Important note
Even though this policy may indicate that a particular service or supply may be considered covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. You need to consult the Evidence of Coverage to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and your plan of benefits, the provisions of your benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Senior Care members, this policy will apply unless Medicare policies extend coverage beyond this Medical Policy & Criteria Statement. Senior Care policies will only apply to benefits paid for under Medicare rules, and not to any other health benefit plan benefits. CMS’s Coverage Issues Manual can be found on the CMS website.

SERVICE: Off-label Use of FDA Approved Drugs

PRIOR AUTHORIZATION: Not applicable.

POLICY: SWHP may consider the off-label use of FDA approved drugs as prescribed by a physician to treat chronic, disabling, or life-threatening illnesses medically necessary when:
1. The drug has been approved by the FDA for at least ONE indication, AND
2. The drug is listed in a standard drug reference compendium for the off-label indication, such as:
   ✓ The United States Pharmacopoeia Drug Information (USPDI), OR
   ✓ American Hospital Formulary Service Drug Information (AFHS-DI)
   ✓ National Comprehensive Cancer Network (NCCN) Drugs and Biologics CompendiumTM
   ✓ Thomson Micromedex DrugDex
   ✓ Clinical Pharmacology

OR,
   The off-label use is supported by substantially accepted peer-reviewed medical literature

OVERVIEW: Off-label or unlabeled drug use is the use of a drug approved by the FDA for other uses or in treatment regimens or patient populations that are not included in approved labeling.

The FDA approves drugs for specific indications that are included in the drug’s labeling. When a drug is used for an indication other than those specifically included in the labeling, it is referred to as an off-label use. Many off-label uses are effective, well-documented in the literature, and widely used.

Unapproved or unlabeled uses of drugs include a variety of situations ranging from completely unstudied to thoroughly investigated drug uses where the FDA has not been asked for approval, whereas approved uses of drugs have been proved to be safe and effective by the FDA after the review of adequate and controlled clinical trials that have documented their uses.

MANDATES: None

SUPPORTING DATA:

CODES:

| CPT Codes: | 
| CPT Not Covered: |
MEDICAL COVERAGE POLICY

SERVICE: Off-label Use of FDA Approved Drugs

Policy Number: 062
Effective Date: 5/26/2015
Last Review: 4/30/2015
Next Review Date: 4/30/2016

ICD9 codes:

ICD9 Not covered:

Hayes Rating:

CMS: See CMS.gov

POLICY HISTORY:

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REFERENCES:
The following scientific references were utilized in the formulation of this medical policy. SWHP will continue to review clinical evidence related to this policy and may modify it at a later date based upon the evolution of the published clinical evidence. Should additional scientific studies become available and they are not included in the list, please forward the reference(s) to SWHP so the information can be reviewed by the Medical Coverage Policy Committee (MCPC) and the Quality Improvement Committee (QIC) to determine if a modification of the policy is in order.