ADMINISTRATIVE POLICY STATEMENT
OHIO MARKETPLACE PLANS

Original Issue Date	Next Annual Review		Effective Date
12/06/2013	04/20/2018		04/20/2017
Policy Name			**Policy Number**
Medical Necessity for Non-Formulary / Non-preferred Medications			AD-0035
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

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A. SUBJECT

CareSource uses a formulary/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 formulary 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 comparative to other existing or newer products.

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

B. BACKGROUND

The intent of CareSource Pharmacy Policy Statements is to encourage appropriate selection of patients 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 patients 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

1. Formulary / Preferred Drug List – a preferred medication list that includes a group of generic and selected brand-name medications
2. Clinical Judgment: Within the scope of the education/knowledge of a pharmacist – medical necessity will be evaluated based on the overall health and well-being of the member – when the member’s day to day health would be impacted, a pharmacist can choose with Clinical Judgment to bypass the medical policy. If the information or decision is outside the scope of a pharmacist’s education/knowledge, a medical director will be involved in those cases.

D. POLICY

CareSource will approve the use of non-formulary (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. Prior authorization requests should be submitted for each non-formulary medication with chart notes and documentation supporting medical necessity.

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1) The indication for use of the requested medication is approved by the FDA

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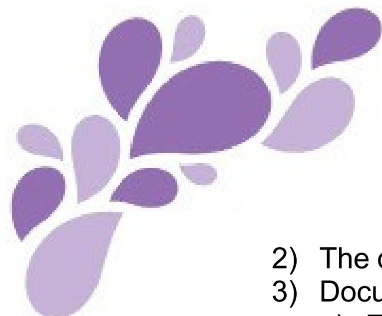

2) The dose of medication requested is appropriate based on age and indication
3) Documented one of the following:
   a) Trial and failure of at least 2 preferred or lower cost alternatives, when available, within the previous 120 days, and trials have been up to 90 days in length OR
   b) Contraindication or intolerance of all other formulary medications based on the patient's diagnosis, other medical conditions or other medication therapy, OR
4) No other medications available on the formulary to treat the patient's condition OR
5) Documentation of a submitted FDA MedWatch form by provider with documented intolerance or lack of efficacy with details on trial and failure of, or intolerance/adverse side effect to brand medications or to generic medications. For a DAW request to be approved, must have tried a product manufactured by 2 different manufacturers.

All other uses of Brand Name Medications are considered experimental/investigational; and 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:

- Documented diagnoses must be confirmed by portions of the individual's medical record which need to be supplied with 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.
- Patient is required to have completed the trial(s) listed in the above criteria unless the patient is unable to tolerate or has a contraindication to trial medications. Documentation such as chart notes or pharmacy claims may be requested to verify trial(s), intolerance, or contraindication(s).
- Refer to the product package insert for dosing, administration and safety guidelines.

E. CONDITIONS OF COVERAGE

HCPCS
CPT

AUTHORIZATION PERIOD

F. RELATED POLICIES/RULES

G. REVIEW/REVISION HISTORY

	DATES	ACTION
Date Issued	12/06/2013	
Date Revised	12/01/2015	
	04/20/2017	Policy separated by State/LOB.
Date Effective	04/20/2017	

H. REFERENCES

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The Administrative Policy Statement detailed above has received due consideration as defined in the Administrative Policy Statement Policy and is approved.

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