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

April 10, 2019

Center for Consumer Information and Insurance Oversight (CCIIO)

This communication was printed, published, or produced and disseminated at U.S. taxpayer expense.

The information provided in this presentation 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 shared. Links to certain source documents may have been provided for your reference. We encourage persons attending the presentation to refer to the applicable statutes, regulations, and other guidance for complete and current information.

HTTPS://WWW.REGTAP.INFO

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Agenda

- Session Guidelines
- Prescription Drug Review Tools
- Live Demo
- Tips to Correct Deficiencies
- Resources
- Live Q&A Session
- Closing Remarks

Intended Audience

- Please be advised that this is not an open press call.
- Members of the press or a media outlet should disconnect the call at this time and contact the Centers for Medicare & Medicaid Services (CMS) Press Office for further information.

Session Guidelines

- This is a 45-minute webinar session.
- Throughout the webinar, you may submit questions via the Q&A Panel.
- We will address questions during the Q&A session at the end of the presentation.
- For questions regarding content or logistics, contact the Registration for Technical Assistance Portal (REGTAP) Registrar at registrar@regtap.info or (800) 257-9520.

Announcements

Prescription Drug Review Tools

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

HTTPS://WWW.REGTAP.INFO

Benefits of Using Review Tools

- Speeds up your reviews
  - Example: Ability to review a large volume of submitted drug lists and identify any drug list that do not meet Essential Health Benefits (EHB) Benchmark drug count requirements.
- Quick and efficient way to identify additional concerns that may not easily be found through hands-on drug list review
  - Example: Identify plans that have unusually large number of restricted drugs.
- Allows for easier comparison of prescription drug benefits across plans
  - Example: Identify plans that may not be offering clinically appropriate formularies.

Overview of the Prescription Drug Review 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) one drug in every USP convention category and class or
    - 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 compliance with the drug count standard.
- The formulary review suite reviews a drug list for coverage, utilization, and potential discrimination.
  - Under 45 CFR 156.125, an issuer does 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.

EHB Category & Class Drug Count Review

- **EHB Category & Class Drug Count Tool**
  - Identifies categories and classes in which the number of covered drugs does 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.
  - Can import Plans & Benefit (P&B) data for plans that are offered both On and Off the Exchanges as well as plans only offered Off the Exchange
  - **New for 2020:**
    - "Substitute RXCUIs" tab has been added identifying any RxNorm Concept Unique Identifiers (RXCUIs) which contain chemically distinct drugs that are not covered on a drug list in categories and classes where the EHB Benchmark Drug Count was not met
    - "Plan Details" tab has a new column, "Deficiency Finder", which locates the deficient counts on the "Category Class Summary" tab

Overview of the Prescription Drug Review Tools

- **Formulary Review Suite**
  - Reviews included in the suite:
    - Non-Discrimination Formulary Outlier
    - Non-Discrimination Clinical Appropriateness

Non-Discrimination Formulary Outlier Review

- **Non-Discrimination Formulary Outlier**
  - Identifies plans that have an unusually large number of restricted drugs as outliers
    - 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 (continued)

- 28 Total USP Categories and Classes
  - USP categories and classes reflective of USPv7.

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, Direct Acting
	Anti-hepatitis C (HCV) Agents, Other
	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

Non-Discrimination Clinical Appropriateness Review

- **Non-Discrimination Clinical Appropriateness**
  - Analyzes the availability of drugs associated with 10 conditions (bipolar disorder, breast cancer, diabetes, hepatitis C, HIV, multiple sclerosis, opioid use disorder, 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

Live Demo

- Drug Count Tool
- Formulary Review Suite

Deficiencies and Justifications

EHB Category & Class Drug Count Review

- 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 EHB Benchmark Drug 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 Drug Count for a particular USP category and class is sufficient.*
    - This justification is unacceptable because the number of drugs covered by the plan in the EHB Category & Class Drug Count Review must meet or exceed the EHB Benchmark Drug Count (see 45 CFR 156.122).

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 determine whether a drug should be covered under the prescription drug benefit. Some issuers may cover a drug under their medical benefit while others cover it under their prescription drug benefit (e.g., injectable aripiprazole; paliperidone; abatacept).
  - *Issuer states that their formulary meets the EHB Benchmark Drug Count.*
    - 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 EHB Category & Class Drug 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 a 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 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

Live Q&A

Questions

Please help us provide an accurate response by identifying your State when asking a question.

To submit or withdraw questions by phone:

- **To submit a question, dial 'star(*) pound(#)' on your phone's keypad.**
- **To withdraw a question, dial 'star(*) pound(#)' on your phone's keypad.**

To submit questions by webinar:

- **Type your question in the text box under the 'Q&A' tab and click 'Send.'**

If you are not able to ask your question during today's session, or if your question is best answered by subject matter experts (SMEs) outside Plan Management (PM), you may submit it via CMS_FEPS@cms.hhs.gov with the subject line "State Question."

State Regulators Webinar Session Survey

- CMS welcomes your feedback regarding this webinar series and values any suggestions that will allow us to enhance this experience for you.
- Shortly after this call, we will send a link to you for a convenient way to submit any ideas or suggestions you wish to provide that you believe would be valuable during these sessions.
- Please take time to complete the survey and provide CMS with any feedback.



Closing Remarks