Qualified Health Plan (QHP) Application Review Tools – Prescription Drug

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Center for Consumer Information and Insurance Oversight (CCIIO)

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

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Disclaimer

The information provided in this presentation is intended only as a general informal summary of technical legal standards. It is not intended to take the place of the statutes, regulations and formal policy guidance that it is based upon. This presentation summarizes current policy and operations as of the date it was presented. Links to certain source documents have been provided for your reference. We encourage audience members to refer to the applicable statutes, regulations and other interpretive materials for complete and current information about the requirements that apply to them.

Agenda

- Benefits of Using Review Tools
- Overview of the Prescription Drug Tools
  - Essential Health Benefit (EHB) Category & Class Drug Count Tool
  - Non-Discrimination Formulary Outlier Tool
  - Non-Discrimination Clinical Appropriateness Tool
- Where to Find Tools, User Guides and References
- Tool Demonstrations
- Tips to Correct Deficiencies
- Q and A

Prescription Drug Tools Review

Benefits of Using Review Tools

- Speeds up reviews
  - Example: Ability to review a large volume of submitted drug lists and identify any drug lists that do not meet EHB Benchmark drug count requirements.
- Quick and efficient way to point out additional concerns that may not easily be found through hands-on drug list review
  - Example: Identify those plans that have unusually low number of unrestricted drugs.
- Allows for easier comparison of prescription drug benefit review across plans
  - Example: Identify the plans that may not be offering clinically appropriate formularies.

Overview of the Prescription Drug Tools

- The EHB Category & Class Drug Count Tool reviews a drug list for adequate coverage of drugs in each United States Pharmacopeia (USP) category and class.
  - Regulations in 45 Code of Federal Regulations (CFR) 156.122 require a health plan providing EHBs to cover at least the greater of one (1) drug in every USP convention category and class or two (2) the same number of prescription drugs in each category and class as the state EHB Benchmark plan. CMS may use data collected to review for the drug count standard.

- The formulary review suite reviews a drug list for coverage, utilization, and discrimination.
  - Under 45 CFR 156.125, issuers do not provide EHB if its benefit design, or the implementation of its benefit design, discriminates on the basis of age, expected length of life, present or predicted disability, quality of life, or other health conditions. In addition, 156.225(b) states that a QHP issuer must not employ marketing practices or benefit designs that have the effect of discouraging the enrollment of individuals with significant health needs in QHPs. CMS uses data collected in the Prescription Drug Template as part of the review for compliance with the non-discrimination standard.

Overview of the Prescription Drug Tools (continued)

- **Category & Class Drug Count**
  - **New for 2018:** Review tool is a stand-alone review tool.
  - Identifies categories and classes that do not meet the EHB Benchmark Drug Count.
  - Generates the unique count of chemically distinct drugs that are submitted on a given drug list for each category and class.

Overview of the Prescription Drug Tools (continued)

- **Formulary Review Suite**
  - The reviews included in the suite are:
    - Non-Discrimination Formulary Outlier
    - Non-Discrimination Clinical Appropriateness
  - Both formulary reviews can be run simultaneously or independent of each other.

Overview of the Prescription Drug Tools (continued)

- **Non-Discrimination Formulary Outlier**
  - Identifies plans that have unusually low number of unrestricted drugs as outliers
    - Not subject to prior authorization and/or step therapy requirements in particular USP categories and classes
  - Calculates outlier thresholds based on all of the drug lists submitted in a given state
    - If there are less than five (5) unique drug lists in a state, all thresholds for each category and class will default to a value of zero (0).
  - Gives the ability to add national outlier thresholds
    - The national outliers will be used in the review, but the excel tool cannot calculate these thresholds.

Non-Discrimination Formulary Outlier Review

- 27 Total USP Categories and Classes
- Three (3) new USP Categories and Classes added for 2018:
  - Antiemetics, Emetogenic Therapy Adjuncts
  - Antivirals, Anti-hepatitis B (HBV) Agents
  - Antivirals, Anti-hepatitis C (HCV) Agents

Non-Discrimination Formulary Outlier Review (continued)

List of USP Categories and Classes under review:

Category	Class
Anti-Addiction/ Substance Abuse Treatment Agents	Opioid Dependence Treatments
	Opioid Reversal Agents
Anticonvulsants	Anticonvulsants, Other
	Calcium Channel Modifying Agents
	Gamma-aminobutyric Acid (GABA) Augmenting Agents
	Glutamate Reducing Agents
	Sodium Channel Agents
Antidepressants	Antidepressants, Other
	Monoamine Oxidase Inhibitors
	SSRIs/SNRIs (Selective Serotonin Reuptake Inhibitors/ Serotonin and Norepinephrine Reuptake Inhibitors)
	Tricyclics
Antiemetics	Emetogenic Therapy Adjuncts

Non-Discrimination Formulary Outlier Review (continued)

Category	Class
Antivirals	Anti-hepatitis B (HBV) Agents
	Anti-hepatitis C (HCV) Agents
	Anti-HIV Agents, Integrase Inhibitors (INSTI)
	Anti-HIV Agents, Non-nucleoside Reverse Transcriptase Inhibitors (NNRTI)
	Anti-HIV Agents, Nucleoside and Nucleotide Reverse Transcriptase Inhibitors (NRTI)
	Anti-HIV Agents, Other
	Anti-HIV Agents, Protease Inhibitors
Anxiolytics	Anxiolytics, Other
	Benzodiazepines
	SSRIs/SNRIs (Selective Serotonin Reuptake Inhibitors/ Serotonin and Norepinephrine Reuptake Inhibitors)
Blood Glucose Regulators	Antidiabetic Agents
	Insulins
Immunological Agents	Immune Suppressants
	Immunomodulators
Respiratory Tract/ Pulmonary Agents	Cystic Fibrosis Agents

Overview of the Prescription Drug Tools

- **Non-Discrimination Clinical Appropriateness**
  - Analyzes the availability of drugs associated with nine (9) conditions (bipolar disorder, breast cancer, diabetes, hepatitis C, HIV, multiple sclerosis, prostate cancer, rheumatoid arthritis and schizophrenia)
  - Ensures that issuers are offering a sufficient number and type of drugs needed to effectively treat these conditions and are not restricting access by lack of coverage or inappropriate use of utilization management techniques

Overview of the Prescription Drug Tools

- All RxNorm Concept Unique Identifiers (RxCUIs) Submitted Report
  - This tab is included in both Prescription Drug Tools.
  - Provides coverage details for RxCUIs submitted on a drug list
  - It also identifies the chemically distinct drug that a particular RxCUI impacts.

Where to Find Tools, User Guides, and References

- CMS has posted the Review tools, the EHB-Rx Crosswalk and a reformatted RxNorm database in the following location:
  - https://www.qhpcertification.cms.gov/s/Review%20Tools
- The Prescription Drug Template and instructions can be found in the following location:
  - https://www.qhpcertification.cms.gov/s/Prescription%20Drugs

Live Demo

- Drug Count Tool
- Formulary Review Suite

Deficiencies and Justifications

EHB-Rx Category & Class Drug Count

- Use the Category Class Details tab in the Drug Count Tool and the RXNorm file to identify drugs available by categories and classes.
- Justification examples:
  - *Issuer states that the generic version of a brand product is covered and should be counted toward the benchmark count.*
    - After review, if the brand product is included within the USP category and class in question and the generic version of this brand product is covered, this justification will be accepted.
    - RxCUIs for generic versions of brand drugs are sometimes assigned National Drug Codes (NDCs) only after a crosswalk update. Those RxCUIs lacking NDCs at the time of update are not included in the crosswalk.
  - *Issuer states that coverage of a portion of the number of drugs in the EHB-Benchmark for a particular USP category and class is sufficient.*
    - This justification is unacceptable because the number of drugs covered by the plan in the Category/Class Benchmark Count Review must meet or exceed the number in the EHB Benchmark.

Deficiencies and Justifications (continued)

Formulary Outlier

- Use the Formulary Outlier Details tab in the Formulary Review Suite to identify categories and classes with too few unrestricted drugs.
- Issuers can remove prior authorization and step therapy requirements from the identified list of drugs.
- Justification examples:
  - *Issuer states that drug ABC is covered under the medical benefit.*
    - If the drug has medical service properties, this justification is always acceptable.
    - The purpose of the Formulary Outlier review is not to indicate where a drug should be covered i.e., Formulary Outlier review does not require that potential medical service drugs are covered under prescription drug benefits e.g., injectable aripiprazole; paliperidone; abatacept.
  - *Issuer states that their formulary meets the EHB benchmark standard.*
    - This justification is unacceptable because the Formulary Outlier review assesses utilization management restrictions (see 45 CFR 156.125, 156.225(b)).
    - The review of an issuer's count of drugs against the Benchmark standard is conducted under the Category/Class Benchmark Count Review.

Deficiencies and Justifications (continued)

Clinical Appropriateness

- Use the Clinical Summary and Clinical Details tab to identify conditions and classes that do not meet the minimum coverage thresholds.
- Cover the missing drug(s) in the identified conditions and classes.
- Justification examples:
  - *Issuer identifies drug that is not on the Clinical Appropriate drug list but has recently become available on the market.*
    - This justification will be accepted only in cases where the issuer identifies a drug that is not currently listed on the Clinical Appropriateness drug list but is included in the clinical guidelines and has recently become available on the market after the development of the Clinical Appropriateness drug list.
  - *Issuer indicates that drug is only covered upon approval of an exceptions process request.*
    - There are no circumstances where this justification will be accepted.
    - Coverage only upon approval through the exceptions process has the same practical effect as not covering the drug at all, since exceptions process review should always be available for any uncovered drug.

Tips for Justifications

- Submit appropriate justifications and supporting documents.
- Use the Combined Prescription Drug Supporting Documentation and Justification form to respond to deficiencies.
- Provide clinical support and/or evidence to justify a drug list's design.
- Cite clinical guidelines to assist with justification submissions.

Questions?

- CMS Help Desk: CMS_FEPS@cms.hhs.gov

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Closing Remarks

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