PHARMACY POLICY STATEMENT

Original Effective Date	Next Annual Review	Last Revision
03/06/2012	11/03/2017	12/12/2016
Policy Name		**Policy Number**
Medical Necessity for Physician Dispense as Written (DAW) Requests		Rx-0013-IN-MCD
Policy Type		
Medical	Administrative	**PHARMACY** Reimbursement

Pharmacy 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, Pharmacy Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Pharmacy 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 Pharmacy Policy Statement. If there is a conflict between the Pharmacy 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. INTRODUCTION

CareSource uses a preferred drug list (formulary) in the states that it services a Medicaid population. The formulary and the preferred products have been approved by the CareSource Pharmacy and Therapeutics (P&T) Committee and the regulatory bodies in each state if required.

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.

B. DEFINITIONS

1. None applicable.

C. POLICY COVERAGE CRITERIA

1. Site of Service

Not applicable.

2. Coverage Criteria

CareSource will review and approve requests for brand name medications where the prescribing physician has requested “Dispense as Written” or “DAW” and consider its use as medically necessary when the following criteria have been met. This policy is not intended to supersede exclusions or drug-specific criteria developed and approved by the CareSource P&T. Prior authorization request should be submitted with chart notes and documentation supporting medical necessity for brand name medication.

Condition	Coverage criteria:
Dispense as Written (DAW) for Brand Name Medication	1) CareSource requires the use of FDA approved generic equivalent medications when available; consideration will be given to using a brand-name medication in the following circumstances: a) Member has tried an FDA approved generic equivalent to the requested brand medication, made by two different manufacturers (if available) for 30 days b) One or more of the following:

	i) Objective data, including but not limited to laboratory results, demonstrating that the generic was not effective is submitted ii) Chart notes that document the lack of effectiveness by stating the specific negative outcomes are submitted iii) The member has a genuine allergic reaction to an INACTIVE ingredient in the generic agent(s). Allergic reactions must be clearly documented in the member's medical record 2) Medications that have a narrow therapeutic index (e.g., Synthroid, Coumadin, Topamax) will be allowed to continue on a brand name medication so long as the member has been established on the brand name medication for at least 30 days.

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 diagnosis must be confirmed by portions of the individual's medical record which need to be supplied with prior authorization request. 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.
- **Allergic reactions:**
  - Gastrointestinal (GI) upset or irritation is not generally considered an allergy or failed treatment. Members should be referred to their physician or pharmacist for advice on dose adjustment, and/or other options to reduce GI upset or irritation.
  - Common documented side effects attributed to the drug (e.g., headache, nausea, blurred vision, fatigue, muscle aches, etc.) are not considered an allergy and would be expected to occur at the same level in both the generic and brand agent.

3. Dosage and Quantity Limits (listed if applicable)

Condition	Dosage and Quantity Limits
Dispense as Written (DAW) for Brand Name Medication	May apply to requested medication

4. Authorization Period

Condition	Approval Period
Dispense as Written (DAW) for Brand Name Medication	The initial authorization Brand Name medication is valid for an appropriate authorization period up to 12 months. Continued treatment may be considered when the member has shown biological/clinical response to treatment. A reauthorization after successful initiation period will be placed for an appropriate authorization period up to 12 months. **ALL** authorizations are subject to continued eligibility.

5. Coding

Not applicable

D. RELATED POLICIES

None.

E. REVIEW/REVISION HISTORY

DATE	ACTION/DESCRIPTION
03/06/2012	Issued, reviewed
06/06/2013	Grammatical errors fixed and removal of technology in reference to P&T committee. Reviewed.
11/03/2014	Formatting updates. Reviewed.
12/01/2015	Reviewed.
12/12/2016	Reviewed. Updated policy format. Separated by line of business. Added approval period up to 12 months for authorization period.

F. REFERENCES

1. None applicable.

The Pharmacy Policy detailed above has received due consideration and is approved.