MEDICAL POLICY STATEMENT

Effective Date	Next Annual Review Date	Last Review / Revision Date
03/2012	05/15/2015	05/15/2014

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CareSource

CSMG Medical Policy Statements are derived from literature based and supported clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services are those health care services or supplies which 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.

A. SUBJECT

Off-label use consideration and Excluded Indications

B. BACKGROUND

The U.S. Food and Drug Administration (FDA) approves drugs for specific indications included in the drug's product information label. Off-label or "unlabeled" drug use is the utilization of an FDA approved drug for uses other than those listed in the FDA approved labeling or in treatment regimens or populations that are not included in approved labeling. Many off-label uses are effective, well documented in the peer-reviewed literature and widely used even though the manufacturer has not pursued the additional indications.

CareSource will employ, at its discretion, drug utilization management programs (i.e., prior authorization) to ensure appropriate and safe use of medications.

C. POLICY

CareSource will review prior authorization requests for the use of medications and consider the use to be 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. CareSource Pharmacy department will keep track of all off label requests submitted to use for analysis and trending for potential recommendations of changes in the formulary.

Off-Label (No FDA approved Indication)

CareSource will consider Off-Label drug use as medically necessary when all of the following criteria have been met.

1. The drug is approved by the United Stated Food and Drug Administration (FDA)
   AND
2. The drug is being prescribed to treat a medical condition not listed in the product label and for which medical treatment is medically necessary (see excluded indications)
   AND

3. The prescribed drug off-label use is supported (and provided to CareSource by the prescribing provider) in any one or more of the following:
    a. Drug Facts and Comparisons; or
    b. Publication Pharmacist Letter or Prescriber Letter; or
    c. National panels and consortiums such as National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), World Health Organization (WHO), AHRQ (Agency for Healthcare Research and Quality), or NCCN (National Comprehensive Cancer Network); or
    d. Commercial External Review Organizations such as MCG, ECRI and Hayes, Inc.; or
    e. Two articles from major scientific or medical peer-reviewed journals (excluding case reports, letters, posters, and abstracts), or published studies having validated and uncontested data, which supports the proposed use for the specific medical condition as safe and effective.
        i. Examples of accepted journals include, but are not limited to: Journal of the American Medical Association (JAMA), New England Journal of Medicine (NEJM), and Lancet
        ii. Accepted study designs include, but are not limited to: randomized, double-blind, placebo controlled clinical trials
    f. Additional resources may include:
        i. Clinical practice guidelines published by consortiums of medical organizations and generally accepted as industry standard
        ii. Specialty and sub-specialty society guidelines, when appropriate, including, but not limited to the following:

Subspecialty	**Specialty Society**
Cardiology	American College of Cardiology: http://www.acc.org
Clinical Cardiac Electrophysiology	Heart Rhythm Society: http://www.HRSonline.org
Critical Care Medicine	Society of Critical Care Medicine: http://www.sccm.org
Endocrinology, Diabetes and Metabolism	American Academy of Clinical Endocrinologists http://www.aace.com
	Endocrine Society (-) http://www.endo-society.org
Gastroenterology	American Gastroenterological Association http://www.gastro.org American College of Gastroenterology http://www.acg.gi.org
Geriatric Medicine	American Geriatrics Society: http://www.americangeriatrics.org
Gynecology/Obstetrics	American College of Obstetricians and Gynecologists: http://www.acog.org
Gynecologic Oncology	Society of Gynecologic Oncologists: http://www.sgo.org

Hematology	American Society of Hematology: http://www.hematology.org
Hospice and Palliative Medicine	American Academy of Hospice and Palliative Medicine http://www.aahpm.org
Infectious Disease	Infectious Disease Society of America: http://www.idsociety.org
Nephrology	American Society of Nephrology: http://www.asn-online.org
Oncology	American Society of Clinical Oncology (ASCO) (+) http://www.asco.org
Pulmonary Disease	American College of Chest Physicians: http://www.chestnet.org
Rheumatology	American College of Rheumatology: http://www.rheumatology.org
Sleep Medicine	American Academy of Sleep Medicine: http://www.aasmnet.org
Surgery of the Hand	American Society for Surgery of the Hand: http://www.hand-surg.org

Excessive Quantity and Dose

CareSource, in the course of managing the utilization of medications and pharmaceutical products, may impose dispensing limits based on quantity or dose. Limits will be established according to FDA-approved dosing guidelines in the manufacturers package insert or other recognized guideline. Requests that are in excess of these limits will be considered as off-label and will be reviewed according to the *Off Label* criteria outlined above, unless drug-specific criteria exist.

Duplicate Therapy

CareSource, in the course or reviewing requests for medication prior authorization, will review members' prescription history through its pharmacy benefit managers (PBM's) claims system. Requests for medications where a member has prescription claims for another medication in the same or similar therapeutic class will be considered duplicate therapy. Unless the physician indicates that the requested medication will replace the duplicate therapy, the request will be deemed off label and will be reviewed according to the *Off Label* criteria outlined above, unless drug-specific criteria exist.

Excluded Indications

CareSource will follow the direction of the state Medicaid programs in the states it services and deny medications that are being used for an excluded indication. Medications used in the treatment of the following indications will be denied as excluded:

- Erectile Dysfunction
- Obesity (Ohio Only)
- Infertility
- Cosmetic
- Treatment of Gender Identity Disorders will be considered cosmetic unless the member has undergone surgical sex reassignment.

Conditions of Coverage

Quantity Limitations	As stated in the UFF (User Friendly Formulary)
Authorization Period	Approved authorizations are designated an appropriate authorization period in the UFF. Continued treatment may be considered when the member has shown biological response to treatment. ALL authorizations are subject to continued eligibility
Data Required on Request	Diagnosis Treatment Failures

D. REVIEW / REVISION HISTORY

06 /06 /2013

E. REFERENCES

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

5/20/2014

Chief Medical Officer **Date**

5/20/2014

Director of Pharmacy Operations **Date**