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OVERVIEW

This policy documents how coverage is provided under Rhode Island General Law Chapter 27-55 for Off-label Uses of Prescription Drugs (see full text below). This service is covered for all Blue Cross & Blue Shield of Rhode Island (BCBSRI) members.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

Medicare Advantage Plans and Commercial Products

Rhode Island General Law § 27-55-2 requires coverage of any drugs including off-label drugs as described below.

Although Rhode Island-mandated benefits do not apply to Medicare Advantage Plans, this service is covered for all BCBSRI members.

COVERAGE

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

Self-funded groups may or may not choose to follow state mandates.

BACKGROUND

Rhode Island General Laws § 27-55-2 mandates coverage of off-label uses of prescription drugs.

Section 27-55-2 Prescription drug coverage. (Effective January 1, 2017)

(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 or disabling or life-threatening chronic disease 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 or disabling or life-threatening chronic disease 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 (Effective January 1, 2017)

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

(1) "Drug" or "drugs" means any substance prescribed by a licensed health-care provider acting within the scope of the provider's license and that is intended for use in the diagnosis, mitigation, treatment or prevention of disease that is taken by mouth, injected into a muscle, the skin, a blood vessel or cavity of the body; applied to the skin; or otherwise assimilated by the body. The term includes only those substances that are approved by the FDA for at least one indication;

(2) "FDA" means the Federal Food and Drug Administration;

(3) "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;

(4) "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;

(5) "Peer-reviewed medical journals" means a published study in a journal or other publication in which original manuscripts have been critically reviewed for scientific accuracy, validity, and reliability by unbiased independent experts, and that has been determined by the International Committee of Medical Journal Editors to have met its Uniform Requirements for Manuscripts Submitted to Biomedical Journals. It does not include publications or supplements to publications that are sponsored to a significant extent by a pharmaceutical manufacturing company or any health insurer, health-care center, hospital service corporation, medical service corporation, or fraternal benefit society that delivers, issues for delivery, renews, amends, or continues a health insurance policy in this state;

(6) "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;

CODING

Not applicable.

RELATED POLICIES

Clinical Trial Mandate Commercial
Clinical Trials Medicare Advantage Plans

PUBLISHED

Provider Update, November 2021
Provider Update, January 2021
Provider Update, January 2020
Provider Update, April 2018
Provider Update, April 2017

REFERENCES

1. Rhode Island General Laws Title 27 Chapter 27-55:
<http://webserver.rilin.state.ri.us/Statutes/TITLE27/27-55/INDEX.HTM>
2. 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.

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