Receptor Modulators (SERM) class.	9	1		0	Not Met
	Coverage of drugs in the Targeted Therapy Inhibitors: Kinase and PARP class.	10	1		1	Met
Diabetes	Coverage of drugs in the Alpha Glucosidase Inhibitors class.	11	1		0	Not Met
	Coverage of drugs in the Biguanide class (Metformin) without prior authorization or step therapy (unrestricted).	12	1		0	Not Met
	Coverage of drugs in the Dipeptidyl Peptidase 4 (DPP-4) Inhibitors class.	13	1		4	Met
	Coverage of drugs in the Glucagon-Like Peptide-1 (GLP-1) Receptor Agonists class.	14	1		1	Met
	Coverage of drugs in the Insulin - Basals class without prior authorization or step therapy (unrestricted).	15	1		0	Not Met
	Coverage of drugs in the Insulin - Prandials class without prior authorization or step therapy (unrestricted).	16	1		0	Not Met
	Coverage of drugs in the Meglitinides class.	17	1		0	Not Met
	Coverage of drugs in the Miscellaneous class.	18	1		0	Not Met
	Coverage of drugs in the Sodium Glucose Co-Transporter 2 (SGLT2) Inhibitors class.	19	1		2	Met
	Coverage of drugs in the Sulfonylureas (2nd Generation) class.	20	1		0	Not Met
	Coverage of drugs in the Thiazolidinediones class.	21	1		0	Not Met
Hepatitis C	Coverage of drugs in the Non-Pangenotypic Direct Acting Antivirals (DAA) class.	22	1		1	Met
	Coverage of drugs in the Pangenotypic Direct Acting Antivirals (DAA) class.	23	1		0	Not Met
	Coverage of drugs in the Nucleoside Analogs class.	24	1		1	Met
	Coverage of drugs in the Combination Drugs class.	25	4		2	Not Met
	Coverage of drugs in the Integrase Strand Transfer Inhibitors class.	26	1		2	Met

... Issuer Summary | Plan Summary | Plan Details | Clinical Summary | Clinical Details | Errors | All RXCUIs Submitted

This particular executive summary shows that the drug list analyzed failed some of the tests (green arrow). If the executive summary had showed that the carrier's drug list(s) met all the thresholds in the Clinical Appropriateness Tool, then just like the high-level summaries seen in the other Electronic Review Tools, this Clinical Summary tab would tell us all we need to know - no further review would be needed.

The first three blue columns show how the results are organized. The Condition column to the far left shows each of the 10 chronic diseases for which thresholds are programmed into the Tool. The next column, "Test Description", lists the drug classes that are used to treat each disease. The third blue column is similar to the Category Class ID column in the Drug Count

Tool. It's merely a number used to denote the combination of condition and class of drugs used to treat that condition.

Note that the "Test Description" column sometimes includes the notation "(unrestricted)", and sometimes does not. In the screen shot above, see yellow highlighted row, which includes (unrestricted) in the Test Description, and the green highlighted area, which does not. This notation, where it appears, means that only drugs with no prior authorization or step therapy requirements count toward the threshold. Where this notation does not appear, any covered drugs count toward the threshold.

The purple column is the "Threshold Selected", which shows the number of drugs in each Class that the HHS clinical experts determined a formulary must cover in order not to discriminate against people with the tested condition. For example, look at the yellow-highlighted row. The Threshold Selected is 1 (red circle). This row means that HHS's clinical experts determined that, in order not to discriminate against diabetics, a formulary must cover at least 1 drug for diabetes in the Insulin – Basals Class without restriction.

Which brings us to the next set of columns, which are the green results columns. The first green column identifies the carrier (this column is really intended for when the Tool is run on multiple carriers' formularies). The next column shows the count of covered drugs in the relevant Class on the drug list being analyzed. If the count meets or exceeds the threshold, this number will be in regular, black font. If the count does not meet the threshold, the number will be in bold, red font. The far right column shows the result, either the threshold was "Met" or "Not Met". A "Not Met" result appears in bold, red font and highlighted.

Clinical Details Tab

The Clinical Details tab shows how each drug in each tested Class is covered. This tab, like the detailed results tabs in the Drug Count Tool, can be used to determine the changes a carrier needs to make to meet a failed test.

The first two blue columns show the tested conditions, and the Classes of drugs for each condition. The blue "Drug Name" column to the right of those is a list of each drug included in the Class being tested. These blue columns are followed by the results for the drug lists being tested.

The Clinical Details tab must be read in conjunction with the Clinical Summary tab, because the Clinical Details tab flags all restrictions and does not flag failed results. You will really only need the information on the Clinical Details tab that pertains to any failed results on the Clinical Summary tab.

Remember that the Test Description column on the Clinical Summary tab included some Classes in which drugs must be covered without restriction, and some Classes whose thresholds could be met even if the drugs were covered with restrictions. The Clinical Details tab shows *all*

restrictions and uncovered drugs in bold, red font so they are easy to see. Unlike bold, red font on other tabs, on this tab bold, red font does not mean an error or deficiency. To see where errors occurred, you need to look at the Clinical Summary tab. (See end of this "Clinical Details tab" section for an example.)

Let's look at these two tabs from a carrier's result to see how they work together. Below is a sample Clinical Summary tab from a result in which the carrier's drug list met all but two of the tests in the Clinical Appropriateness Tool.

Condition	Test Description	Condition Test ID	Threshold Selected	69364 Drug Lists	List 1 Test Count	List 1 Result
			Clinical Appropriateness Result:	1 List Not Met	2 Tests Not Met	
Bipolar Disorder	Coverage of drugs in the Antidepressants class.	1	4		4	Met
	Coverage of drugs in the Mood Stabilizers class.	2	4		5	Met
	Coverage of drugs in the Second Generation Antipsychotics class.	3	7		9	Met
Breast Cancer	Coverage of drugs in the Alkylating Agents	4	1		0	Not Met
	Coverage of drugs in the Antimetabolites class.	5	1		1	Met
	Coverage of drugs in the Aromatase Inhibitors class.	6	1		3	Met
	Coverage of drugs in the Folic Acid Metabolites class.	7	1		1	Met
	Coverage of drugs in the Miscellaneous class.	8	1		6	Met
	Coverage of drugs in the Selective Estrogen Receptor Modulators (SERM) class.	9	1		3	Met
	Coverage of drugs in the Targeted Therapy Inhibitors: Kinase and PARP class.	10	1		3	Met
Diabetes	Coverage of drugs in the Alpha Glucosidase Inhibitors class.	11	1		2	Met
	Coverage of drugs in the Biguanide class (Metformin) without prior authorization or step therapy (unrestricted).	12	1		1	Met
	Coverage of drugs in the Dipeptidyl Peptidase 4 (DPP-4) Inhibitors class.	13	1		4	Met
	Coverage of drugs in the Glucagon-Like Peptide-1 (GLP-1) Receptor Agonists class.	14	1		5	Met
	Coverage of drugs in the Insulin - Basals class without prior authorization or step therapy (unrestricted).	15	1		5	Met
	Coverage of drugs in the Insulin - Prandials class without prior authorization or step therapy (unrestricted).	16	1		2	Met
	Coverage of drugs in the Meglitinides class.	17	1		2	Met
	Coverage of drugs in the Miscellaneous class.	18	1		2	Met
	Coverage of drugs in the Sodium Glucose Co-Transporter 2 (SGLT2) Inhibitors class.	19	1		3	Met
	Coverage of drugs in the Sulfonylureas (2nd Generation) class.	20	1		3	Met
	Coverage of drugs in the Thiazolidinediones class.	21	1		1	Met
Hepatitis C	Coverage of drugs in the Non-Pangenotypic Direct Acting Antivirals (DAA) class.	22	1		5	Met
	Coverage of drugs in the Pangenotypic Direct Acting Antivirals (DAA) class.	23	1		2	Met
	Coverage of drugs in the Nucleoside Analogs class.	24	1		1	Met
	Coverage of drugs in the Combination Drugs class.	25	4		14	Met
	Coverage of drugs in the Integrase Strand Transfer Inhibitors class.	26	1		2	Met

Instructions | Output Descriptions | Issuer Summary | Plan Summary | Plan Details | Clinical Summary | Clinical Details | All RXCUIs Submitted

Now we will look at the Clinical Details tab from that same result (screen shot below). As discussed, all restrictions and uncovered drugs in the tested Classes are shown in bold, red font.

For example, look at the yellow highlighted row. This shows this formulary's coverage of second-generation antipsychotics for treatment of bipolar disorder. The result shows that the formulary covers a total of 9 drugs in this class (purple arrows), and covers 6 of those drugs

without restrictions (green arrows). The formulary covers three drugs in this Class with a prior authorization requirement (reflected by "PA" in bold, red font in the "List 1 coverage" column).

Condition	Class	Drug Name	69364 Drug Lists	List 1 Coverage
Bipolar Disorder	Antidepressants	Bupropion		Unrestricted
		Fluoxetine		Unrestricted
		Paroxetine		Unrestricted
		Tranylcypromine		Unrestricted
		Covered Count		**4**
		Unrestricted Count		**4**
	Mood Stabilizers	Carbamazepine		Unrestricted
		Lamotrigine		Unrestricted
		Lithium		Unrestricted
		Oxcarbazepine		Unrestricted
		Valproate		Unrestricted
		Covered Count		**5**
		Unrestricted Count		**5**
	Second Generation Antipsychotics	Aripiprazole		Unrestricted
		Asenapine		***PA***
		Cariprazine		***PA***
		Clozapine		Unrestricted
		Lurasidone		***PA***
		Olanzapine		Unrestricted
		Quetiapine		Unrestricted
		Risperidone		Unrestricted
		Ziprasidone		Unrestricted
		Covered Count		**9**
		Unrestricted Count		**6**
Breast Cancer	Alkylating Agents	Cyclophosphamide		***Uncovered***
		Covered Count		**0**
		Unrestricted Count		**0**
	Antimetabolites	Capecitabine		Unrestricted
		Covered Count		**1**
		Unrestricted Count		**1**
	Aromatase Inhibitors	Anastrozole		Unrestricted
		Exemestane		Unrestricted
		Letrozole		Unrestricted
		Letrozole; Ribociclib		***Uncovered***
		Covered Count		**3**
		Unrestricted Count		**3**
	Folic Acid Metabolites	Leucovorin		Unrestricted
		Covered Count		**1**
		Unrestricted Count		**1**
	Miscellaneous	Alendronate		Unrestricted
		Calcitriol		Unrestricted
		Cholecalciferol		Unrestricted
		Doxercalciferol		Unrestricted
		Ergocalciferol		Unrestricted
		Megestrol Acetate		Unrestricted
		Risedronate		***Uncovered***
		Covered Count		**6**
		Unrestricted Count		**6**
		Raloxifene		Unrestricted
		Tamoxifen		Unrestricted

Instructions | Output Descriptions | Issuer Summary | Plan Summary | Plan Details | Clinical Summary | **Clinical Details** | All RXCUIs Submitted

When we look at the Clinical Summary tab for this formulary in the screen shot on pg. 46, we see that this drug list met the threshold for coverage of drugs in the Second-Generation Antipsychotics for treatment of bipolar disorder. The applicable threshold is 7 covered drugs in this Class. Note that this formulary covers only 6 drugs in this class without restriction. In this case, the drug list still meets the test, because covered drugs in this Class for this condition count toward the threshold whether they are covered with or without restriction. We know that because the "Test Description" column on the Clinical Summary tab does not say "Unrestricted".

Now let's look at a result where there is a deficiency. The Clinical Summary tab below shows a drug list that did not meet the threshold for coverage of drugs in the "Insulin – Prandials" Class (yellow highlighted row identified with a red arrow). This is a Class in which the threshold for covered drugs is 1 (purple circle) for treatment of diabetes. Also, the threshold number of drugs in this Class must be covered for diabetes <u>without restriction</u> (red circle). This drug list includes

no drugs in this Class covered without restriction (green circle), so the result for this test is "Not Met".

C20 | Coverage of drugs in the Insulin - Prandials class without prior authorization or step therapy (unrestricted

	Condition	Test Description	Condition Test ID	Threshold Selected	69364 Drug Lists	List 1 Test Count	List 1 Result
3				Clinical Appropriateness Result:	1 List Not Met	30 Tests Not Met	
14		Coverage of drugs in the Targeted Therapy Inhibitors: Kinase and PARP class.	10	1		1	Met
15	Diabetes	Coverage of drugs in the Alpha Glucosidase Inhibitors class.	11	1		0	Not Met
16		Coverage of drugs in the Biguanide class (Metformin) without prior authorization or step therapy (unrestricted).	12	1		0	Not Met
17		Coverage of drugs in the Dipeptidyl Peptidase 4 (DPP-4) Inhibitors class.	13	1		4	Met
18		Coverage of drugs in the Glucagon-Like Peptide-1 (GLP-1) Receptor Agonists class.	14	1		1	Met
19		Coverage of drugs in the Insulin - Basals class without prior authorization or step therapy (unrestricted).	15	1		0	Not Met
20		Coverage of drugs in the Insulin - Prandials class without prior authorization or step therapy (unrestricted).	16	1		0	Not Met
21		Coverage of drugs in the Meglitinides class.	17	1		0	Not Met
22		Coverage of drugs in the Miscellaneous class.	18	1		0	Not Met
23		Coverage of drugs in the Sodium Glucose Co-Transporter 2 (SGLT2) Inhibitors class.	19	1		2	Met
24		Coverage of drugs in the Sulfonylureas (2nd Generation) class.	20	1		0	Not Met
25		Coverage of drugs in the Thiazolidinediones class.	21	1		0	Not Met
26	Hepatitis C	Coverage of drugs in the Non-Pangenotypic Direct Acting Antivirals (DAA) class.	22	1		1	Met
27		Coverage of drugs in the Pangenotypic Direct Acting Antivirals (DAA) class.	23	1		0	Not Met
28		Coverage of drugs in the Nucleoside Analogs class.	24	1		1	Met
29	HIV	Coverage of drugs in the Combination Drugs class.	25	4		2	Not Met
30		Coverage of drugs in the Integrase Strand Transfer Inhibitors class.	26	1		2	Met
31		Coverage of drugs in the Non-Nucleoside Analog Reverse Transcriptase Inhibitors class.	27	1		1	Met
32		Coverage of drugs in the Nucleoside Analog Reverse Transcriptase Inhibitors class.	28	1		0	Not Met
33		Coverage of drugs in the Nucleotide Analog Reverse Transcriptase Inhibitors class.	29	1		1	Met
34		Coverage of drugs in the Pharmacokinetic Enhancers class.	30	1		1	Met
35		Coverage of drugs in the Protease Inhibitors class.	31	1		1	Met
36		Coverage of drugs in the Antispasticity Agents class.	32	1		0	Not Met
37		Coverage of drugs in the Benzodiazepines	33	2		0	Not Met

... | Issuer Summary | Plan Summary | Plan Details | Clinical Summary | Clinical Details | Errors | All RXCUIs Submitted

The carrier will need to resolve this result. Of course, the Plan Details tab "Deficiency Message" column will tell the carrier what the problem is, and tell the carrier how to resolve it. That tab shows this result:

H5 | WAF001

Issuer Data					Formulary Data			Deficiency Results:	Formulary Outlier Deficiencies: 0 Clinical Appropriateness Deficiencies: 150 Detailed Deficiency Results				
State	Issuer ID	Standard Component ID	Plan Marketing Name	Metal Level	Formulary ID	Number of Drug Tiers	Drug List ID		Review Flagged	Category; Class or Condition Class	Coverage Requirement	Drug Count & Threshold	Deficiency Message
WA	69364	69364WA1220008	Silver 3000 EPO Individual and Family Network	Silver	WAF002	7	1		Clinical Appropriateness	Diabetes condition; Insulin - Prandials class (ID: 16)	Covered; Unrestricted	0 out of 1	The drug list associated with this plan covers 0 unrestricted drug(s) in the Diabetes condition; Insulin - Prandials class. The minimum threshold for this drug class is 1. Please modify the drug list associated with this plan to meet or exceed this requirement, or submit an appropriate justification. The drug list associated with this plan covers

But we can also use the Clinical Details tab (screen shot, below). On that tab, the result for "Insulin – Prandials" for treatment of diabetes shows that this formulary does cover one drug in this Class for diabetes (yellow highlighted row, red arrow). The test threshold is one drug in this Class for diabetes. So far, so good. The problem is that this one drug is covered with restrictions: prior authorization and step therapy (indicated by the "PA, ST" in bold, red font in the purple circle).

L109

Condition	Class	Drug Name	69364 Drug Lists	List 1 Coverage
Diabetes		Unrestricted Count		0
	Dipeptidyl Peptidase 4 (DPP-4) Inhibitors	Alogliptin		PA
		Linagliptin		PA, ST
		Saxagliptin		PA, ST
		Sitagliptin		ST
		Covered Count		4
		Unrestricted Count		0
	Glucagon-like Peptide-1 (GLP-1) Receptor Agonists	Albiglutide		Uncovered
		Dulaglutide		Uncovered
		Exenatide		ST
		Liraglutide		Uncovered
		Lixisenatide		Uncovered
		Semaglutide		Uncovered
		Covered Count		1
		Unrestricted Count		0
	Insulin - Basals	Insulin Aspart/Aspart Protamine Mixture		Uncovered
		Insulin Degludec		Uncovered
		Insulin Detemir		Uncovered
		Insulin Glargine		Uncovered
		Insulin Lispro/Lispro Protamine Mixture		Uncovered
		Insulin NPH		PA, ST
		Covered Count		1
		Unrestricted Count		0
	Insulin - Prandials	Insulin Aspart		Uncovered
		Insulin Glulisine		Uncovered
		Insulin Lispro		Uncovered
		Insulin, Aspart, Human		Uncovered
		Regular Insulin, Human		PA, ST
		Covered Count		1
		Unrestricted Count		0
	Meglitinides	Nateglinide		Uncovered
		Repaglinide		Uncovered
		Covered Count		0
		Unrestricted Count		0
	Miscellaneous	Bromocriptine		Uncovered
		Colesevelam		Uncovered
		Pramlintide		Uncovered
		Covered Count		0
		Unrestricted Count		0
	Sodium Glucose Co-Transporter 2 (SGLT2) Inhibitors	Canagliflozin		PA
		Dapagliflozin		PA
		Empagliflozin		Uncovered
		Ertugliflozin		Uncovered
		Covered Count		2
		Unrestricted Count		0
	Sulfonylureas (2nd Generation)	Glimepiride		Uncovered
		Glipizide		Uncovered
		Glyburide		Uncovered

... | Issuer Summary | Plan Summary | Plan Details | Clinical Summary | Clinical Details | Errors | All RXCUIs Submitted

To resolve this result, the carrier has some choices. It may remove the prior authorization and step therapy requirements from the covered drug, it may add a second drug to the formulary that is covered without restrictions, or it may write an acceptable justification why this formulary design does not discriminate against diabetics.

One other note on the screen shot above: you can see that the "Unrestricted Count" result is zero (purple arrows), and we know that this is a deficiency. However, this deficiency is not flagged on this tab; the zero appears in regular, black font. That's why this tab must be used in conjunction with the Clinical Summary tab, where deficiencies are flagged.

All RxCUIs Submitted Tab

This tab is somewhat misnamed, because it includes not only those RxCUIs on the drug list being analyzed, but all drugs available to meet the benchmark in a particular Category Class. This tab includes the same information as the Clinical Details tab, with additional information about each drug, such as the dosage and route of administration that will satisfy the Category Class (see red circles in the screen shot below). This information can be critical to resolving a "Not Met" result. See the earlier discussion about how dosage and route of administration affect results.

N22

	RXCUI	Retired?	Review(s) Impacted	RxNorm Description	Chemically Distinct Drug	Brand Name (if Applicable)	Dose Form	Category/Condition & Class Impacted	69364 Drug Lists	List 1 Coverage
4	213460	No	Clinical Appropriateness, Formulary Outlier	abacavir 300 MG Oral Tablet [Ziagen]	abacavir	Ziagen	Oral Tablet	CA: 28 | FO: 18		Not Covered
5	213461	No	Clinical Appropriateness, Formulary Outlier	abacavir 20 MG/ML Oral Solution [Ziagen]	abacavir	Ziagen	Oral Solution	CA: 28 | FO: 18		Tier 4 - Unrestricted
6	242679	No	Clinical Appropriateness, Formulary Outlier	abacavir 300 MG Oral Tablet	abacavir		Oral Tablet	CA: 28 | FO: 18		Tier 2 - Unrestricted
7	242680	No	Clinical Appropriateness, Formulary Outlier	abacavir 20 MG/ML Oral Solution	abacavir		Oral Solution	CA: 28 | FO: 18		Tier 2 - Unrestricted
8	616018	No	Clinical Appropriateness, Formulary Outlier	abatacept 250 MG Injection [Orencia]	abatacept	Orencia	Injection	CA: 49 | FO: 26; 27		Not Covered
9	1145932	No	Clinical Appropriateness, Formulary Outlier	1 ML abatacept 125 MG/ML Prefilled Syringe [Orencia]	abatacept	Orencia	Prefilled Syringe	CA: 49 | FO: 26; 27		Tier 6 - PA
10	1799230	No	Clinical Appropriateness, Formulary Outlier	1 ML abatacept 125 MG/ML Auto-Injector [Orencia]	abatacept	Orencia	Auto-Injector	CA: 49 | FO: 26; 27		Tier 6 - PA
11	1925255	No	Formulary Outlier	0.4 ML abatacept 125 MG/ML Prefilled Syringe [Orencia]	abatacept	Orencia	Prefilled Syringe	FO: 26; 27		Not Covered
12	1925257	No	Formulary Outlier	0.7 ML abatacept 125 MG/ML Prefilled Syringe [Orencia]	abatacept	Orencia	Prefilled Syringe	FO: 26; 27		Tier 6 - PA
13	1946836	No	Clinical	abemaciclib 50 MG Oral Tablet [Verzenio]	abemaciclib	Verzenio	Oral Tablet	CA: 10		Not Covered
14	1946840	No	Clinical Appropriateness	abemaciclib 100 MG Oral Tablet [Verzenio]	abemaciclib	Verzenio	Oral Tablet	CA: 10		Not Covered
15	1946844	No	Clinical Appropriateness	abemaciclib 150 MG Oral Tablet [Verzenio]	abemaciclib	Verzenio	Oral Tablet	CA: 10		Not Covered
16	1946848	No	Clinical Appropriateness	abemaciclib 200 MG Oral Tablet [Verzenio]	abemaciclib	Verzenio	Oral Tablet	CA: 10		Not Covered
17	1100075	No	Clinical	abiraterone acetate 250 MG Oral Tablet	abiraterone		Oral Tablet	CA: 45		Not Covered
18	1100079	No	Clinical Appropriateness	abiraterone acetate 250 MG Oral Tablet [Zytiga]	abiraterone	Zytiga	Oral Tablet	CA: 45		Tier 5 - PA
19	1918042	No	Clinical	abiraterone acetate 500 MG Oral Tablet	abiraterone		Oral Tablet	CA: 45		Not Covered
20	1918044	No	Clinical Appropriateness	abiraterone acetate 500 MG Oral Tablet [Zytiga]	abiraterone	Zytiga	Oral Tablet	CA: 45		Tier 5 - PA
21	2046585	No	Clinical Appropriateness	abiraterone acetate 125 MG Oral Tablet [Yonsa]	abiraterone	Yonsa	Oral Tablet	CA: 45		Not Covered
22	199149	No	Clinical Appropriateness, Formulary Outlier	Acarbose 50 MG Oral Tablet	Acarbose		Oral Tablet	CA: 11 | FO: 24		Tier 1 - Unrestricted
23	199150	No	Clinical Appropriateness, Formulary Outlier	Acarbose 100 MG Oral Tablet	Acarbose		Oral Tablet	CA: 11 | FO: 24		Tier 1 - Unrestricted
24	200132	No	Clinical Appropriateness, Formulary Outlier	Acarbose 25 MG Oral Tablet	Acarbose		Oral Tablet	CA: 11 | FO: 24		Tier 1 - Unrestricted
			Clinical Appropriateness,							Not Covered

... Output Descriptions | Issuer Summary | Plan Summary | Plan Details | Clinical Summary | Clinical Details | All RXCUIs Submitted | Errors

The default is for this tab to be sorted alphabetically by chemically distinct drug. But, like all tabs in these Tools, it can be sorted many ways, to present the data in the manner most useful

to your task. The tab consists of blue columns with information about the available drugs, and green columns with information about coverage of those drugs in the drug list(s) being analyzed.

The first column lists the RxCUIs. The second tells whether that RxCUI is retired (retired RxCUIs cannot be used to satisfy a Category Class benchmark). The third column tells which of the Formulary Review Suite Tools is impacted by coverage of that particular drug. The fourth column is the description of the drug. The fifth column is the name of the chemically distinct drug, while the sixth is the brand name of the drug, if the particular RxCUI refers to a preparation of the drug that has a brand name. The seventh column is the form of the drug (tablet, oral solution, injection, etc.).

The last blue column on the right is a very important column; it lists the Category Class of the drug, and the tested condition(s) impacted. If a carrier's Tool results showed that its drug list did not cover sufficient drugs in in a particular Category Class for a particular tested condition, the carrier would need to add drugs to its formulary to correct that deficiency. The carrier can use this tab to find all drugs from which it could choose. You would want to sort the data on this tab by this column, so that each drug that impacts a certain Category and Class and Condition would be listed together.

The way the data is shown in this column takes a minute to grasp. Let's look at one line on this tab.

1243843	No		Tablet [Janumet]	Metformin; sitagliptin	Janumet	Extended Release Oral Tablet	CA: 12; 13 | FO: 24	
1243848	No	Clinical Appropriateness, Formulary Outlier	24 HR Metformin hydrochloride 500 MG / sitagliptin 50 MG Extended Release Oral Tablet [Janumet]	Metformin; sitagliptin	Janumet	Extended Release Oral Tablet	CA: 12; 13 | FO: 24	Tier 3 - Unrestricted

The data in the red circles tells us this line refers to RxCUI 124348, which is an extended release oral tablet of a drug with the brand name Janumet. Janumet is a combination of the drugs Metformin and Sitagliptin. In the particular drug list being tested, this drug is covered on tier 3 without restrictions.

The data in the green circle tells us that this drug impacts both the Clinical Appropriateness and the Formulary Outlier tools. Finally, the data in the purple circle tells us which Category Classes and tested conditions the drug impacts. This row says "CA: 12,13 | FO: 24". There doesn't seem to be an explanation of this rather cryptic result in the Tool but, after crawling around the tabs for a bit, OIC determined that this result means the following:

CA stands for the Clinical Appropriateness Tool. On the Clinical Appropriateness tool, this drug impacts Condition Test IDs 12 and 13. Hence "CA: 12.13". The Condition Test IDs are found on the Clinical Summary tab of the tool results, and refer to a particular Category Class of drugs for a particular condition. Condition Test ID 12, for example, refers to coverage of drugs in the Biguanide class without prior authorization or step therapy, to treat diabetes.

FO stands for the Formulary Outlier tool. On the Formulary Outlier Tool, this drug impacts Category Class ID 24, which is "Blood Glucose Regulators, Antidiabetic Agents."

So if the carrier needed to cover an additional drug for its formulary to pass any of these three tests, and did not already cover Janumet, this tab would tell the carrier that adding Janumet to its formulary is one option.

Errors tab

The errors tab included with the Formulary Review Suite results shows where there is some problem with the tool's processing of the data. This tab will show that a carrier included drug lists on its Rx Drug Template that have not been used for any of its plans (see screen shot below).

B3 | Asuris Ind Med RX drug template IndTemp.xls

	A	B	C	D	E
2		File	Error Message	Error Type	
3		Asuris Ind Med RX drug template IndTemp.xls	Issuer ID 69364 (Individual) Drug List ID 2 is unused and therefore will not be reviewed by the Formulary Review Suite.	Unused Drug List	
4		Kaiser Options SG Medical RX Drug Template S	Issuer ID 25768 (SHOP (Small Group)) Drug Lis	Unused Drug List	
5		Regence BlueShield Ind Med RX Drug Template	Issuer ID 87718 (Individual) Drug List ID 2 is un	Unused Drug List	
6		Regence of Oregon Ind Medical RX Drug Templ	Issuer ID 71281 (Individual) Drug List ID 2 is un	Unused Drug List	
7					
8					
9					

You want to check this tab to see if it shows any other errors. If it does, those errors may need to be resolved so that the user gets results for each drug list they are trying to test. We will not discuss other errors that may appear on this tab. If you run into other errors, look at the description of the error and see if that tells you whether, and how, you need to resolve it. You may need to contact HHS at their CMS Help Desk at CMS_FEPS@cms.hhs.gov or via phone at 1-855-CMS-1515. Be aware that this Help Desk can take a long time to respond to requests.

Non-Discrimination Formulary Outlier Review Tool

Carriers are not required to run this tool, or to report results. OIC runs this test marketwide, for reasons that will be explained below. But this section will explain what the tool does and what the results mean, in case OIC runs this marketwide test, and the results show an issue.

The Drug Count Tool, described earlier, reviews formularies to determine that they cover a sufficient number of each kind of drugs. The Non-Discrimination Formulary Outlier Tool reviews formularies to determine whether the plan provides enrollees appropriate access to those drugs. Requiring an enrollee to do something before they can access a covered drug is considered a "restriction" on access to that drug. The Non-Discrimination Formulary Outlier Tool counts how many drugs in certain Category Classes are subject to two restrictions: either preauthorization or

step therapy, or both. The Tool identifies formularies that have an unusually high number of restrictions on drugs in those Category Classes. (See Section 1 on the Output Descriptions tab.)

The purpose of this analysis is to look for discrimination on the basis of a health status, which is prohibited by the ACA. The tool analyzes plans to see whether they discourage people with certain conditions from purchasing their plans by overly restricting access to the drugs needed by people with these conditions.

For Plan Year 2020, the Non-Discrimination Formulary Outlier Tool (Formulary Outlier Tool) analyzes drugs in 28 Categories.

The reason the Tool doesn't work when run on a single carrier's formularies is that the Tool measures formularies against each other. This Tool needs 5 or more drug lists to compare, and no carrier in Washington has that many drug lists. (The particular methodology this Tool uses to calculate outliers, Tukey's Outlier methodology, needs at least 5 data points to calculate outliers.) The Tool creates benchmarks – the number of restrictions in a Category Class on most of the formularies tested – to identify outliers.

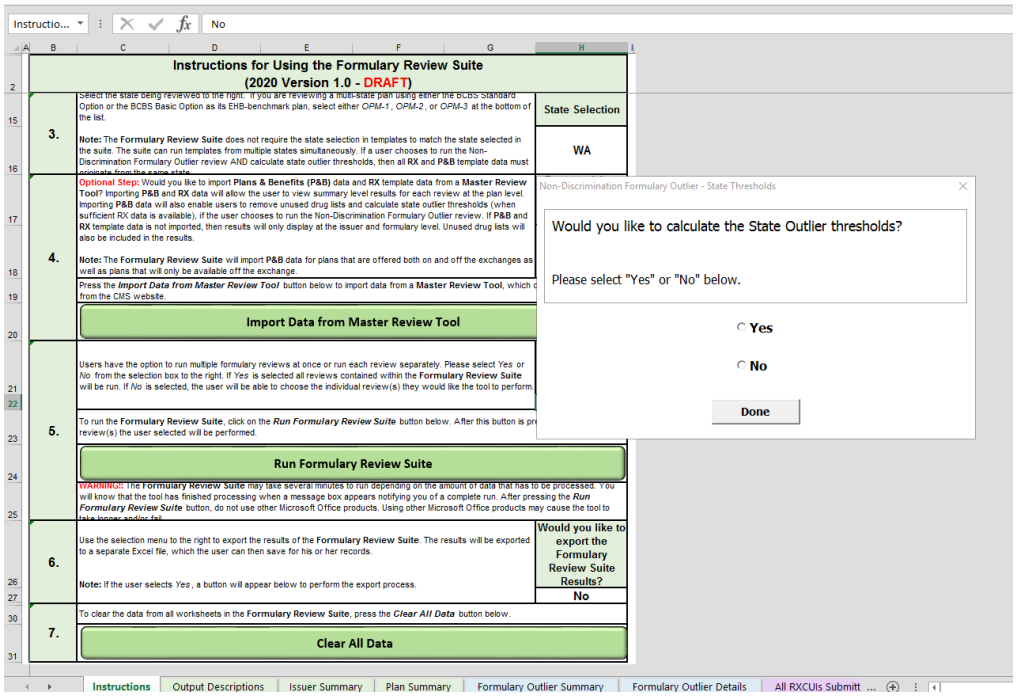
The need to compare formularies against each other to look for outliers makes sense if you think about what an outlier is. You can't have "outliers" in a group of one or two; a group of one couldn't have any outliers, and it isn't correct to say that a group of two has outliers, either. The tallest of two people cannot be said to be an "outlier" in terms of height.

The Formulary Outlier Tool is designed as a market-wide Tool. When run on an entire market, the Tool identifies formularies with more restrictions than other formularies on certain drugs. However, in order to analyze the entire Individual and Small Group markets' plans, the user must have the binder templates for every carrier. Since OIC has access to all of the templates but the carriers initially do not, OIC runs the Tool on the markets as a whole and then looks more closely at formularies flagged as outliers.

Instructions Tab

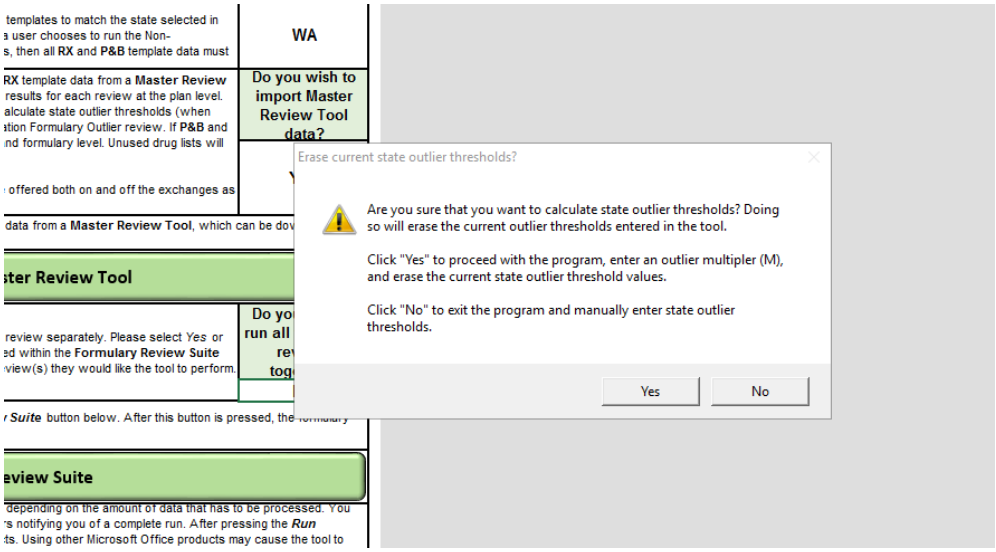
To run this Tool, you will need to run the Master Review Tool using the data for all the formularies you wish to compare. When OIC runs the Formulary Outlier Tool, we input Master Review Tool results for all formularies from all carriers in the Washington market. You will also need to create a folder that contains the Prescription Drug Templates for all carriers whose formularies you wish to compare.

Using those sets of data, the instructions for running the Formulary Outlier Tool are exactly the same as given in the section called "Instructions tab", above, until the user gets to the question "Do you Want to Run All Formulary Reviews Together". Again, the user answers "No", and again a dialog box pops up asking which tool the user wants to run. To run the Formulary Outlier Tool, however, the user would choose this Tool in the dialog box. When you do that, get ready for a series of dialog boxes. First, the following dialog box appears:



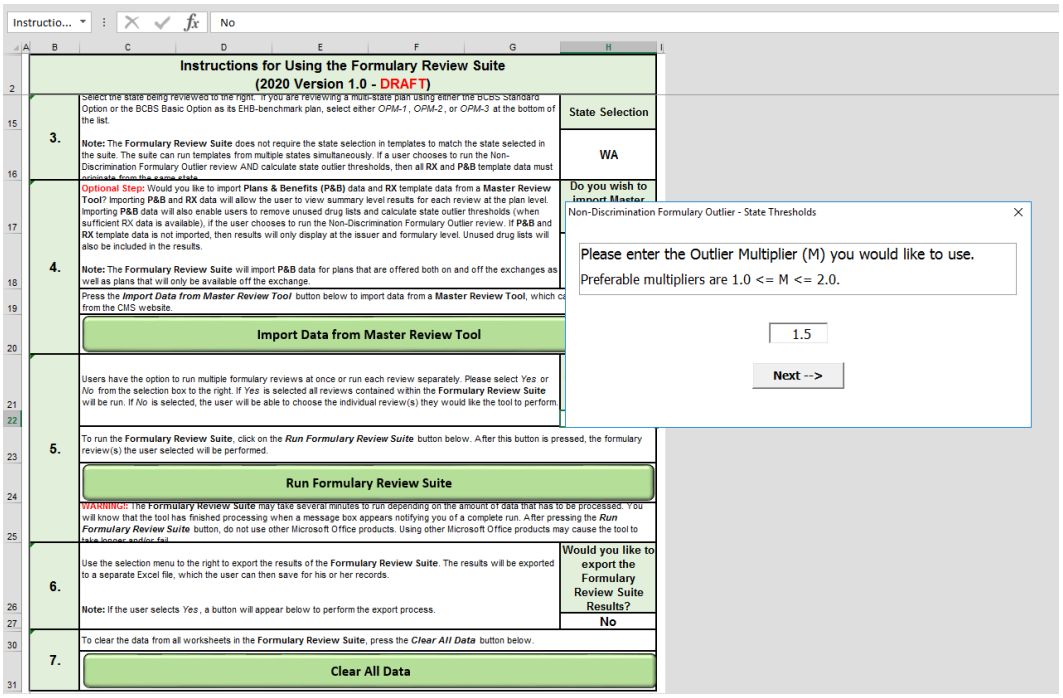
The user should click the radio button to answer "Yes" to this question. That's because the Tool does not have default values for the states programmed into it. Therefore, if you don't manually enter the state outlier thresholds, the Tool will use a "null" value, meaning that it won't apply any state threshold. In other words, every formulary would pass the Tool because the Tool wouldn't be measuring against anything.

When you answer "Yes" to calculate State Outlier thresholds, the following dialog box appears:



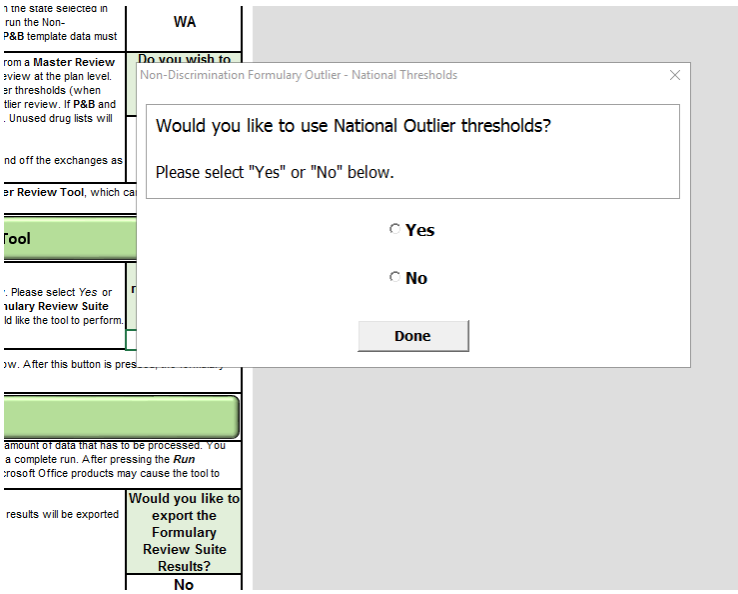
This simply means that answering "Yes" would erase the current thresholds entered into the Tool. As stated, there are no default state values programmed in. All this means is you would be erasing any values you had manually entered during previous use of the Tool. Click the "Yes" button.

You will then see this dialog box:



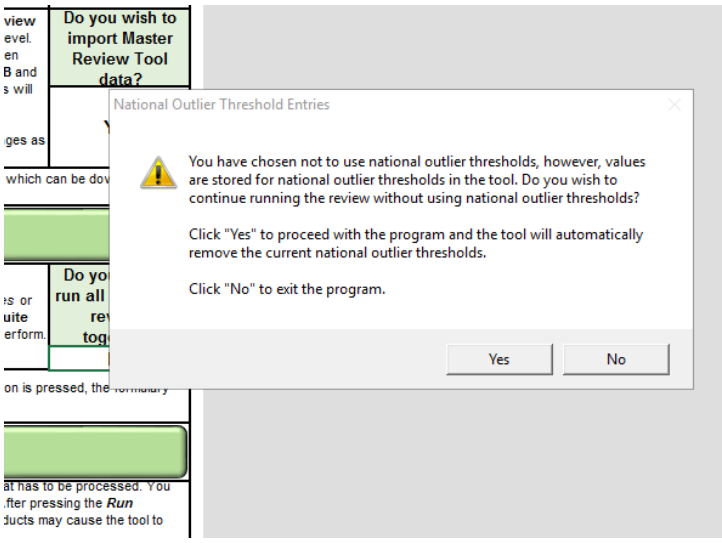
The Tool is programmed with a default Outlier Multiplier of 1.5 if the user chooses to calculate state thresholds. This is the Outlier Multiplier OIC instructs carriers to use, so simply click "Next". Explanation further on in this section will illustrate what this multiplier means.

Once you select "Next", yet another dialog box appears asking whether you want to use National Outlier thresholds.



OIC does not use these thresholds to measure Washington plans, so click the radio button for "No", and then click the "Done" button.

In a shocking twist, yet another dialog box appears.



This box is basically asking you "Are you sure? Because the tool is preprogrammed with national outlier thresholds you could use." You're sure. Click the "Yes" button.

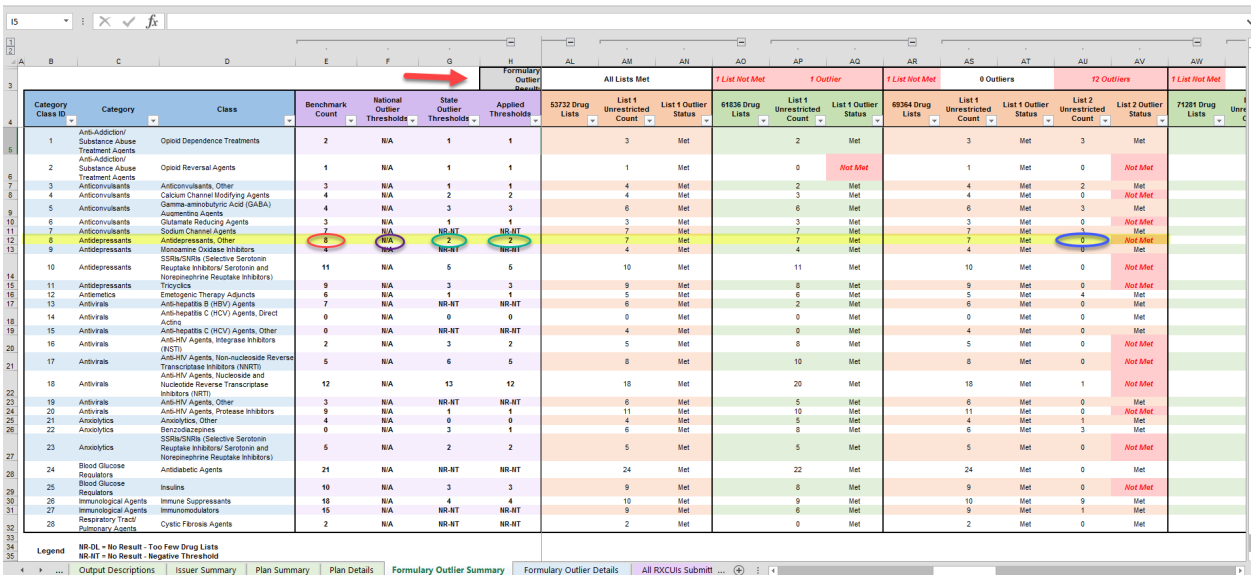
One more dialog box appears, asking you to select the folder where you've stored all the Prescription Drug Templates on which you want to run the Tool, and then the Tool begins to run. This one takes a while when it is run on the entire Washington market.

Issuer Summary, Plan Summary, and Plan Details Tabs

The only difference between the way these tabs show results for the Formulary Outlier Tool and for the Clinical Appropriateness Tool is that the Formulary Outlier Tool results are provided in blue columns.

Formulary Outlier Summary Tab

This tab shows the results only of the Formulary Outlier Tool. The results are shown at the drug list level. The results on this tab look like this:



Category Class ID	Category	Class	Benchmark Count	National Outlier Thresholds	State Outlier Thresholds	Applied Thresholds	53732 Drug Lists	List 1 Unrestricted Count	List 1 Outlier Status	61836 Drug Lists	List 1 Unrestricted Count	List 1 Outlier Status	69364 Drug Lists	List 1 Unrestricted Count	List 1 Outlier Status	List 2 Unrestricted Count	List 2 Outlier Status	71281 Drug Lists
						Formulary Outlier Result	All Lists Met			1 List Not Met	1 Outlier		1 List Not Met	0 Outliers		12 Outliers		1 List Not Met
1	Anti-Addiction/ Substance Abuse Treatment Agents	Opioid Dependence Treatments	2	N/A	1	1		3	Met		2	Met		3	Met	3	Met	
2	Anti-Addiction/ Substance Abuse Treatment Agents	Opioid Reversal Agents	1	N/A	1	1		1	Met		0	Not Met		1	Met	0	Not Met	
3	Anticonvulsants	Anticonvulsants, Other	3	N/A	1	1		4	Met		2	Met		4	Met	2	Met	
4	Anticonvulsants	Calcium Channel Modifying Agents	4	N/A	2	2		4	Met		3	Met		4	Met	0	Not Met	
5	Anticonvulsants	Gamma-aminobutyric Acid (GABA) Augmenting Agents	4	N/A	3	3		6	Met		6	Met		6	Met	3	Met	
6	Anticonvulsants	Glutamate Reducing Agents	3	N/A	1	1		3	Met		3	Met		3	Met	0	Not Met	
7	Anticonvulsants	Sodium Channel Agents	7	N/A	NR-NT	NR-NT		7	Met		7	Met		7	Met	3	Met	
8	Antidepressants	Antidepressants, Other	8	N/A	2	2		7	Met		7	Met		7	Met	0	Not Met	
9	Antidepressants	Monoamine Oxidase Inhibitors	4	N/A	NR-NT	NR-NT		4	Met		4	Met		4	Met	0	Met	
10	Antidepressants	SSRIs/SNRIs (Selective Serotonin Reuptake Inhibitors/ Serotonin and Norepinephrine Reuptake Inhibitors)	11	N/A	5	5		10	Met		11	Met		10	Met	0	Not Met	
11	Antidepressants	Tricyclics	9	N/A	3	3		9	Met		8	Met		9	Met	0	Not Met	
12	Antiemetics	Emetogenic Therapy Adjuncts	6	N/A	1	1		5	Met		6	Met		5	Met	4	Met	
13	Antivirals	Anti-hepatitis B (HBV) Agents	7	N/A	NR-NT	NR-NT		6	Met		2	Met		6	Met	0	Met	
14	Antivirals	Anti-hepatitis C (HCV) Agents, Direct Acting	0	N/A	0	0		0	Met		0	Met		0	Met	0	Met	
15	Antivirals	Anti-hepatitis C (HCV) Agents, Other	0	N/A	NR-NT	NR-NT		4	Met		0	Met		4	Met	0	Met	
16	Antivirals	Anti-HIV Agents, Integrase Inhibitors (INSTI)	2	N/A	3	2		5	Met		8	Met		5	Met	0	Not Met	
17	Antivirals	Anti-HIV Agents, Non-nucleoside Reverse Transcriptase Inhibitors (NNRTI)	5	N/A	6	5		8	Met		10	Met		8	Met	0	Not Met	
18	Antivirals	Anti-HIV Agents, Nucleoside and Nucleotide Reverse Transcriptase Inhibitors (NRTI)	12	N/A	13	12		18	Met		20	Met		18	Met	1	Not Met	
19	Antivirals	Anti-HIV Agents, Other	3	N/A	NR-NT	NR-NT		6	Met		5	Met		6	Met	0	Not Met	
20	Antivirals	Anti-HIV Agents, Protease Inhibitors	9	N/A	1	1		11	Met		10	Met		11	Met	0	Not Met	
21	Anxiolytics	Anxiolytics, Other	4	N/A	0	0		4	Met		5	Met		4	Met	1	Met	
22	Anxiolytics	Benzodiazepines	0	N/A	3	1		6	Met		8	Met		6	Met	3	Met	
23	Anxiolytics	SSRIs/SNRIs (Selective Serotonin Reuptake Inhibitors/ Serotonin and Norepinephrine Reuptake Inhibitors)	5	N/A	2	2		5	Met		5	Met		5	Met	0	Not Met	
24	Blood Glucose Regulators	Antidiabetic Agents	21	N/A	NR-NT	NR-NT		24	Met		22	Met		24	Met	0	Met	
25	Blood Glucose Regulators	Insulins	10	N/A	3	3		9	Met		8	Met		9	Met	0	Not Met	
26	Immunological Agents	Immune Suppressants	18	N/A	4	4		10	Met		9	Met		10	Met	9	Met	
27	Immunological Agents	Immunomodulators	15	N/A	NR-NT	NR-NT		9	Met		6	Met		9	Met	1	Met	
28	Respiratory Tract/ Pulmonary Agents	Cystic Fibrosis Agents	2	N/A	NR-NT	NR-NT		2	Met		0	Met		2	Met	0	Met	

Legend: NR-DL = No Result - Too Few Drug Lists; NR-NT = No Result - Negative Threshold

Output Descriptions | Issuer Summary | Plan Summary | Plan Details | Formulary Outlier Summary | Formulary Outlier Details | All RXCUIs Submitt ...

Again, there is an executive summary at the top. The "Formulary Outlier Result" box (red arrow) shows whether any formularies failed the Formulary Outlier Tool.

The first three columns on the left, in blue, will be the same regardless of whether the Tool is run on one formulary or many. These columns show the 27 Category Classes that the test reviews. **Note:** Remember that Category Class IDs are just numbers used only by HHS for these Electronic Review Tools. There's nothing official about them; they're just a shorthand way for the tools to identify Category Classes. That's why the Category Class IDs assigned to these particular groups of drugs by the Formulary Outlier Tool are not the same as the Category Class IDs assigned to the same groups of drugs by the Drug Count Tool. It doesn't mean anything. Just remember that the name of the Category Class name is what matters, not the number.

The next four columns, in purple, show the thresholds applied. The first column shows the Benchmark Count. For purposes of the Formulary Outlier Tool, this benchmark is either the state benchmark or the reevaluated benchmark, whichever is lower. An outlier is a multiplier of this benchmark calculated by a method called Tukey's Outlier calculation. (I don't know the math behind this calculation; but I know that the outlier will be calculated using the threshold we input when we ran the Tool, which was 1.5.)

Note: Using Tukey's Outlier calculation, it is possible that the answer is less than zero – i.e., a negative outlier. In that case, the default value will be set to zero.

Let's look at an example of how this tool works. Category Class 8, Antidepressants – Other, has a state Benchmark Count of 8 (Yellow highlighted row in screen shot above, red circle). We input a threshold of 1.5, so the test will flag as an outlier any plan that covers 2 or fewer drugs in this Category Class without restrictions (green arrows). If the Tool flags an outlier, we need more information to determine whether covering so few drugs without restrictions in the flagged Category Class is discriminatory against people with health conditions that are treated with these drugs.

The next purple column is where the National Outlier thresholds would appear, if the user had chosen to use them. Carriers are asked not to use them, so this column simply says "N/A".

The next two columns are where you can really see why this tool is not very useful when run on one issuer's formularies alone. Below is a screen shot of the Tool run on only one issuer's formularies.

Marketplace Type:	Individual
Formulary Outlier Result:	All Lists Met

Category Class ID	Category	Class	Benchmark Count	National Outlier Thresholds	State Outlier Thresholds	Applied Thresholds	23371 Drug Lists	List 1 Unrestricted Count	List 1 Outlier Status
1	Anti-Addiction/ Substance Abuse Treatment Agents	Opioid Dependence Treatments	2	N/A	NR-DL	NR-DL		4	N/A
2	Anti-Addiction/ Substance Abuse Treatment Agents	Opioid Reversal Agents	1	N/A	NR-DL	NR-DL		1	N/A
3	Anticonvulsants	Anticonvulsants, Other	3	N/A	NR-DL	NR-DL		3	N/A
4	Anticonvulsants	Calcium Channel Modifying Agents	4	N/A	NR-DL	NR-DL		3	N/A
5	Anticonvulsants	Gamma-aminobutyric Acid (GABA) Augmenting Agents	4	N/A	NR-DL	NR-DL		4	N/A
6	Anticonvulsants	Glutamate Reducing Agents	3	N/A	NR-DL	NR-DL		2	N/A
7	Anticonvulsants	Sodium Channel Agents	7	N/A	NR-DL	NR-DL		5	N/A
8	Antidepressants	Antidepressants, Other	8	N/A	NR-DL	NR-DL		4	N/A
9	Antidepressants	Monoamine Oxidase Inhibitors	4	N/A	NR-DL	NR-DL		2	N/A
10	Antidepressants	SSRIs/SNRIs (Selective Serotonin Reuptake Inhibitors/ Serotonin and Norepinephrine Reuptake Inhibitors)	11	N/A	NR-DL	NR-DL		8	N/A
11	Antidepressants	Tricyclics	9	N/A	NR-DL	NR-DL		9	N/A
12	Antiemetics	Emetogenic Therapy Adjuncts	6	N/A	NR-DL	NR-DL		4	N/A
13	Antivirals	Anti-hepatitis B (HBV) Agents	7	N/A	NR-DL	NR-DL		5	N/A
14	Antivirals	Anti-hepatitis C (HCV) Agents	5	N/A	NR-DL	NR-DL		8	N/A
15	Antivirals	Anti-HIV Agents, Integrase Inhibitors (INSTI)	2	N/A	NR-DL	NR-DL		3	N/A
16	Antivirals	Anti-HIV Agents, Non-nucleoside Reverse Transcriptase Inhibitors (NNRTI)	5	N/A	NR-DL	NR-DL		5	N/A
17	Antivirals	Anti-HIV Agents, Nucleoside and Nucleotide Reverse Transcriptase Inhibitors (NRTI)	12	N/A	NR-DL	NR-DL		16	N/A
18	Antivirals	Anti-HIV Agents, Other	3	N/A	NR-DL	NR-DL		6	N/A
19	Antivirals	Anti-HIV Agents, Protease Inhibitors	9	N/A	NR-DL	NR-DL		7	N/A
20	Anxiolytics	Anxiolytics, Other	4	N/A	NR-DL	NR-DL		3	N/A
21	Anxiolytics	Benzodiazepines	0	N/A	NR-DL	NR-DL		8	N/A
22	Anxiolytics	SSRIs/SNRIs (Selective Serotonin Reuptake Inhibitors/ Serotonin and Norepinephrine Reuptake Inhibitors)	5	N/A	NR-DL	NR-DL		5	N/A
23	Blood Glucose Regulators	Antidiabetic Agents	21	N/A	NR-DL	NR-DL		10	N/A
24	Blood Glucose Regulators	Insulins	10	N/A	NR-DL	NR-DL		6	N/A
25	Immunological Agents	Immune Suppressants	17	N/A	NR-DL	NR-DL		14	N/A
26	Immunological Agents	Immunomodulators	15	N/A	NR-DL	NR-DL		9	N/A
27	Respiratory Tract/ Pulmonary Agents	Cystic Fibrosis Agents	3	N/A	NR-DL	NR-DL		1	N/A

Legend NR-DL = No Result - Too Few Drug Lists

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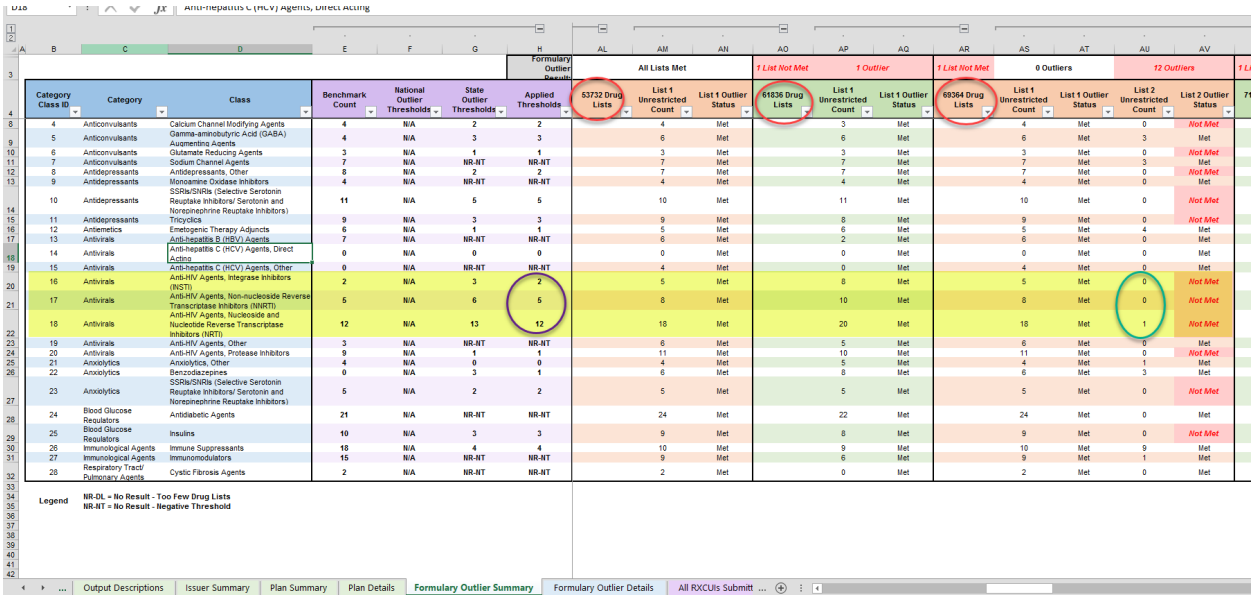
A quick glance shows you that there are no results on this tab. The Tool counted the number of restricted drugs in each Category Class on the formulary, but that's all it did. All the results are NR-DL, which the key at the bottom of the tab tells us means "No result – too few drug lists". The Tool didn't compare anything to find outliers, because there was nothing to compare. The particular carrier whose results are shown in the screen shot above uses the same drug list for every formulary.

Most carriers' formularies have only one or two drug lists. There's no way to calculate outliers on a set of one thing. You can't calculate the tallest person in a group of one person. The same is true of a group of two. Sure, one may be taller, but that cannot be called an "outlier". To have an outlier, you need a norm. For that reason, Tukey's Outlier calculation, which is used to calculate the outlier thresholds, needs at least 5 data points. So the results in the "State Outlier Thresholds" and "Applied Thresholds" are all "NR-DL".

Let's return to the results of the Tool run marketwide, so that we can look at the rest of the columns on this tab.



Category Class ID	Category	Class	Benchmark Count	National Outlier Thresholds	State Outlier Thresholds	Formulary Outlier Results: Applied Thresholds	All Lists Met: 53732 Drug Lists	List 1 Unrestricted Count	List 1 Outlier Status	1 List Not Met, 1 Outlier: 61836 Drug Lists	List 1 Unrestricted Count	List 1 Outlier Status	1 List Not Met, 0 Outliers: 69364 Drug Lists	List 1 Unrestricted Count	List 1 Outlier Status	12 Outliers: List 2 Unrestricted Count	List 2 Outlier Status
4	Anticonvulsants	Calcium Channel Modifying Agents	4	N/A	2	2		4	Met		3	Met		4	Met	0	Not Met
5	Anticonvulsants	Gamma-aminobutyric Acid (GABA) Augmenting Agents	4	N/A	3	3		6	Met		6	Met		6	Met	3	Met
6	Anticonvulsants	Glutamate Reducing Agents	3	N/A	1	1		3	Met		3	Met		3	Met	0	Not Met
7	Anticonvulsants	Sodium Channel Agents	7	N/A	NR-NT	NR-NT		7	Met		7	Met		7	Met	3	Met
8	Antidepressants	Antidepressants, Other	8	N/A	2	2		7	Met		7	Met		7	Met	0	Not Met
9	Antidepressants	Monoamine Oxidase Inhibitors	4	N/A	NR-NT	NR-NT		4	Met		4	Met		4	Met	0	Met
10	Antidepressants	SSRIs/SNRIs (Selective Serotonin Reuptake Inhibitors/ Serotonin and Norepinephrine Reuptake Inhibitors)	11	N/A	5	5		10	Met		11	Met		10	Met	0	Not Met
11	Antidepressants	Tricyclics	9	N/A	3	3		9	Met		8	Met		9	Met	0	Not Met
12	Antiemetics	Emetogenic Therapy Adjuncts	6	N/A	1	1		5	Met		6	Met		5	Met	4	Met
13	Antivirals	Anti-hepatitis B (HBV) Agents	7	N/A	NR-NT	NR-NT		6	Met		2	Met		6	Met	0	Met
14	Antivirals	Anti-hepatitis C (HCV) Agents, Direct Acting	0	N/A	0	0		0	Met		0	Met		0	Met	0	Met
15	Antivirals	Anti-hepatitis C (HCV) Agents, Other	0	N/A	NR-NT	NR-NT		4	Met		0	Met		4	Met	0	Met
16	Antivirals	Anti-HIV Agents, Integrase Inhibitors (INSTI)	2	N/A	3	2		5	Met		8	Met		5	Met	0	Not Met
17	Antivirals	Anti-HIV Agents, Non-nucleoside Reverse Transcriptase Inhibitors (NNRTI)	5	N/A	6	5		8	Met		10	Met		8	Met	0	Not Met
18	Antivirals	Anti-HIV Agents, Nucleoside and Nucleotide Reverse Transcriptase Inhibitors (NRTI)	12	N/A	13	12		18	Met		20	Met		18	Met	1	Not Met
19	Antivirals	Anti-HIV Agents, Other	3	N/A	NR-NT	NR-NT		6	Met		5	Met		6	Met	0	Met
20	Antivirals	Anti-HIV Agents, Protease Inhibitors	9	N/A	1	1		11	Met		10	Met		11	Met	0	Not Met
21	Anxiolytics	Anxiolytics, Other	4	N/A	0	0		4	Met		5	Met		4	Met	1	Met
22	Anxiolytics	Benzodiazepines	0	N/A	3	1		6	Met		8	Met		6	Met	3	Met
23	Anxiolytics	SSRIs/SNRIs (Selective Serotonin Reuptake Inhibitors/ Serotonin and Norepinephrine Reuptake Inhibitors)	5	N/A	2	2		5	Met		5	Met		5	Met	0	Not Met
24	Blood Glucose Regulators	Antidiabetic Agents	21	N/A	NR-NT	NR-NT		24	Met		22	Met		24	Met	0	Met
25	Blood Glucose Regulators	Insulins	10	N/A	3	3		9	Met		8	Met		9	Met	0	Not Met
26	Immunological Agents	Immune Suppressants	18	N/A	4	4		10	Met		9	Met		10	Met	9	Met
27	Immunological Agents	Immunomodulators	15	N/A	NR-NT	NR-NT		9	Met		6	Met		9	Met	1	Met
28	Respiratory Tract/ Pulmonary Agents	Cystic Fibrosis Agents	2	N/A	NR-NT	NR-NT		2	Met		0	Met		2	Met	0	Met

Legend
NR-DL = No Result - Too Few Drug Lists
NR-NT = No Result - Negative Threshold

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The "Applied Threshold" column is the actual threshold the carrier's formulary was compared against to obtain the result presented. According to HHS, carriers are required to meet both the state and national threshold for each Category and Class. So the Applied Threshold should be the greater of the state or national threshold. However, the Applied Threshold is capped at the state's benchmark value, in order to avoid penalizing drug lists that meet, but do not exceed, the state benchmarks. That's why Washington does not ask carriers to apply the national thresholds: if they're capped at the state benchmark anyway, what would be the point?

The green column to the far right in our screen shot, above, are the results. At the top is shown the HIOS ID of the carrier whose formulary results are shown in that set of columns (red circles).

If more than one carrier's formularies are tested, the results will be shown in alternating green and orange sets of columns. The middle column shows the number of drugs in the formulary in that particular Category Class covered without restrictions. This is the number that is measured against the Applied Threshold. The final column, "List X Outlier Status", shows whether a Drug List met the threshold.

As discussed above, when this test is run on only one carrier's formularies, and the carrier has less than 5 Drug Lists, the Tool cannot identify outliers. That's why, in the screen shot we saw of a single carrier's results, all results say "N/A" in regular black font. When a Drug List has been tested for outliers, as in the screen shot above where the tool was run on multiple carriers' formularies, the result will say either "Met" in regular black font, or "Not Met", highlighted, in bold red font.

We can see there are some outliers (see, for example, yellow highlighted rows). Carrier 69364's drug list 2 has outliers in several Category Classes, including several Classes in the Antivirals Category. The applied thresholds for unrestricted drugs in these Category Classes (purple circle) are higher than the number of drugs covered in these Category Classes on drug list 2 (green circle).

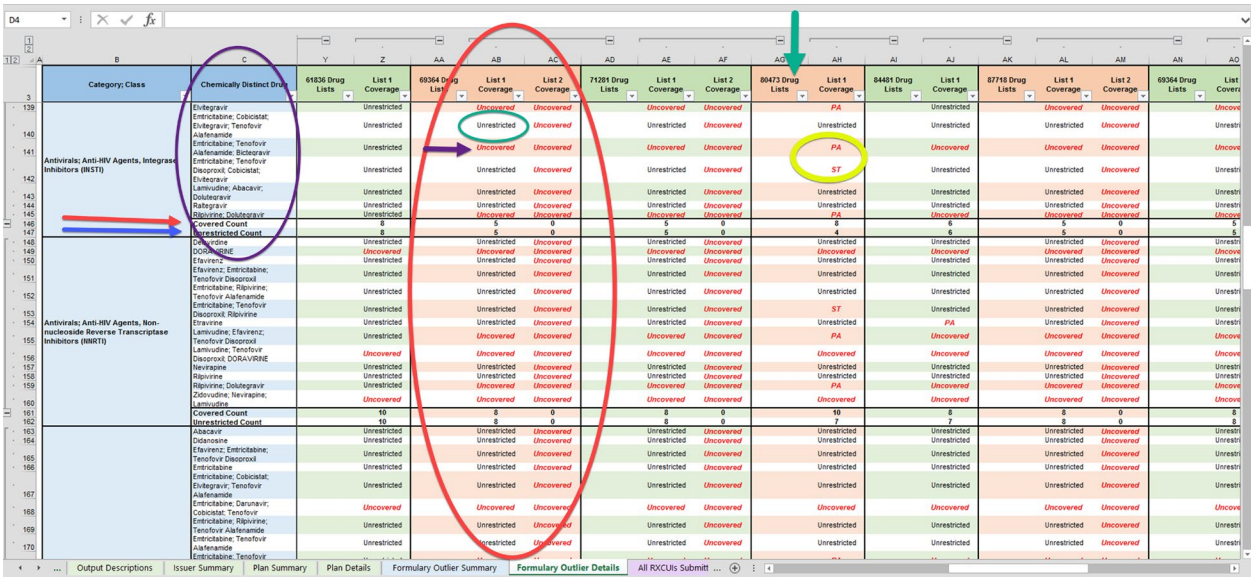
OIC may ask for additional information about the formulary, or even send an Objection asking for correction or a justification of each "Not Met" result. Let's look at the next tab to see what the possible corrections exist for the results in two of the yellow-highlighted rows.

Formulary Outlier Details Tab

The Formulary Outlier Details tab shows more detailed information on each of the Category Classes, and coverage of each on the drug lists analyzed. The Formulary Outlier Details tab must be read in conjunction with the Formulary Outlier Summary tab, because the Formulary Outlier Details tab flags restrictions. It does **not** flag failed results. The Formulary Outlier Details tab shows *all* restrictions and uncovered drugs in bold, red font so they are easy to see. Unlike bold, red font on other tabs, on this tab bold, red font does not mean an error or deficiency. To see where errors occurred, you need to look at the Formulary Outlier Summary tab.

You will really only need the information on the Formulary Outlier Details tab that pertains to any failed results on the Formulary Outlier Summary tab.

Note that this review is different from the Clinical Appropriateness review, in that the Clinical Appropriateness review includes some Classes in which thresholds can be met even if the drugs are covered with restrictions. The Formulary Outlier Tool thresholds can only be met by coverage of drugs without restrictions. Regardless of what the "Covered Count" row (red arrow) shows, it is the "Unrestricted Count" (blue arrow) that determines whether a formulary is an outlier on this Tool.



Category; Class	Chemically Distinct Drug	61836 Drug Lists	List 1 Coverage	69364 Drug List	List 1 Coverage	List 2 Coverage	71281 Drug Lists	List 1 Coverage	List 2 Coverage	80473 Drug Lists	List 1 Coverage	84481 Drug Lists	List 1 Coverage	87718 Drug Lists	List 1 Coverage	List 2 Coverage	69364 Drug Lists
Antivirals; Anti-HIV Agents, Integrase Inhibitors (INSTI)	Elvitegravir		Unrestricted		Uncovered	Uncovered		Uncovered	Uncovered		PA		Unrestricted		Uncovered	Uncovered	
	Emtricitabine; Cobicistat; Elvitegravir; Tenofovir Alafenamide		Unrestricted		Unrestricted	Uncovered		Unrestricted	Uncovered		Unrestricted		Unrestricted		Unrestricted	Uncovered	
	Emtricitabine; Tenofovir Alafenamide; Bictegravir		Unrestricted		Uncovered	Uncovered		Uncovered	Uncovered		PA		Uncovered		Uncovered	Uncovered	
	Emtricitabine; Tenofovir Disoproxil; Cobicistat; Elvitegravir		Unrestricted		Unrestricted	Uncovered		Unrestricted	Uncovered		ST		Unrestricted		Unrestricted	Uncovered	
	Lamivudine; Abacavir; Dolutegravir		Unrestricted		Unrestricted	Uncovered		Unrestricted	Uncovered		Unrestricted		Unrestricted		Unrestricted	Uncovered	
	Rategravir		Unrestricted		Unrestricted	Uncovered		Unrestricted	Uncovered		Unrestricted		Unrestricted		Unrestricted	Uncovered	
	Rilpivirine; Dolutegravir		Unrestricted		Uncovered	Uncovered		Uncovered	Uncovered		PA		Uncovered		Uncovered	Uncovered	
	Covered Count		8		5	0		5	0		8		6		5	0	
	Unrestricted Count		8		5	0		5	0		4		6		5	0	
Antivirals; Anti-HIV Agents, Non-nucleoside Reverse Transcriptase Inhibitors (NNRTI)	Delavirdine		Unrestricted		Unrestricted	Uncovered		Unrestricted	Uncovered		Unrestricted		Unrestricted		Unrestricted	Uncovered	
	DORAVIRINE		Uncovered		Uncovered	Uncovered		Uncovered	Uncovered		Uncovered		Uncovered		Uncovered	Uncovered	
	Efavirenz		Unrestricted		Unrestricted	Uncovered		Unrestricted	Uncovered		Unrestricted		Unrestricted		Unrestricted	Uncovered	
	Efavirenz; Emtricitabine; Tenofovir Disoproxil		Unrestricted		Unrestricted	Uncovered		Unrestricted	Uncovered		Unrestricted		Unrestricted		Unrestricted	Uncovered	
	Emtricitabine; Rilpivirine; Tenofovir Alafenamide		Unrestricted		Unrestricted	Uncovered		Unrestricted	Uncovered		Unrestricted		Unrestricted		Unrestricted	Uncovered	
	Emtricitabine; Tenofovir Disoproxil; Rilpivirine		Unrestricted		Unrestricted	Uncovered		Unrestricted	Uncovered		ST		Unrestricted		Unrestricted	Uncovered	
	Etravirine		Unrestricted		Unrestricted	Uncovered		Unrestricted	Uncovered		Unrestricted		PA		Unrestricted	Uncovered	
	Lamivudine; Efavirenz; Tenofovir Disoproxil		Unrestricted		Uncovered	Uncovered		Uncovered	Uncovered		PA		Uncovered		Uncovered	Uncovered	
	Lamivudine; Tenofovir Disoproxil; DORAVIRINE		Uncovered		Uncovered	Uncovered		Uncovered	Uncovered		Uncovered		Uncovered		Uncovered	Uncovered	
	Nevirapine		Unrestricted		Unrestricted	Uncovered		Unrestricted	Uncovered		Unrestricted		Unrestricted		Unrestricted	Uncovered	
	Rilpivirine		Unrestricted		Unrestricted	Uncovered		Unrestricted	Uncovered		Unrestricted		Unrestricted		Unrestricted	Uncovered	
	Rilpivirine; Dolutegravir		Unrestricted		Uncovered	Uncovered		Uncovered	Uncovered		PA		Uncovered		Uncovered	Uncovered	
	Zidovudine; Nevirapine; Lamivudine		Uncovered		Uncovered	Uncovered		Uncovered	Uncovered		Uncovered		Uncovered		Uncovered	Uncovered	
	Covered Count		10		8	0		8	0		10		8		8	0	
	Unrestricted Count		10		8	0		8	0		7		7		8	0	
	Abacavir		Unrestricted		Unrestricted	Uncovered		Unrestricted	Uncovered		Unrestricted		Unrestricted		Unrestricted	Uncovered	
	Didanosine		Unrestricted		Unrestricted	Uncovered		Unrestricted	Uncovered		Unrestricted		Unrestricted		Unrestricted	Uncovered	
	Efavirenz; Emtricitabine; Tenofovir Disoproxil		Unrestricted		Unrestricted	Uncovered		Unrestricted	Uncovered		Unrestricted		Unrestricted		Unrestricted	Uncovered	
	Emtricitabine		Unrestricted		Unrestricted	Uncovered		Unrestricted	Uncovered		Unrestricted		Unrestricted		Unrestricted	Uncovered	
	Emtricitabine; Cobicistat; Elvitegravir; Tenofovir Alafenamide		Unrestricted		Unrestricted	Uncovered		Unrestricted	Uncovered		Unrestricted		Unrestricted		Unrestricted	Uncovered	
	Emtricitabine; Darunavir; Cobicistat; Tenofovir		Uncovered		Uncovered	Uncovered		Uncovered	Uncovered		Uncovered		Uncovered		Uncovered	Uncovered	
	Emtricitabine; Rilpivirine; Tenofovir Alafenamide		Unrestricted		Unrestricted	Uncovered		Unrestricted	Uncovered		Unrestricted		Unrestricted		Unrestricted	Uncovered	
	Emtricitabine; Tenofovir Alafenamide		Unrestricted		Unrestricted	Uncovered		Unrestricted	Uncovered		Unrestricted		Unrestricted		Unrestricted	Uncovered	
	Emtricitabine; Tenofovir																

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In the first two columns, which are blue, you can see that the default for this tab is to be arranged by Category Class. Although you can sort the tab just as you can all the other tabs in the electronic review tools, there doesn't seem to be much reason to do that here. The first blue column is the "Category Class" column. In the next blue column, the "Chemically Distinct Drug" column, each drug in the Category Class is listed.

Let's look at the Outliers identified in the highlighted rows on our last screen shot, to see what additional information this tab gives us.

The first outlier was in the Category Class "Antvirals; Anti-HIV Agents, Integrase Inhibitors (INSTI)". Here is a good illustration of the Category Class titles being much more important than the Category Class numbers: the numbers aren't even listed on the Formulary Outlier Details tab. So we scroll down to this section of the tab, and see the result above.

The red circled result is the one for carrier 69364. Looking at the "Antvirals; Anti-HIV Agents, Integrase Inhibitors (INSTI)" Category Class, we notice that there are 7 chemically distinct drugs available to meet this Category Class (purple circle). Look at the row labeled "Covered Count" that follows the list of these chemically distinct drugs (red arrow). The result in this row for carrier 69364's drug list 2 tells us that this drug list covers none of the 7 drugs available.

The green and orange columns to the right show us the details of each drug's coverage on each drug list. When the tool is run on multiple carriers' formularies, as in the screen shot, or on multiple markets, these results will appear in alternating orange and green columns.

Look at the results for carrier 69364's drug list 1, just to the left of the results for drug list 2. This is the drug list that passed the Tool. The 4 drugs covered without restrictions are all indicated in the "List 1 Coverage" column by the word "unrestricted" written in regular black font (green

circle). Three drugs in this Category Class are not covered on this drug list, so the result says "uncovered" in red font for those drugs (purple arrow).

If we look at the results for carrier 80473 (green arrow), we see that drugs which are covered, but with restrictions, are marked with the notation "PA", if the restriction is prior authorization, and "ST", if the restriction is step therapy (yellow circle). If a drug has both prior authorization and step therapy requirements, both notations will appear. Restrictions appear in bold, red font.

If a drug has a step therapy requirement, it will say "ST" in bold red font. If a drug has both prior authorization and step therapy requirements, it will have both notations in the result in the List X Coverage column. (See purple circle in screen shot above.)

We saw on the Formulary Outlier Summary tab that, for the Category Class Antvirals; Anti-HIV Agents, Integrase Inhibitors (INSTI)", the Applied Threshold is 2. That means that this drug list must include 2 drugs in this Category Class covered without restrictions. Since it currently has no covered drugs in this Category Class, the carrier will need to resolve this outlier by adding 2 covered drugs in this Category Class, both covered without restrictions. Alternatively, the carrier may need to provide OIC with an acceptable justification why this result is not discriminatory against people whose health status requires treatment with these drugs. This path to correction is pretty obvious. However, remember that the Plan Details tab also includes a "Deficiency Message" for each "Not Met" result which tells the carrier how it might correct the outlier.

All RxCUIs Submitted and Errors tabs

These tabs work the same as described with regard to the Clinical Appropriateness Tool.

Justifications

As discussed with respect to the Drug Count Tool, HHS uses a list of FDA-approved and available drugs called the HHS Essential Health Benefits Rx Crosswalk (Rx Crosswalk). This is the list of drugs against which carriers' Drug Lists are measured. The Rx Crosswalk must be finalized at some point in order to be programmed into the Electronic Review Tools, but drugs go off and come on the market with great frequency. Thus, the Rx Crosswalk as used in the Tools cannot be current and complete, because it is static. In addition, carriers structure their coverage of prescription drugs differently. Other features of a plan's design may make what appears to a Tool to be an outlier a nondiscriminatory element of coverage.

Carriers can therefore submit justifications to show that their Drug Lists do meet the applicable benchmarks and thresholds, despite the results of the Electronic Review Tools. There are forms designed for this purpose. Carriers can complete and attach as many Justification Forms as necessary on the Form Schedule tab in their binders, along with the Electronic Review Tool results.

There are only a few different types of justifications, and each justification must be evaluated on its own. However, there are some general rules about what types of justification OIC can accept, and what types we cannot accept.

Unacceptable Justifications

Clinically-based disagreements

OIC Health Forms Compliance Analysts are not clinicians. We are not qualified to evaluate clinically-based justifications. We rely upon the clinical expertise of the clinicians at HHS whose expertise is programmed into the Electronic Review Tools. Clinicians on behalf of carriers may disagree with those HHS experts, but OIC cannot judge those disagreements.

As a result, clinical disagreements with the clinical assumptions underlying the Tools' methodology are not acceptable justifications for failing results on one of the Electronic Drug Tools. Although a carrier may disagree that such is clinically justified, it must meet the requirements built into the tools.

For example, in the discussion of the Clinical Appropriateness Tool, above, we saw a carrier that failed to meet the threshold for coverage of long-acting insulin analogs for diabetes. The carrier's justification was as follows:

> Data currently available do not support using insulin analogs over human insulin. Insulin analogs are second-line alternatives to NPH isophane and regular human insulin. Formulary includes Humulin N, Humulin R and Humulin 70/30 with no PA/ST restrictions.

This is a clinical argument about whether such drugs are clinically appropriate to be used as first-line treatment of diabetes. The clinicians at HHS whose expertise is programmed into the test clearly disagree. They determined that, in order for a formulary not to discriminate against diabetics, it must cover at least 1 long acting insulin analog. OIC must rely upon those clinicians' expertise, and will therefore stand by the requirement. This carrier must cover at least 1 long acting insulin analog without restrictions.

Another clinical Justification reads:

> Of the additional entities available in the Antidepressants/Tricyclics category and class (Category Class ID 29: amoxapine, clomipramine, imipramine, trimipramine), none have shown any clinically significant advantage over other tricyclic antidepressants already on the formulary without restriction.
>
> We respectfully request to maintain prior authorization requirements that currently exist on these 4 additional entities.

OIC cannot make judgments about the clinical advantage of one drug over another drug in a class. Again, OIC relies upon the clinical expertise built into the tools, and would require this carrier to remove restrictions so as to meet the threshold in this Category Class.

A drug is not on the formulary because it is a medical service drug

As defined above, a medical service drug is one that must be administered to the patient in a clinical setting. For example, many chemotherapy drugs are given intravenously over a period of minutes or hours, and must be administered in a clinical setting for several reasons. Short-acting anesthesia agents used during procedures, because they require close monitoring of the patient, are another example. There are a host of medical service drugs.

Both HHS and OIC now require that issuers include all covered drugs on their drug lists. This includes drugs with no RxCUIs, drugs that do not apply to any Category Class, and "medical service" drugs. The CMS 2020 QHP Application Instructions state:

> The drug list should include all drugs on the issuer's formulary, even if they do not fall in one of the categories and classes identified in the summary of EHB benchmark information, available at https://www.qhpcertification.cms.gov/s/Prescription%20Drugs. **This includes all drugs deemed by the user as "medical service drugs."**

CMS 2020 QHP Application Instructions, Version 1, Pg. 51 (emphasis added).

As a result, OIC does not accept this justification. A carrier who submits this justification must revise its Rx Drug Template Drug List tab to include all medical service drugs, so that these drugs can be counted toward the benchmarks and thresholds. The carrier should then re-run the Tool(s) using the new Rx Drug Template. If failure to include a medical service drug was the cause of an error on one of the Tools, this change will resolve the error.

Acceptable Justifications

Background

Remember how HHS defined a formulary being "substantially equal" to the benchmark plan's formulary? A plan does not have to cover the same drugs as the benchmark plan, it can cover different drugs in the same Category Class, as long as it covers as many, or more, of them. So the Drug Count Tool needs to have a list of all possible drugs in each Category Class. It does. Actually, it has two.

HHS Essential Health Benefits Rx Crosswalk

The first list is called the HHS Essential Health Benefits Rx Crosswalk ("Rx Crosswalk"). It is basically a list of all FDA-approved drugs by RxCUI (see below for a definition of RxCUI). You can download the Crosswalk by clicking on the "EHB Rx Crosswalk" link on this page, or by going to www.QHPCertification.cms.gov. At the bottom of this page, under "Resources", is a link to "Review Tools." A link to the EHB Rx Crosswalk is located about halfway down the page,

under "Drug Count Tool." Each year, the RX Crosswalk includes drugs approved as of a particular date. For example, the Rx Crosswalk for Plan Year 2020 includes RxCUIs for all FDA-approved drugs as of October 1, 2018.

RxNorm

The second list is a database called RxNorm, which is a list of all valid RxCUIs. It is updated more than annually. For Plan Year 2020, CCIIO requires issuers to use the October 1, 2018 full month RxNorm list (apparently because that was when they finalized the Rx Crosswalk for Plan Year 2020).

The dates of these two lists are going to become important to know when we talk about justifications, below.

What's an RxCUI?

An RxCUI a unique number assigned to a particular dosage and administration route of a drug. (CUI stands for Concept Unique Identifier.) For example, the antibiotic Clindamycin has many RxCUIs. The 150 Mg. oral capsule of Clindamycin is RxCUI 197518. The 300 mg. oral capsule is RxCUI 284215. The 10 Mg/Ml topical lotion is RxCUI 197519. The 12 mg./50 ml. intravenous injection is RxCUI 309335.

So you can see that RxCUIs are pretty specific. They are way more specific than Category Class IDs, which refer to a whole group of similar drugs, and they are even more specific than just the name of the drug. They're the name + the dosage + the route of administration of the drug. (Oral capsule, topical lotion, and IV solution are all routes of administration.)

Unfortunately, because there are so many thousands of drugs (just look at a Drug List tab on the RX template), and their status changes so frequently, the Rx Crosswalk list simply cannot be kept current and complete. At some point, the Drug Count Tool programmers have to upload a version of the Rx Crosswalk, so the Drug Count Tool has something to count against. But, by definition, that list is static and so does not reflect the changes that occur after it is uploaded. Therefore, carriers may submit justifications for situations when a drug list actually does meet a Category Class, but the Tool doesn't recognize a new drug or version of a drug that came out too late to be on the Rx Crosswalk (for Plan Year 2020, after October 1, 2018). In fact, probably the majority of justifications are the result of deficiencies in the Rx Crosswalk.

A generic version of a drug has become available since October 1, 2018

That gets us to this acceptable justification. Generic forms of many drugs will have come on the market since the current Rx Crosswalk was finalized in October, 2018. None of these newer generic drugs, of course, are on the current Rx Crosswalk. Generic drugs have different RxCUIs than their brand-name counterparts.

So imagine that a carrier submits a Drug List that includes a new generic drug that came on the market in January of 2019. This new generic satisfies one of the Category Classes, so the plan

actually covers a sufficient number of drugs in that Category Class. However, the tool does not recognize this drug's RxCUI, so it does not count the drug towards that Category Class. The carrier includes a justification in its binder explaining that, and OIC accepts it.

This is a classic example of a justification that is acceptable because it is not based upon clinical judgment and can be confirmed.

Here's an old, but still illustrative, example of how this might look. Let's say carrier 18699 submits Drug Count Tool results that show it covers only 5 drugs in the Category Class, "Genitourinary agents; antispasmodics, urinary". The benchmark is 7 drugs in this Category Class. The carrier submits the following justification using the Washington State Justification Form for this Tool:

Formulary – Category & Class Drug Count Review Tool

Supporting Documentation and Justification

Formulary for Click here to enter text. **quarter, 20**Click here to enter text..
Issuer: Click here to enter text.

Instructions: *Each prescription drug must be listed on a separate row. You may add additional rows to the table below as needed.*
Note: Justification forms must be converted to a PDF format prior to uploading in SERFF. DO NOT upload the WORD version.

Drug List ID(s)	Category	Class	Benchmark count	Covered Count	Justification*	RxCUIs (if applicable)
2	Genitourinary	Antispasmodics	7	5	We cover 2 additional drugs	485421
	Agents	, Urinary			which were approved after April,	485423
					2018	

***Justification – see below**:
Indicate the appropriate letter in the Justification Column or describe an "other" justification.

A: There are no longer sufficient drugs in this Category/Class available to meet the benchmark. The formulary includes all drugs that are available in this Category/Class. The HHS EHB Rx Crosswalk (Rx Crosswalk) lists all drugs available at the time of its finalization. If the Rx Crosswalk includes sufficient drugs to meet the benchmark, please provide documentation that one or more of those drugs has become unavailable since the current Rx Crosswalk was finalized.

B: The formulary covers drugs in this Category/Class which have become available since the date the current EHB Prescription Drug Crosswalk was published. Please list the RxCUIs of these covered drugs.

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C: Other: Please explain why the list of drugs covered provides the Prescription Drug EHB despite covering fewer drugs in the Category/Class than the benchmark.

Please Note: OIC cannot accept clinically-based justifications, such as opinions regarding the efficacy of particular drugs on the EHB Rx Crosswalk.

OIC can accept this justification if the Analyst can confirm that these two additional drugs are covered. Here's what they do:

Using the RxCUIs provided in the Justification Form, the OIC Analyst goes to the All RxCUIs Submitted tab and does a "find" for these RxCUIs. The OIC Analyst finds these RxCUIs and, from that, can sort the list by chemically distinct drug. They see this:

	RxCUI	Retired?	Reassigned RxCUI	Crosswalk Status	EHB-Rx Classification	Chemically Distinct Drug ID	Chemically Distinct Drug	Category & Class Impacted	Impact Category Class Revie	18699 Drug Lists	Drug List 1
2455	485421	N/A	N/A	RxNorm Database	N/A	223	darifenacin	N/A	No		Covered
2456	485423	N/A	N/A	RxNorm Database	N/A	223	darifenacin	N/A	No		Covered
2457	543021	No	N/A	EHB Rx Crosswalk	N/A	223	darifenacin	119	Yes		Not Covered
2458	543027	No	N/A	EHB Rx Crosswalk	N/A	223	darifenacin	119	Yes		Not Covered

The All RxCUIs Submitted tab shows that RxCUIs 485421 and 485423 are covered. Now the Analyst needs to make sure that these drugs have the same dosage/route of administration combinations as the RxCUIs that satisfy Category Class 119. If they do, then OIC can accept the carrier's justification.

The screen shot above shows that the drug we're working with is called darifenacin. Notice that there are four dosage / route of administration versions of darifenacin on this list, but two of them are not covered (highlighting). We can see that they're RxCUIs 543021 and 543027. The carrier's Justification Form said that there are new generics of the same things that are covered.

We can see that RxCUIs 485421 and 485423 are both darifenacin (the correct drug). So far so good.

We Google the two, covered, RxCUIs. We see that RxCUI 485421 is darifenacin in a 15 mg Extended Release oral tablet. That means that it can legitimately be substituted for RxCUI 543021, which is the same thing. We also see that RxCUI 485423 is the 7.5 mg extended release oral tablet of darifenacin, which is the same as RxCUI 543027. Bingo. The justification checks out and the carrier has met the benchmark in this Category Class.

> **ProTip:** Any time you see the extended release version of a drug excluded, one thing that should come to mind is the carrier may cover the regular version, but not the extended release form of the drug. This is common. But if a carrier cannot meet the benchmark without covering the extended release form of a drug, the carrier must cover it.

Drugs in this Category and Class Are No Longer Available

This justification could be necessary because the drugs have been discontinued by the manufacturer, have been deemed unsafe by the FDA, or have been removed from market by the manufacturer due to safety concerns.

If it is no longer possible to meet the benchmark, the tool as released for that Plan Year will likely already have flagged that issue. (See discussion of "Benchmark Reevaluation" column in the Drug Count Tool.)

The Drug Count Tool's Category Class Details tab identifies every chemically distinct drug and the Category Class in which it can be counted toward the benchmark. The All RxCUIs Submitted tab gives more detailed information on each drug on the carrier's Drug List(s) and the Category Classes into which a particular RxCUI falls. If the number of drugs available on the market is insufficient to meet a Category Class for a particular Plan Year as of the time the Rx Crosswalk is finalized, review of these two tabs will identify that problem.

If such a problem has been identified, this justification is acceptable.

If a carrier needs to submit a justification that it cannot meet the benchmark in a Category Class due to unavailability of enough drugs, and this unavailability has not been identified using the information in the Drug Count Tool, OIC will need more information. Such a justification means the carrier is saying that the drug has become unavailable since the time the Rx Crosswalk was finalized for that Plan Year.

In order to evaluate whether this justification can be accepted, the OIC Analyst will review the Category Class Details and All RXCUIs submitted tabs of the carrier's Drug Count Tool results, to establish that there is not another drug that can be covered to meet the benchmark. If there is, then the carrier must cover that other drug.

If there is no other drug that can be covered to meet the benchmark, OIC will need confirmation that the drug has become unavailable, especially if other carriers have not submitted this same justification. If the carrier has not included with the justification some documentation that the drug has become unavailable, OIC will request it via an Objection. OIC will evaluate the documentation to ensure that it supports the carrier's justification.