ADMINISTRATIVE POLICY STATEMENT
INDIANA MEDICAID

Original Issue Date	Next Annual Review		Effective Date
12/06/2013	08/01/2019		08/01/2018
Policy Name			**Policy Number**
Medical Necessity for Non-Preferred Medications			PAD-0003-IN-MCD
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 Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Administrative Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Administrative Policy Statement. If there is a conflict between the Administrative Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination.

Contents of Policy

A. SUBJECT

CareSource uses a preferred medication list that is established, reviewed and approved by the CareSource Pharmacy and Therapeutics (P&T) Committee and the regulatory bodies in each state in which CareSource functions. The preferred drug list is reviewed routinely, and medication can be removed from the preferred list when the brand name becomes generically available or when it is no longer cost-effective compared to other existing or newer products.

For new drugs or new indications for drugs, the P&T Committee generally reviews for preferred status decision after 180 days from market release. CareSource will follow the guidance of the state Medicaid programs in the states that it services to enforce clinically appropriate lower cost agents as first line therapy for our preferred agents.

B. BACKGROUND

The intent of CareSource Pharmacy Policy Statements is to encourage appropriate selection of members for therapy according to product labeling, clinical guidelines, and/or clinical studies as well as to encourage use of preferred agents. The CareSource Pharmacy Policy Statement is a guideline for determining health care coverage for our members with benefit plans covering prescription drugs. Pharmacy Policy Statements are written on selected prescription drugs requiring prior authorization or step therapy. The Pharmacy Policy Statement is used as a tool to be interpreted in conjunction with the member's specific benefit plan.

NOTE: *The Introduction section is for your general knowledge and is not to be construed as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals and is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider can also be a place where medical care is given, like a hospital, clinic or lab. This policy informs providers about when a service may be covered.*

C. DEFINITIONS

- Clinical Judgment: decisions made within the scope of the expertise of a pharmacist following the review of subjective and objective medical data for a member. A pharmacist can use Clinical Judgment for a benefit determination for an exception request for a Non-Preferred Drug. If the request is outside the scope of a pharmacist's expertise, a benefit determination will be made in collaboration with a medical director.
- Drug: a medication or substance which induces a physiologic effect on the body of a member (i.e., medication, agent, drug therapy, treatment, product, biosimilar drugs, etc.).
- Medical Necessity: see 405 IAC 5-2-17 on page 7 at http://www.in.gov/legislative/iac/T04050/A00050.PDF.
- Non-Preferred Drug: a drug not on the Preferred Drug List.
- Preferred Drug List: a list of prescription drugs which includes a group of selected generic and brand-name drugs which are covered by CareSource.

D. POLICY

CareSource will approve the use of non-preferred medications and consider their use as medically necessary when the following criteria have been met for situations as listed

below. This policy will not supersede drug-specific criteria developed and approved by the CareSource P&T Committee nor drug or therapeutic category benefit exclusions. Prior authorization requests should be submitted for each non-preferred medication with chart notes and documentation supporting medical necessity.

I. The indication for use of the requested medication is approved by the FDA AND
II. The dose of medication requested is based on FDA-Approved labeling for the age and indication AND
III. Documented one of the following:
    A. Trial and failure of at least 2 preferred or lower cost alternatives, when available, and each trial has been 90 days in length OR
    B. Contraindication or intolerance of ALL other preferred medications based on the member's diagnosis, medical conditions or other medication therapies AND
IV. Combination Products: A clinical reason supported by chart notes why the member is unable to take the active ingredients of the combination product separately as individually prescribed medications must be provided AND
V. Long Acting Formulations: A clinical reason supported by chart notes why the member is unable to use the immediate release formulation of the preferred drug must be provided.

All other uses of Brand Name Medications are considered experimental/investigational; therefore, will follow CareSource's off-label policy.

Please note that this policy is reviewed on an annual basis. New drugs and indications receiving FDA approval may not be reflected in this policy immediately.

Notes:

- Drug specific criteria takes precedence over the Medical Necessity for Non-preferred Medications Policy.
- The start date and duration of a trial must be provided.
- There must be paid claims if the member was enrolled with CareSource during the trial with the preferred or lower cost alternative.
- Non-adherence to formulations requiring multiple daily doses does not guarantee the member will meet the requirements of medical necessity. Chart notes should be provided on the member's physical or mental characteristics to determine if the member meets the requirements of medical necessity.
- Documented diagnoses must be confirmed by portions of the individual's medical record which need to be supplied with the prior authorization requests. These medical records may include, but are not limited to test reports, chart notes from provider's office, or hospital admission notes.
- Refer to the product package insert for dosing, administration and safety guidelines.

E. CONDITIONS OF COVERAGE

As above.

F. RELATED POLICIES/RULES

None applicable.

G. REVIEW/REVISION HISTORY

DATES		ACTION
Date Issued	12/06/2013	
Date Revised	12/01/2015	
	04/20/2017	Policy separated by State/LOB.
	07/05/2018	Policy name changed. “Formulary/Preferred” definition changed to “Preferred” throughout the document based on state’s preference. Combination Products and Long Acting Formulations requirements added, trial length requirement decreased to 90 days, DAW requests and FDA MedWatch form requirements removed. Definitions and Notes expanded.
Date Effective	08/01/2018	

H. REFERENCES

Not applicable.