

Medical Coverage Policy



Off-Label Use of Prescription Drugs for Cancer Mandate

Device/Equipment Drug Medical Surgery Test Other

Effective Date:	7/12/2013	Policy Last Updated:	2/19/2013
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Prospective review is recommended/required. Please check the member agreement for preauthorization guidelines.

Prospective review is not required.

Description:

This policy addresses the Rhode Island General Law mandating the coverage of any drugs, including off-label drugs used for the treatment of cancer.

Rhode Island Law

Rhode Island General Laws 27-55-2 mandates coverage of off-label uses of prescription drugs. This law is concerned with coverage of any drug used for the treatment of cancer.

Section 27-55-2 Prescription drug coverage.

(a) No health insurer issuing a policy which provides coverage for prescription drugs shall exclude coverage of any drug used for the treatment of cancer on the grounds that the drug has not been approved by the FDA for that indication, provided that the drug is recognized for treatment of that indication in one of the standard reference compendia, or in the medical literature. It is the responsibility of the prescribing physician to submit to the insurer documentation supporting the proposed off-label use or uses, if requested by the issuer.

(b) Any coverage of a drug which serves as the primary treatment required by this chapter shall also include medically necessary services associated with the administration of the drug.

(c) No coverage is required under this chapter: (1) for any drug which has not been fully licensed or approved by the FDA, (2) for the use of any drug when the FDA has determined that use to be contraindicated, or (3) for any experimental drug not approved for any indication by the FDA. The provisions of this section apply to drugs used in the treatment for cancer only and nothing in this section is construed to create, impair, alter, limit, modify, enlarge, abrogate or prohibit reimbursement for medications used in the treatment of any other disease or condition.

(d) Nothing in this section is construed to prevent the application of contractual deductibles or co-payment provisions or managed care review."

Section 27-55-3 Advisory panel on off-label uses of prescription drugs.

The director of the department of health shall appoint an advisory panel of seven (7) medical experts. The purpose of the advisory panel is to make recommendations to the director regarding whether a particular off-label use is medically appropriate, whenever a particular dispute about payment for this off-label use is referred to the director of the department of health. Parties seeking to refer a dispute to the director shall do so in writing within thirty (30) days of the denial of coverage of the drug. The members of the panel shall include seven (7) licensed Rhode Island physicians, including: (1) a physician appointed by a hospital and medical services corporation; (2) a physician appointed by the Rhode Island Medical Society; (3) three (3) medical oncologists appointed by the society of Rhode Island Clinical Oncologists; (4) a physician appointed by the Rhode Island Association of Health Maintenance Organizations from a member plan; and (5) a Rhode Island physician appointed by the Health Insurance Association of America. The members of the advisory panel shall serve at the pleasure of the director of the department of health and shall receive no compensation for their service on this advisory panel."

Section 27-55-1 Definitions.

For the purpose of this chapter, the following words and terms have the following meanings:

- (1) "FDA" means the federal food and drug administration;
- (2) "Health insurer" means all persons, firms, corporations or other organizations offering and assuring health services on a prepaid or primarily expense incurred basis including, but not limited to, policies of accident or sickness insurance, as defined in chapter 18 of this title, nonprofit hospital or medical service plans, whether organized under chapter 19 or 20 of this title or under any public law or by special act of the general assembly, health maintenance organizations, and any other entity, which insures or reimburses for diagnostic, therapeutic or preventive services to a determined population on the basis of a periodic premium;
- (3) "Medical literature" means published scientific studies published in at least two (2) articles from major peer reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer reviewed medical journal;
- (4) "Standard reference compendia" means: (i) the United States Pharmacopoeia drug information, (ii) the American Medical Association drug evaluations, or (iii) the American Hospital Formulary Service drug information;
- (5) "Drug" means the primary anti-cancer or antineoplastic agent or agents."

Medical Criteria:

None

Policy:

Rhode Island General Law 27-55-2 requires coverage of any drugs including off-label drugs used for the treatment of cancer.

BlueCHiP for Medicare

Rhode Island mandated benefits generally do not apply to Plan 65, FEHBP, Medicare Advantage. In this policy, coverage is included for BlueChiP for Medicare.

Coverage:

Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage or Subscriber Agreement for applicable pharmacy/drug benefits/coverage.

Related Topics:

None

Published:

Provider Update, May 2013
Provider Update, March 2012
Provider Update, May 2011
Provider Update, April 2010
Provider Update, April 2009
Policy Update, August 2006

References:

Rhode Island General Laws Title 27 Chapter 27-55 § 27-55-2 - Off-Label Uses of Prescription drugs

<http://webserver.rilin.state.ri.us/Statutes/TITLE27/27-55/27-55-2.HTM>

Centers for Medicare and Medicaid Services (CMS): Medicare Benefit Policy Manual Chapter 15 – Covered Medical and Other Health Services, Ch. 50 - Drugs and Biologicals, Sec. 50.4.5 - Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen.

Medicare Benefit Policy Manual Ch 15.pdf

Review History:

02/19/2013: Annual review of the policy.

This medical policy is made available to you for informational purposes only. It is not a guarantee of payment or a substitute for your medical judgment in the treatment of your patients. Benefits and eligibility are determined by the member's subscriber agreement

or member certificate and/or the employer agreement, and those documents will supersede the provisions of this medical policy. For information on member-specific benefits, call the provider call center. If you provide services to a member which are determined to not be medically necessary (or in some cases medically necessary services which are non-covered benefits), you may not charge the member for the services unless you have informed the member and they have agreed in writing in advance to continue with the treatment at their own expense. Please refer to your participation agreement(s) for the applicable provisions. This policy is current at the time of publication; however, medical practices, technology, and knowledge are constantly changing. BCBSRI reserves the right to review and revise this policy for any reason and at any time, with or without notice.