Medical Coverage Policy

New Cancer Therapies Mandate

☐ Device/Equipment  ☐ Drug  ☐ Medical  ☐ Surgery  ☐ Test  ☒ Other

| Effective Date: | 1/1/1998 | Policy Last Updated: | 02/22/2013 |

☐ Prospective review is recommended/required. Please check the member agreement for preauthorization guidelines.

☒ Prospective review is not required.

Description:
This is an administrative policy to document Rhode Island General Law (RIGL) 27-20-27 New Cancer Therapies – Under Investigation.

Medical Criteria:
None

Policy:
The State of Rhode Island mandate (Nonprofit Medical Service Corporations: Section 27-20-27) requires the coverage of New Cancer Therapies – Under Investigation, as stated below:

RIGL 27-20-27 New Cancer Therapies – Under Investigation
Every individual or group hospital or medical expense insurance policy or individual or group hospital or medical service plan contract delivered, issued for delivery or renewed in this state shall provide coverage for new cancer therapies still under investigation as outlined in this chapter.

RIGL 27-20-27.1 "Reliable evidence" defined. "Reliable evidence" means:
(1) Evidence including published reports and articles in authoritative, peer reviewed medical and scientific literature;
(2) A written informed consent used by the treating facility or by another facility studying substantially the same service; or
(3) A written protocol or protocols used by the treating facility or protocols of another facility studying substantially the same service.

RIGL 27-20-27.2 Conditions of coverage.
As provided in § 27-20-27, coverage shall be extended to new cancer therapies still under investigation when the following circumstances are present:
(1) Treatment is being provided pursuant to a phase II, III or IV clinical trial* which has been approved by the National Institutes of Health (NIH) in cooperation with the National Cancer Institute (NCI), community clinical oncology programs; the Food and Drug Administration in the form of an investigational new drug (IND) exemption; the Department of Veterans' Affairs; or a qualified nongovernmental research entity as identified in the guidelines for NCI cancer center support grants;

(2) The proposed therapy has been reviewed and approved by a qualified institutional review board (IRB);

(3) The facility and personnel providing the treatment are capable of doing so by virtue of their experience, training, and volume of patients treated to maintain expertise;

(4) The patients receiving the investigational treatment meet all protocol requirements;

(5) There is no clearly superior, noninvestigational alternative to the protocol treatment;

(6) The available clinical or preclinical data provide a reasonable expectation that the protocol treatment will be at least as efficacious as the noninvestigational alternative; and

(7) The coverage of new cancer therapy treatment provided pursuant to a phase II clinical trial is not required for only that portion of that treatment that is provided as part of the phase II clinical trial and is funded by a national agency, such as the National Cancer Institute, the Veteran's Administration, the Department of Defense, or funded by commercial organizations such as the biotechnical and/or pharmaceutical industry or manufacturers of medical devices. Any portions of a phase II trial which are customarily funded by government, biotechnical and/or pharmaceutical and/or medical device industry sources in Rhode Island or in other states shall continue to be funded in Rhode Island and coverage pursuant to this section supplements, does not supplant customary funding.

RIGL 27-20-27.3 Managed care

Nothing in this chapter shall preclude the conducting of managed care reviews and medical necessity reviews by an insurer, hospital or medical service corporation, or health maintenance organization. A nonprofit medical service corporation may, as a condition of coverage, require its members to obtain new cancer therapies still under investigation as outlined in this chapter from providers and facilities designated by the nonprofit medical service corporation to render these new cancer therapies.

*Clinical trials are conducted in a series of steps, called phases:

**Phase I:** Researchers test a new drug or treatment in a small group of people for the first time to evaluate its safety, determine a safe dosage range, and identify side effects.

**Phase II:** The drug or treatment is given to a larger group of people to see if it is effective and to further evaluate its safety.
**Phase III:** The drug or treatment is given to large groups of people to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the drug or treatment to be used safely.

**Phase IV:** Studies are done after the drug or treatment has been marketed to gather information on the drug's effect in various populations and any side effects associated with long-term use.

**Coverage:**
Rhode Island mandated benefits generally do not apply to Plan 65, FEHBP, and Medicare Advantage plans.

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

**Published:**
Provider Update, April 2013
Provider Update, April 2012
Provider Update, March 2011
Provider Update, April 2010
Provider Update, June 2009
Provider Update, March 2008
Policy Update, March 2007

**References:**
Accessed on 12/5/07; 1/8/09; 1/6/11, 1/3/12:
http://www.rilin.state.ri.us/Statutes/TITLE27/27-20/27-20-27.HTM.

**History:**
April 2013 - Annual Update

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