MEDICAL POLICY STATEMENT

Original Effective Date	Next Annual Review Date	Last Review / Revision Date
12/06/2013	11/03/2016	12/01/2015
Policy Name		**Policy Number**
Medical Necessity for Non-Formulary Medications		**AD-0008**

Medical 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.

Medical 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 Medical Policy Statement. If there is a conflict between the Medical 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.

For Medicare plans please reference the below link to search for Applicable National Coverage Descriptions (NCD) and Local Coverage Descriptions (LCD):

A. SUBJECT

Medical Necessity for Non-Formulary Medications

B. BACKGROUND

C. DEFINITIONS

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 education/knowledge a medical director will be involved in cases.

D. POLICY

CareSource uses a preferred drug list (Formulary). This formulary and the preferred products have been approved by the CareSource Pharmacy, Therapeutics and Technology (P&T) Committee, and the regulatory bodies in each state that CareSource functions.

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 Medicaid and Exchange programs in the states that it services to enforce clinically appropriate lower cost agents as first line therapy for our formulary preferred agents. 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.

I. Non-Formulary Medications:

A. The diagnosis (when applicable) for use of the requested agent is approved by the FDA or recognized as being appropriate
AND

B. Trials of a preferred or lower cost alternative(s), when available, should have occurred within the previous 120 days and have been up to 90 days in length:

NOTE: For non-preferred medications when a formulary agent with the same active ingredient is available in a similar or different formulation.

1. For single ingredient agents
   a. A trial of the formulary preferred agent will need to be completed
   b. Then a clinical reason as to why the patient is unable to use the agents separately must be provided, after an adequate trial of the formulary preferred options, when clinically appropriate
2. For combination products
   a. When all ingredients of the product are available on formulary:
      (1) An adequate trial of the formulary preferred options must be completed
      (2) Then a clinical reason as to why the patient is unable to use the agents separately must be provided
3. When at least one ingredient is on formulary and the other(s) are non-formulary
   a. Then a trial of the formulary agent and a formulary alternative for the non-formulary ingredient must be trialed
   b. Followed by the use of the formulary agent and the non-formulary agent separately if available
   c. Then a clinical reason as to why the patient is unable to use the agents separately must be provided
4. When the products contained in the combination are not available as formulary options
   a. Then applicable trials for each agent will need to be completed
   b. Then a clinical reason as to why the patient is unable to use the agents separately must be provided

Note: For purposes of this policy, hydrochlorothiazide (HCTZ) will not be considered an appropriate trial ingredient for combination products.

5. Samples:
   Samples are not counted or considered as applicable for Continuity of Care or as a trialed medication – however Clinical Judgment (supported by chart notes) can always be used to bypass this

Note: Clinical Judgment will be used to bypass trial lengths if:

A. The member has a documented drug interaction with the preferred or lower cost alternative agent(s) which would cause harm
OR

B. The patient has had a documented adverse drug experience with the preferred or lower cost alternative(s) and is not able to complete the trial of lower cost or preferred agent(s)

For Medicare Plan members, reference the Applicable National Coverage Determinations (NCD) and Local Coverage Determinations (LCD). Compliance with NCDs and LCDs is required where applicable.

CONDITIONS OF COVERAGE

QUANTITY LIMITATIONS
DATA REQUIRED ON REQUEST Diagnosis
Treatment Failures

AUTHORIZATION PERIOD
Approved authorizations are designated an appropriate authorization period. Continued treatment may be considered when the member has shown biological response to treatment. **ALL** authorizations are subject to continued eligibility.

E. RELATED POLICIES/RULES

F. REVIEW/REVISION HISTORY

Date Issued:	12/06/2013
Date Reviewed:	12/06/2013, 12/01/2015
Date Revised:	07/09/2015

G. REFERENCES
N/A

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