Policy

CL-38 Medicare Part D Formulary Requirements

Key Points

- **This Policy applies to Elixir and activities managed by the Clinical Operations Department, specifically the Formulary Clinical Pharmacists.**
- **Elixir submits formularies similar to those in widespread distribution that include a wide range of drugs across a broad distribution of therapeutic categories and classes. Formularies are designed in a manner that does not substantially discourage enrollment by any one group of beneficiaries.**

1. Categories and Classes.
   - 1.1. Include drug categories consistent with Part D requirements for appropriate disease state coverage.
   - 1.2. Utilize the United States Pharmacopeia (USP) classification system[1].
   - 1.3. Each category or class includes at least two drugs, as defined by two chemically distinct drugs.
     - 1.3.1. Exception to the two drug minimum occurs when only one drug is available for the particular category/class.
     - 1.3.2. When available and appropriate, multiple dosage forms and/or strengths for each unique chemical entity within a category/class designation.
   - 1.4. In cases where CMS requires more than two drugs in a given category or class, Elixir will comply with those guidelines.
   - 1.5. In cases where a new drug becomes available before a new classification within USP is available, Elixir adds the medication to the formulary with one of the following processes:
     - 1.5.1. Addition of the Part D drug into an existing USP category and class, when clinically appropriate.
     - 1.5.2. Placement of the Part D drug into an “Other” class, when available.
     - 1.5.3. Addition of a new class under an existing Category, in order to accommodate the new Part D drug in a clinically relevant manner.
     - 1.5.4. Placement in a Miscellaneous Therapeutic Agents category.

2. Formulary Benefit Management Tools.

2.1. Utilization Management Edits Requiring CMS Submission and Approval:

2.1.1. Elixir submits all utilization management edit requirements applied at point of sale (POS) to CMS

2.1.1.1. Prior Authorization (PA)

2.1.1.2. Step Therapy (ST)

2.1.1.3. Quantity Limits (QL) not based on FDA maximum daily dose limits.

2.1.2. Elixir provides clinical guidance and recommendations to plan sponsors to complete HPMS utilization edits

2.1.2.1. Opioid Specific Safety Edits

2.1.3. POS Edit types

2.1.3.1. Hard reject: Stops the pharmacy from processing the claim until an override is entered by a Plan representative

2.1.3.2. Soft Reject: Stops the pharmacy from processing the claim until the pharmacist submits a drug utilization review (DUR) or prospective payment system (PPS) code

2.1.3.3. Message only alert: Does not stop the claim from processing; Provides information related to coverage or clinical concern to the pharmacy

2.2. Utilization Management Edits Not Requiring CMS Submission and Approval

2.2.1. Edits that are established on the basis of preventing unsafe dosing of drugs as part of the concurrent DUR requirements for all Part D Drugs are not submitted to CMS

2.2.1.1. Screening for potential problems due to therapeutic duplication

2.2.1.2. Age and/or gender related contraindications

2.2.1.3. Over-utilization and under-utilization

2.2.1.4. Drug-drug interactions

2.2.1.5. Incorrect drug dosage or duration of therapy

2.2.1.6. Drug-allergy contraindications

2.2.1.7. Clinical abuse/misuse

3. Application of Prior Authorization.

3.1. Consistently utilize PA for those drugs with the highest likelihood of non-Part D covered uses based on the following criteria:

3.1.1. High likelihood that coverage is available under Parts A or B for the drug based on how the drug is prescribed, dispensed, or administered

3.1.2. High likelihood that the drug is excluded from Part D coverage

3.1.3. High likelihood of use for non-medically accepted indications

3.2. Practices that are not conducted when creating the PA forms:

3.2.1. Requirements more restrictive than CMS approved prior authorization criteria

3.2.2. Limited access or Step Therapy restrictions not consistent with the CMS-approved formulary

3.2.3. Quantity limits inconsistent with the FDA maximum dosing or not consistent with the CMS-approved formulary

3.2.4. Prior authorization criteria not submitted for HPMS approved formulary medications

3.2.5. Steering of physicians or beneficiaries to a sponsor's and/or PBM's own specialty pharmacy for any drugs which are not restricted to select pharmacies based on manufacturer or FDA distribution limitations

4. Long-term Care Accessibility.

4.1. Elixir supports the provision of necessary drug treatments for beneficiaries in Long-Term Care (LTC) facilities by coverage of dosage forms widely utilized in the LTC setting

4.1.1. Unit dose products

4.1.2. Liquid, chewable, and parenteral formulations

4.1.3. Nebulizer solutions when Part B coverage is not available

5. Specialty Tiers.

5.1. When applicable to the Plan design, Elixir will utilize specialty tier (or tiers) for very high cost medications and unique items

5.1.1. Plan sponsors can choose to implement up to two specialty tiers. In the two tier model, one of the tiers must be for preferred specialty medications with lower cost sharing than the non-preferred tier.

5.1.2. Cost-sharing limitations followed as described by CMS

5.1.3. Drugs included on the specialty tier exceed the CMS defined dollar-per-month threshold as defined in the final rule

5.1.3.1. Only the specific drug products that exceed the threshold are added to the specialty tier

6. Protected Classes.

6.1. Elixir develops formularies that cover all or significantly all CMS identified protected class medications.

6.1.1. Immunosuppressant's used for prophylaxis of organ transplant rejection

6.1.2. Antidepressants

6.1.3. Antipsychotics

6.1.4. Anticonvulsants

6.1.5. Antiretrovirals

6.1.6. Antineoplastics

6.2. New protected class medications are added to formularies within the CMS mandated 90-day expedited review period for P&T Committees.

7. Multiple Formularies.

7.1. Elixir will not submit more than one formulary unless there are meaningful differences between multiple formulary submissions in order to reduce confusion amongst beneficiaries.

8. Formulary Performance and Content Review.

8.1. Elixir designs formulary lists in order to pass the following CMS checks:

8.1.1. Inclusion of all clinically relevant and appropriate categories and classes

8.1.2. Sufficient drug coverage within each formulary category and class

8.1.3. Appropriate tiering of medications so as not to discourage enrollment of certain beneficiaries

8.1.3.1. Tier 1 is lowest cost sharing tier, except where a Plan designates a Select Care tier

8.1.4. Adequate coverage of drugs for specific disease states, above and beyond protected classes

8.1.5. Availability of most commonly prescribed drug classes for the Medicare population

8.1.6. Inclusion of all commercially available vaccines not available for coverage under Part B

8.1.7. Appropriate application of utilization management (UM) edits, including criteria for approval

8.2. In the event CMS identifies a problem with a formulary or UM component, Elixir will work with CMS and the plan sponsor to quickly resolve the issue

8.2.1. Formulary update and/or UM criteria revision

8.2.2. Submission of clinical justification for appropriateness of the status in question

Resources

- Centers for Medicare & Medicaid Services, "Medicare Prescription Drug Benefit Manual Chapter 6 – Part D Drugs and Formulary Requirements", last revision date 01/15/2016, https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf
- CMS-4192-F, Contract Year 2023 Medicare Advantage and Part D Final Rule

[1] USP classification system information available at www.usp.org