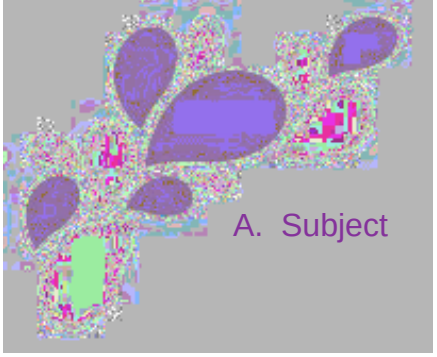
Administrative Policy Statement
OHIO MEDICAID

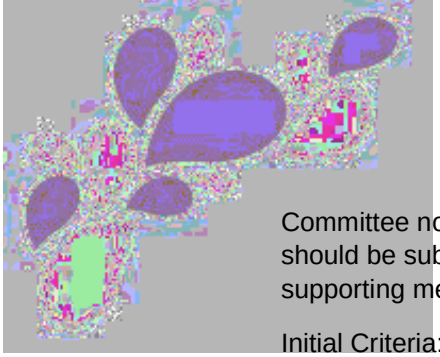
Policy Name	Policy Number	Date Effective
Medical Necessity for Non-Formulary Medications	PAD-0001-OH-MCD	3/15/2023

Policy Type			
Medical	ADMINISTRATIVE	Pharmacy	Reimbursement

Administrative Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of



A. Subject



Committee nor drug or therapeutic category benefit exclusions. Prior authorization requests should be submitted for each non-formulary medication with chart notes and documentation supporting medical necessity.

Initial Criteria:

I. In accordance with the drug's package insert, the requested medication meets ALL of the following:
    a. FDA-approved indication and age;
    b. FDA-approved dosage;
    c. Member does not have any contraindication; AND
II. Chart notes along with any relevant screening results are provided to confirm the diagnosis; AND
III. The requested medication is being prescribed by or in consultation with an appropriate specialist, when applicable *(e.g., a formulary product from the same class requires a specialist in its prior authorization criteria, or the indication is a complex/rare disease state likely to require experience managing the specific diagnosis*); AND
IV. Documentation has been provided supporting one of the following:
    a. Adequate trial and failure or intolerance of ALL formulary alternatives in the same drug class that can be used for the same diagnosis (*start/end dates must be provided or if member was a Caresource member during trial, must have paid claims in history*); OR
    b. If there is no alternative in the same drug class, must have adequate trial and failure or intolerance of TWO formulary alternatives, if available, that can be used for the requested indication according to clinical guidelines or standard of care (*start/end dates must be provided or if member was a Caresource member during trial, must have paid claims in history*); OR
    c. Member has contraindication to ALL other formulary medications based on the member's diagnosis, medical conditions, or other medication therapies; OR
    d. There are no other medications available on the formulary to treat member's condition (e.g., orphan drug); AND
V. If the requested medication is a combination product, the member has also tried a 90-day trial of the active ingredients separately taken at the same time AND a clinical reason supported by chart notes why the separate agents cannot be used (*request for the purpose of convenience does not meet medical necessity*); AND
VI. If the requested medication is a long-acting product, the member has also tried a 90-day trial of a short-acting product AND/OR have a clinical reason why the short-acting product cannot be used.

Initial approval is limited to the length of request but no more than 6 months.

Renewal Criteria:

I. Chart notes have been provided showing the member has had a positive response to therapy; AND
II. The requested use and dosage remain consistent with FDA-approved prescribing information in the drug package insert.

Renewal approval is limited to the length of request but no more than 12 months.

Notes:

- Adequate trial is defined as a stable dose for up to 90 days or a duration specified in treatment guidelines or package insert as a sufficient duration to observe benefit from

treatment. The pharmacist reviewer may also use clinical judgement to determine a sufficient duration of treatment.

- The member's medication trials and adherence are determined by review of pharmacy claim data over preceding 12 months or as reported in chart notes. Additional information may be requested on a case-by-case basis to complete the clinical review.
- All other uses of Non-Formulary medications are considered experimental/investigational; therefore, wile3e9edi5a (edi)3oe7.r6(PAD)3 (-7)Tj -0.0043-1 (1.7e)68 1 1 6 96 Tw ( )Tj -0.852 Tc 0.0abdil28 (

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