Avera Health Plans

Pharmacy Policy

Major Section: Pharmacy **Policy Number:** PP-031515-114	**Subject:** Formulary Exception
Effective Date: 01/01/14 **Last Reviewed:** 3/11/15	**Replaces Policy Number:** PP-051514-114

IMPORTANT – Please read prior to using this policy.
This policy applies to all products unless specific contract limitations, exclusions or exceptions apply. Avera Health Plans' pharmacy policy contains general information only and does not guarantee coverage. The member's specific benefit documents and any applicable federal or state regulations supersede the policy and are used to make coverage determinations.

Final benefit determinations are subject to all terms and conditions of the member's coverage documents including, but not limited to, Certificate of Coverage, Summary Plan Document, Benefit Summary or Schedule of Benefits. If there is a conflict between this policy and the applicable coverage document for a member, the coverage document will govern.

This information is intended for personal reference only. Prior to the use of this policy, any persons referencing this policy must first identify member eligibility, any federal or state regulatory requirements and the plan benefit coverage. The information belongs to Avera Health Plans and unauthorized copying, use and distribution are prohibited. This policy is intended to serve only as a reference resource and is not intended to address every aspect of a clinical situation.

This policy may be amended, updated or discontinued by Avera Health Plans in its sole and absolute judgment at any time for any or no reason without recourse from any Avera Health Plans member or family member who may be subject to this policy.

POLICY STATEMENT
This policy outlines the criteria for the drug formulary exception process for non-covered medications on a closed drug formulary. Either the prescriber or the member may initiate the process.

DEFINITIONS
AMA – American Medical Association
Closed Drug formulary – A formulary which provides coverage for some drugs, but not others, regardless of the number of drug classes affected
CPT – Current Procedural Terminology
FDA –U.S. Food and Drug Administration
HCPCS – Healthcare Common Procedure Coding System
ICD – International Classification of Disease

REGULATORY REQUIREMENTS
None

BACKGROUND
Avera Health Plans will review requests for non-covered medications on a closed drug formulary. The process can be initiated via fax, telephone or mail by a member, member's designated representative or the prescriber. Annually and after updates, the health plan communicates to members and prescribing practitioners how prescribing practitioners must provide information to support an exception request**.**

Exception requests are granted when the requested medication meets medical necessity criteria for an exception.

MEDICAL CRITERIA FOR COVERAGE DETERMINATION:
For formulary exceptions**,** supporting clinical information needed from prescribing practitioner must indicate:

1. That the non-covered medication is necessary for treating a member's condition because all covered medications on any tier would not be as effective or would have adverse effects or member is not a candidate for the covered medication,
2. The number of doses under a dose restriction has been or is likely to be ineffective, or
3. The alternative listed on the drug formulary or required to be used in accordance with step therapy has been or is likely to be ineffective.
4. Other factors considered include: age, treatment progress, comorbidities, psychosocial status, home environment (when applicable)
5. The medication is not being used for an indication that is considered an exclusion outlined in the certificate of coverage.

The following process occurs when a request of this nature is considered:
1. The Avera Health Plans pharmacist will perform a scientific literature search to evaluate safety and efficacy of the requested medication.
2. Perform a review of the member's medical record, including any additional information submitted by the member and/or the prescribing practitioner to support the exception request.
3. Determines that covered medications (on the drug formulary) will not achieve the desired therapeutic goal.
4. Consult with the Chief Medical Officer for final determination.

Avera Health Plans notifies members and prescribing practitioners how prescribing practitioners must provide information to support an exception request annually in member and provider newsletters.

Avera Health Plans makes formulary exception determinations and notifies members and prescribing practitioners in accordance with HSV-026 Timeliness of UM Decisions and UM Notification Process.

In the event of a denial of a formulary exception, notification to the member and prescribing practitioner includes:

- The opportunity for prescribing practitioners to discuss the denial decision with a physician or other appropriate reviewer

- The specific reasons for the denial, in easily understandable language
- A reference to the benefit provision, guideline, protocol or other similar criterion on which the denial decision is based
- A statement that members can obtain a copy of the actual benefit provision, guideline, protocol or other similar criterion on which the denial decision was based, upon request
- A description of appeal rights, including the right to submit written comments, documents or other information relevant to the appeal
- An explanation of the appeal process, including the right to member representation and time frames
- A description of the expedited appeal process for urgent preservice or urgent concurrent denials
- Notification that expedited external review can occur concurrently with the internal appeals process for urgent care and ongoing treatment

If a member chooses to submit an appeal for the denial of a formulary exception, Avera Health Plans adheres to the process set forth in HSV-002 Appeals Policy

DURATION OF AUTHORIZATION
To be determined by Chief Medical Officer.

CRITERIA FOR EXTENDED AUTHORIZATION
1. Improvement in clinical signs and symptoms.

The authorization can be extended (length of extension to be determined by Chief Medical Officer if the above criteria are met). Annual reviews can be completed if clinical effectiveness is documented.

REFERENCES
1. **Services, Centers for Medicare & Medicaid.** Exceptions. *CMS. gov.* [Online] April 9, 2013. [Cited: Oct. 23, 2013.] http://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Exceptions.html.

2. **Centers for Medicare & Medicaid.** Chapter 6 - Part D Drugs and Formulary Requirements. *Medicare Prescription Drug Benefit Manual.* [Online] Feb. 19, 2010. [Cited: Oct. 23, 2013.] http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter6.pdf.

CODING

CPT Codes
None

Revenue Codes
None

HCPCS codes
None

Diagnosis codes
None

POLICY UPDATES

Date	Description
10/23/13	Policy developed.
11/13/13	Approved by Pharmacy and Therapeutics Committee.
01/01/14	Original policy effective date.
04/24/14	Policy updated.
05/14/14	Approved by Pharmacy and Therapeutics Committee.
05/15/14	Updated policy effective date.
02/23/15	Policy updated.
03/11/15	Approved by Pharmacy and Therapeutics Committee.
03/15/15	Updated policy effective date.