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2015 QUALIFIED HEALTH PLAN APPLICATION REVIEW TOOLS USER GUIDE: NON-DISCRIMINATION FORMULARY CLINICAL APPROPRIATENESS TOOL

Loading and Analyzing the Data

Table of Contents

Non-Discrimination Formulary Clinical Appropriateness Tool User Guide	1
Using this Guide	1
Non-Discrimination Formulary Clinical Appropriateness Tool: Loading the Data	2
Non-Discrimination Formulary Clinical Appropriateness Tool: Analysis	5
Appendix: Acronyms and Terms	10

NON-DISCRIMINATION FORMULARY CLINICAL APPROPRIATENESS TOOL USER GUIDE

Tool	Function
Non-Discrimination Formulary Clinical Appropriateness Tool	<ul style="list-style-type: none">• Analyzes the availability of drugs associated with four conditions:<ul style="list-style-type: none">– Diabetes.– Rheumatoid arthritis.– Bipolar disorder.– Schizophrenia.• Ensures that issuers are offering a sufficient number of drugs, as recommended in clinical guidelines, needed to effectively treat these conditions.

The Non-Discrimination Formulary Clinical Appropriateness Tool offers one methodology of ensuring that (1) issuers are offering a sufficient number of drugs, as recommended by clinical guidelines, for effective treatment; and (2) issuers are not restricting access by lack of coverage or inappropriate use of management techniques. The tool analyzes the availability of drugs associated with four conditions: diabetes, rheumatoid arthritis, bipolar disorder, and schizophrenia.

Use of the tool by state regulators or issuers is optional. These tools can be run for the following plan types: plans that are only offered on the Marketplace, plans that are only offered off the Marketplace, or for all submitted standard plans on and off the Marketplace.

For the tool to run, it is imperative that users do not change the worksheet names, format, and overall structure (e.g., adding or deleting rows or columns, changing field names, copying or deleting worksheets), as this could impact the functioning of the tool macros. However, filters have been added to the table headings in many of the stand-alone tools and these may be used without disrupting tool use.

Using this Guide

The following characteristics are intended to focus the user to where actions are warranted:

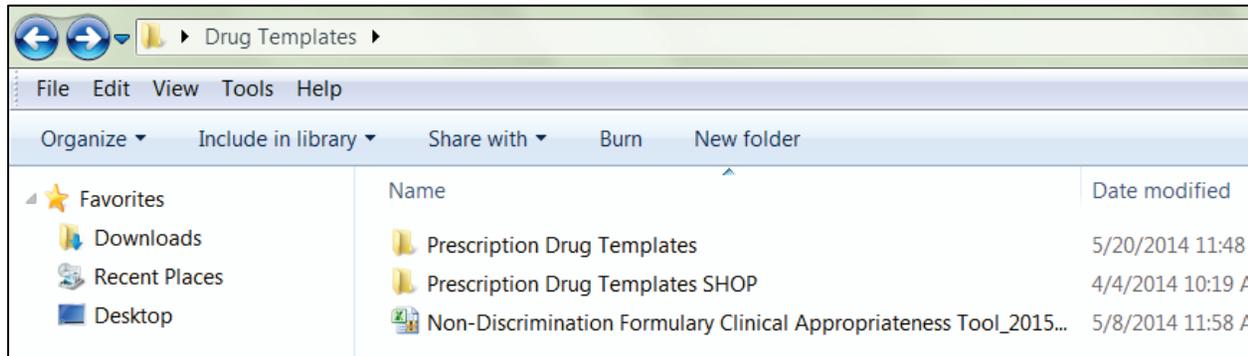
- Items that appear in *italics* are features. (e.g., See the *Instructions tab* in the Master Review Tool.)
- Items that are in **bold** type are functions. (e.g., **Click “Save.” Click “Import Data from Master Review Tool.”**)
- For space considerations, screenshots of Excel worksheets may not include the full data picture.

NON-DISCRIMINATION FORMULARY CLINICAL APPROPRIATENESS TOOL: LOADING THE DATA

Before you can begin the Non-Discrimination Formulary Clinical Appropriateness Tool steps, **download** the tool from SERVIS (https://servis.cms.gov/resources/document_detail?doc_detail_id=c2de042d-bf0e-4e2a-46da-53691d3dc025) (states) or CMSzONE (<https://zone.cms.gov/document/2015-qhp-application-review-tools>) (issuers).

If you are using this stand-alone tool, we recommend that you review the validation steps in the Master Review Tool *Benefit Cost Sharing tab* to understand the logic of the tool and where justifications may overcome the tool's automated results.

1. **Place** all of the prescription drug Excel templates to be reviewed into a folder that you can easily access. Issuers may submit separate sets of templates for individual and Small Business Health Options Program (SHOP) plans. In this case, an issuer can submit two drug lists with the same ID – one for the individual Marketplace and one for the SHOP Marketplace. For this tool to distinguish between these two drug lists, the tool will need to be run once for both sets of templates.



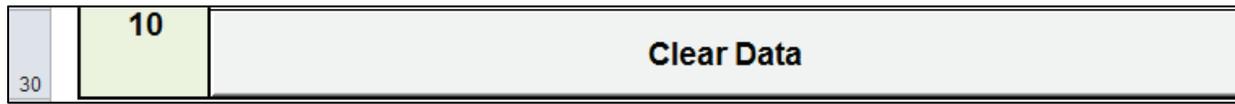
For consideration: The default and recommended threshold values are shown; a higher value will result in a more stringent review, while a lower value will result in a more lenient review. You may input the test threshold values for the review calculations for each review test. To reset the thresholds to the suggested values, **click** the “**Reset Thresholds**” button. Note: Threshold values are restricted to values between zero and the highest number possible for a particular test.

2		The clinical appropriateness review ensures that enrollees have access to the drugs recommended in clinical guidelines for four medical conditions: diabetes, rheumatoid arthritis, bipolar disorder and schizophrenia.		
2		Please input the test threshold values that you would like to use for the review calculations for each review test. Enter your threshold in the "Threshold" column below. The default and recommended threshold values are shown below; a higher value will result in a more stringent review, while a lower value will result in a more lenient review. Ultimately, the states will choose the final review threshold values. To reset the thresholds to the suggested values, please click the "Reset Thresholds" button below.		
2		Note: Threshold values are restricted to values between zero and the highest number possible for a particular test.		
Condition	Test Description	Threshold		
Diabetes	Coverage of the diabetes drug classes	11		
	Coverage of metformin without prior authorization or step therapy (unrestricted)	1		
	Coverage of second generation sulfonylurea without prior authorization or step therapy (unrestricted)	3		
Rheumatoid Arthritis	Coverage of methotrexate without prior authorization or step therapy (unrestricted)	1		
	Coverage of the disease-modifying antirheumatic drugs (other than methotrexate)	3		
	Coverage of Anti-TNF and Non-TNF biologic drugs	3		
Bipolar Disorder & Schizophrenia	Coverage of clozapine	1		
	Coverage of mood stabilizer drugs without prior authorization or step therapy (unrestricted)	4		
	Coverage of second generation and atypical antipsychotic drugs	9		
Reset Thresholds				

2. After thresholds are confirmed, **save** the workbook before you run the tool.
3. Click “Run Review Tool” in row 23.



4. **Save** the workbook again.
5. To clear the data from all the worksheets to facilitate analysis of another set of data such as SHOP, **click “Clear Data”** in row 30.



Note: If there is an error tab displayed, this tab lists any errors that were found while running the review. This tab will not be displayed if no data errors were detected.

Note: If you wish to change the thresholds, you will have to rerun this review. Please follow the instruction steps again. You do not need to clear the data to rerun the review, but know the previous results will be overwritten if the tool is run again.

Warning! Depending on the number of templates and drug lists that are run, this process could take several minutes. After pressing the button, do not do anything with Excel until the process has finished. If you interrupt the process, you will need to restart the process.

NON-DISCRIMINATION FORMULARY CLINICAL APPROPRIATENESS TOOL: ANALYSIS

- The *Summary tab* displays the overall results of the non-discrimination formulary clinical appropriateness tests. The results for each individual test will be shown, as well as the results for the overall clinical appropriateness review for each drug list.

Condition	Master Review Tool Reference	Test Description	Threshold Selected	Test Results:	12345	12345	12345	12345	12345
				Not Met	Not Met	Not Met	Not Met	Not Met	Not Met
Diabetes	Diabetes Review: 2 Review Step: a	Coverage of the diabetes drug classes	11	Met	Met	Met	Met	Met	Met
	Diabetes Review: 3 Review Step: a	Coverage of metformin without prior authorization or step therapy (unrestricted)	1	Met	Met	Met	Met	Met	Met
	Diabetes Review: 4 Review Step: a - c	Coverage of second generation sulfonylurea without prior authorization or step therapy (unrestricted)	3	Met	Met	Met	Met	Met	Met
Rheumatoid Arthritis	Rheumatoid Arthritis Review: 2 Review Step: a	Coverage of methotrexate without prior authorization or step therapy (unrestricted)	1	Met	Met	Met	Met	Met	Met
	Rheumatoid Arthritis Review: 3 Review Step: a - c	Coverage of the disease-modifying antirheumatic drugs (other than methotrexate)	3	Not Met	Not Met	Not Met	Not Met	Not Met	Not Met
	Rheumatoid Arthritis Review: 4 Review Step: a - g	Coverage of Anti-TNF and Non-TNF biologic drugs	3	Met	Met	Met	Met	Met	Met
Bipolar Disorder & Schizophrenia	Bipolar & Schizophrenia Review: 2 Review Step: a	Coverage of clozapine	1	Met	Met	Met	Met	Met	Met
	Bipolar & Schizophrenia Review: 3 Review Step: a - e	Coverage of mood stabilizer drugs without prior authorization or step therapy (unrestricted)	4	Met	Met	Met	Met	Met	Met
	Bipolar & Schizophrenia Review: 4 Review Step: a - i	Coverage of second generation and atypical antipsychotic drugs	9	Met	Met	Met	Met	Met	Met

2. The *Diabetes Tests*, *Rheumatoid Arthritis Tests*, and *Bipolar and Schizophrenia Tests* tabs display the results for the specific tests that are being reviewed for the diabetes, rheumatoid arthritis, and bipolar and schizophrenia conditions, respectively, for each drug list. If the “Drug” column has a value of “All” for a particular condition and class, then the test is based on all the drugs in a particular condition and class. Otherwise, the test is based on the individual drug that is listed. The test can be for:

- Covered Count: The number of RxCUIs the drug list contains for the specific test.
- Unrestricted Count: The number of RxCUIs the drug list contains for the specific test without prior authorization or step therapy requirements.

Condition	Master Review Tool Reference	Class	Drug	Test	12345	12345	12345	12345	12345
Diabetes	Review: 2 Review Step: a	Insulin - Short Acting	All	Covered Count	3	3	3	3	3
Diabetes	Review: 2 Review Step: a	Insulin - Intermediate Acting	All	Covered Count	5	5	5	5	5
Diabetes	Review: 2 Review Step: a	Insulin - Long Acting	All	Covered Count	4	4	4	4	4
Diabetes	Review: 2 Review Step: a	Insulin Analogs	All	Covered Count	12	12	12	12	12
Diabetes	Review: 2 Review Step: a	Biguanides	All	Covered Count	49	49	49	49	49
Diabetes	Review: 2 Review Step: a	Sulfonylureas	All	Covered Count	50	50	50	50	50
Diabetes	Review: 2 Review Step: a	Alpha-glucosidase inhibitors	All	Covered Count	9	9	9	9	9
Diabetes	Review: 2 Review Step: a	Glucagon-like peptide-1 (GLP-1) receptor agonists	All	Covered Count	4	4	4	4	4
Diabetes	Review: 2 Review Step: a	Thiazolidinediones	All	Covered Count	34	34	34	34	34
Diabetes	Review: 2 Review Step: a	Meglitinides	All	Covered Count	9	9	9	9	9
Diabetes	Review: 2 Review Step: a	DPP-4 inhibitors	All	Covered Count	23	23	23	23	23
Diabetes	Review: 2 Review Step: a	Sodium glucose co-transporter 2 (SGLT2) inhibitors	All	Covered Count	0	0	0	0	0
Diabetes	Review: 3 Review Step: a	Biguanides	metformin	Unrestricted Count	41	41	41	41	41
Diabetes	Review: 4 Review Step: a	Sulfonylureas	glimepiride	Unrestricted Count	8	8	8	8	8
Diabetes	Review: 4 Review Step: b	Sulfonylureas	glyburide	Unrestricted Count	17	17	17	17	17
Diabetes	Review: 4 Review Step: c	Sulfonylureas	glipizide	Unrestricted Count	13	13	13	13	13

Note: The *RxCUI counts* in these three tabs are different from the covered and unrestricted drug counts in the *Detailed Drug Counts* tab. These counts do not match across tabs.

3. In the *Detailed Drug Count* tab, the total number of chemically distinct drugs that are covered and the total that are unrestricted are counted and displayed.

This tab displays the results of the review for each drug in the conditions and classes being reviewed. For each drug list, each drug is either:

- *Uncovered*: The drug list does not contain any RxCUIs associated with the drug.
- *Unrestricted*: The drug list contains at least one RxCUI associated with the drug without prior authorization or step therapy.
- *Restricted with Prior Authorization (PA)*: All of the RxCUIs on the drug list associated with the drug have only a prior authorization requirement.
- *Restricted with Step Therapy (ST)*: All of the RxCUIs on the drug list associated with the drug have only a step therapy requirement.
- *Restricted with Both Prior Authorization and Step Therapy (PA, ST)*: All of the RxCUIs on the drug list associated with the drug have either prior authorization or step therapy requirements. Some RxCUIs may have both requirements.

Condition	Class	Chemically Distinct Drug	12345	ZZ	1	2	1
Diabetes	Insulin – Short Acting	regular insulin	Unrestricted	Unrestricted	Unrestricted	Unrestricted	Unrestricted
		Covered Count	1	1	1	1	1
		Unrestricted Count	1	1	1	1	1
Diabetes	Insulin – Intermediate Acting	insulin NPH	Unrestricted	Unrestricted	Unrestricted	Unrestricted	Unrestricted
		Covered Count	1	1	1	1	1
		Unrestricted Count	1	1	1	1	1
Diabetes	Insulin – Long Acting	insulin detemir	Unrestricted	Unrestricted	Unrestricted	Unrestricted	Unrestricted
		insulin glargine	Unrestricted	Unrestricted	Unrestricted	Unrestricted	Unrestricted
		Covered Count	2	2	2	2	2
Diabetes	Insulin Analogs	insulin aspart	Unrestricted	Unrestricted	Unrestricted	Unrestricted	Unrestricted
		insulin glulisine	Unrestricted	Unrestricted	Unrestricted	Unrestricted	Unrestricted
		insulin lispro	Unrestricted	Unrestricted	Unrestricted	Unrestricted	Unrestricted
Diabetes	Insulin Analogs	aspart/aspart protamine mixture	Unrestricted	Unrestricted	Unrestricted	Unrestricted	Unrestricted
		lispro/lispro protamine mixture	Unrestricted	Unrestricted	Unrestricted	Unrestricted	Unrestricted
		Covered Count	5	5	5	5	5
Diabetes	Biguinides	metformin	Unrestricted	Unrestricted	Unrestricted	Unrestricted	Unrestricted
		Covered Count	1	1	1	1	1
		Unrestricted Count	1	1	1	1	1
Diabetes	Sulfonylureas	chlorpropamide	Unrestricted	Unrestricted	Unrestricted	Unrestricted	Unrestricted
		tobutamide	Unrestricted	Unrestricted	Unrestricted	Unrestricted	Unrestricted
		tolazamide	Unrestricted	Unrestricted	Unrestricted	Unrestricted	Unrestricted
		glipizide	Unrestricted	Unrestricted	Unrestricted	Unrestricted	Unrestricted
		glyburide	Unrestricted	Unrestricted	Unrestricted	Unrestricted	Unrestricted
		glimperide	Unrestricted	Unrestricted	Unrestricted	Unrestricted	Unrestricted
		Covered Count	6	6	6	6	6
Unrestricted Count	6	6	6	6	6		
		acarbose	Unrestricted	Unrestricted	Unrestricted	Unrestricted	Unrestricted

4. Using the data in Non-Discrimination Clinical Appropriateness Tool tabs, **go to** the Master Review Tool *Clinical Appropriateness tab* and indicate if an issuer’s drug lists have met the formulary requirement. For each issuer’s drug list, **populate** “Met” or “Not Met” from the drop-down menus at the top of each column in the row.

Users may select if the overall standard is “Met” or “Not Met” at the top of the worksheet which will auto-populate the summary review. This is the only information auto-populated to the review summary from this tab.

Review	Review step	Review description and procedure	Step description	Source	Validation Results												
					<table border="1"> <tr> <td>HIOS Issuer ID, Formulary ID:</td> <td>67899, ZZFO05</td> <td>67899, ZZFO06</td> <td>67899, ZZFO01</td> </tr> <tr> <td>Drug list ID:</td> <td></td> <td></td> <td></td> </tr> <tr> <td>SELECT REVIEW RESULT:</td> <td>Met</td> <td>Not Met</td> <td>Met</td> </tr> </table>	HIOS Issuer ID, Formulary ID:	67899, ZZFO05	67899, ZZFO06	67899, ZZFO01	Drug list ID:				SELECT REVIEW RESULT:	Met	Not Met	Met
HIOS Issuer ID, Formulary ID:	67899, ZZFO05	67899, ZZFO06	67899, ZZFO01														
Drug list ID:																	
SELECT REVIEW RESULT:	Met	Not Met	Met														
18			◆ Insulin—Long Acting		Met												
19			◆ Insulin Analogs		Met												
20			◆ Biguanides		Met												
21			◆ Sulfonylureas		Met												
22			◆ Alpha-glucosidase inhibitors		Met												
23			◆ Glucagon-like peptide-1 (GLP-1) receptor agonists		Met												
24			◆ Thiazolidinediones		Met												
25			◆ Meglitinides		Met												
26			◆ DPP-4 inhibitors		Met												
27			◆ Sodium Glucose co-transporter 2 (SGLT2) inhibitors.		Met												
28			After all classes have been checked, moved to next review.		Met												
29	3	Determine whether metformin is covered without step therapy and prior authorization.			Met												
30	a		Count the number of RxCUIs associated with metformin without prior authorization and step therapy. If 0, mark as “Not Met.”	RxCUI, Tier Level, Prior Authorization Required, Step Therapy Required	Met												
31	4	Determine whether all-second-generation sulfonylureas are covered without step therapy and prior authorization.			Met												

Each standard provides space for user determined evaluation of whether the standards are “Met” or “Not Met.” Additional information on standards review may be included in the space adjacent to the standard review steps.

- Once completed, **open** the Master Review Tool *Review Summary* tab to see the auto-populated results in row 17.

Section/Standard	Function of Review	L	M	N	O	P	Q
ECP	Ensure issuers have ECPs, where available, that meet the policy standards.	Not Met					
Category Class Drug Count	Ensure compliance with EHBs and check for discrimination by counting drugs in each USP category and class.	Met	Met	Met	Not Met	Not Met	Not Met
Non-Discrimination Formulary	Identifies plans with an unusually large number of drugs that require step therapy or prior authorization in one of five	Not Met	Met	Met	Not Met	Not Met	Not Met
Non-Discrimination Clinical Appropriateness	Ensures that enrollees have access to the drugs recommended in clinical guidelines for four diseases.	Met	Not Met	Not Met	Met	Met	Met
Benefit Cost Sharing	Check in-network out-of-pocket maximum costs for individual and family EHB coverage against the annual dollar limit and ensure the cost sharing variations and catastrophic plans meet all requirements.	Met	Met	Met	Met	Met	Met
Meaningful Difference	Identify if an issuer submits one or more QHPs of the same plan type and metal level in a county and review further for network, deductible, and out-of-pocket maximum differences.	Met	Met	Met		Met	
Non-Discrimination Benefit	Perform an outlier analysis on selected benefits cost-sharing.	Met	Met	Met	Met	Met	Met
Service Area	Confirm that issuers include full counties or have a justifiable reason for partial counties.	Not Met	Not Met	Not Met		Met	
OVERALL PLAN VALIDATION		Not Met					

- Save the Master Review Tool after you have completed the clinical appropriateness review.

APPENDIX: ACRONYMS AND TERMS

Acronym	Definition
AAAHC	Accreditation Association for Ambulatory Health Care
AV	actuarial value
AVC	actuarial value calculator
APTC	advance premium tax credits
ACA	Affordable Care Act
API	Application Programming Interface
BCBS	Blue Cross Blue Shield
BPCK	branded pack
CCIO	Center for Consumer Information and Insurance Oversight
CMS	Centers for Medicare & Medicaid Services
COA	certificate of authority
CALT	Collaborative Application Lifecycle Tool
CAHPS	Consumer Assessment of Healthcare Providers and Systems
CSR	cost-sharing reduction
DOB	date of birth
DIT	data integrity tool
DMARDs	disease-modifying antirheumatic drugs
DOI	Department of Insurance

Acronym	Definition
DPP	diabetes prevention program
DSH	disproportionate share hospital
EIDM	Electronic imaging and document management
EIN	employer identification number
ECP	essential community provider
EHB	essential health benefit
EPO	exclusive provider organization
FEIN	Federal employer identification number
FPL	Federal poverty level
FQHC	Federally qualified health center
FFM	Federally-facilitated Marketplace
GSA	General Services Administration
GPCK	generic pack
HHS	U.S. Department of Health and Human Services
HIOS	Health Insurance Oversight System
HIPAA	Health Insurance Portability and Accountability Act
HMO	health maintenance organization
HPSA	health professional shortage area
HRA	health reimbursement arrangement

Acronym	Definition
HSA	health savings account
ISS	interactive survey system
MCO	managed care organization
MOOP	maximum out-of-pocket
M	multiplier
NAIC	National Association of Insurance Commissioners
NCQA	National Committee for Quality Assurance
NPI	national provider identifier
OIG	Office of the Inspector General
OOPM	out-of-pocket maximum
POS	point of service
PPO	preferred provider organization
PA	prior authorization
QHP	qualified health plan
RXCUI	RxNorm Concept Unique Identifier
SBC	summary of benefits and coverage
SBD	semantic branded drug
SCD	semantic clinical drug
SHOP	Small Business Health Options Program

Acronym	Definition
SEP	special enrollment period
SBM	State-based Marketplace
SPM	State Partnership Marketplace
SSN	Social Security number
SGLT2	sodium glucose co-transporter 2 inhibitors
ST	step therapy
TIN	taxpayer identification number
TNF	tumor necrosis factors
TTY	term types
UMLS	Unified Medical Language System
UCAA	Uniform Certificate of Authority Application
USP	United States Pharmacopeia
.xlms	Excel macro-enabled workbook