SCOPE:
Washington Health Care Authority (HCA), Envolve Pharmacy Solutions (PBM), and Coordinated Care Health Plan (Plan)

PURPOSE:
To outline the review criteria for request for drug not on the Apple Health preferred drug list (PDL) and request for drug with no coverage criteria, establish by the HCA and Coordinated Care.

POLICY/Criteria:

*Provider must submit documentation supporting that member has met all approval criteria*

It is the policy of the Washington HCA and Coordinated Care that non-PDL medications are medically necessary when the following criteria are met:

Initial Approval Criteria: (must meet 1, 2 and 4 OR 3 and 4)
1. Failure of at least two* PDL agents within the same therapeutic class or PDL drugs that are recognized as standards of care for the treatment of member’s diagnosis at up to maximally indicated doses, each used for the appropriate duration of treatment or for ≥ 30 days for diseases requiring maintenance treatment. Trial and failure of PDL agents must be supported by one of the following (a, b, or c):
   a. Presence of claims in pharmacy claims history;
   b. Documented contraindication(s) or clinically significant adverse effects to ALL PDL agents within the same therapeutic class or PDL drugs that are recognized as standards of care for the treatment of member’s diagnosis;
   c. If member received drug samples of PDL medications from the prescriber to meet this requirement, a copy of the sample logs must be submitted for review to be considered at the discretion of the utilization management reviewer. Submitted sample log must include all of the following: medication name, dose/strength, lot number, expiration date, quantity dispensed, date sample was provided, and initials/title of the dispenser;

2. Exceptions:
a. The HCA and Coordinated Care have established specific trial/fail requirement prior to approve some of the non-preferred agents. Please see attachment: The Apple Health trial/fail requirement prior to approve the non-preferred agents.

b. Request for drug without coverage criteria (must meet all):
   o The drug is prescribed for an FDA-approved indication, dose and frequency;
   o The request is for new drug approved by the FDA within the last 12 months without a custom coverage criteria; OR
   o Request is for an existing drug prescribed for new indication approved by the FDA within the last 12 months without a custom coverage criteria;
   o If request is for a non-formulary agent, failure of an adequate trial of at least 2 formulary agents that are FDA-approved for the same indication and/or drugs that are considered the standard of care for the indication, when such agents exist, at maximum indicated doses, unless member experiences clinically significant adverse effect or has contraindication(s);

3. Request for continuity of care for drug therapy initiated with samples of drugs NOT on the PDL is subject to criterion 1 & 2 above, unless member meets all of the following (a-d):
   a. Member is new to the health plan;
   b. Requested medication is for one of the following disease states (i, ii, iii, or iv):
      i. Seizures;
      ii. Heart failure;
      iii. Human immunodeficiency virus (HIV);
      iv. Psychotic disorders (e.g., schizophrenia, bipolar disorder, etc.);
   c. Office progress notes and/or prior authorization form indicate member has been on requested medication for at least 30 days, is stable, and responding positively to therapy;
   d. A copy of the sample log supporting current use of requested medication is submitted for review to be considered at the discretion of the utilization management reviewer. Submitted sample log must include all of the following: medication name, dose/strength, lot number, expiration date, quantity dispensed, date sample was provided, and initials/title of the dispenser;
4. Dose does not exceed FDA approved maximum recommended dose for the relevant indication and health plan approved daily quantity limit.

**Approval duration:** Duration of request or 12 months (whichever is less)

*Provided two (2) agents exist in the therapeutic category with comparable labeled indications.

**Utilization management review staff should use the above clinical criteria as well as clinical discretion when making coverage decision for requests for medically necessary drug not on PDL.

**Continued Therapy:** (must meet all):

1. Currently receiving medication via Centene benefit, or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed FDA approved maximum recommended dose for the relevant indication and health plan approved daily quantity limit.

**Approval duration:** Duration of request or 12 months (whichever is less)

**REFERENCES:** Apple Health Preferred Drug List

**ATTACHMENT:** The Apple Health trial/fail requirement prior to approve the non-preferred agents

**DEFINITIONS:** N/A

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POLICY AND PROCEDURE

**DEPARTMENT:** Pharmacy Operations  
**DOCUMENT NAME:** Request for Medically Necessary Drug not on the PDL  
**APPROVED DATE:** 01/2018  
**REPLACES DOCUMENT:** CP.PMN.16  
**EFFECTIVE DATE:** 01/2018  
**PRODUCT TYPE:** Medicaid  
**POLICY NUMBER:** WA.PHAR.61

POLICY AND PROCEDURE APPROVAL

Pharmacy & Therapeutics Committee: Approval on file  
Pharmacy Director: Approval on file  
Sr. V.P., Chief Medical Officer: Approval on file

*NOTE: The electronic approval is retained in Compliance 360.*