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§ 38.2-3418.8. Coverage for clinical trials for treatment studies on cancer.

A. Notwithstanding the provisions of § 38.2-3419, each insurer proposing to issue individual or group accident and sickness insurance policies providing hospital, medical and surgical, or major medical coverage on an expense-incurred basis; each corporation providing individual or group accident and sickness subscription contracts; and each health maintenance organization providing a health care plan for health care services shall provide coverage for patient costs incurred during participation in clinical trials for treatment studies on cancer, including ovarian cancer trials, under any such policy, contract or plan delivered, issued for delivery, or renewed in this Commonwealth on and after July 1, 1999.

B. The reimbursement for patient costs incurred during participation in clinical trials for treatment studies on cancer shall be determined in the same manner as reimbursement is determined for other medical and surgical procedures. Such coverage shall have durational limits, dollar limits, deductibles, copayments and coinsurance factors that are no less favorable than for physical illness generally.

C. For purposes of this section:

"Cooperative group" means a formal network of facilities that collaborate on research projects and have an established NIH-approved peer review program operating within the group. "Cooperative group" includes (i) the National Cancer Institute Clinical Cooperative Group and (ii) the National Cancer Institute Community Clinical Oncology Program.

"FDA" means the Federal Food and Drug Administration.

"Member" means a policyholder, subscriber, insured, or certificate holder or a covered dependent of a policyholder, subscriber, insured or certificate holder.

"Multiple project assurance contract" means a contract between an institution and the federal Department of Health and Human Services that defines the relationship of the institution to the federal Department of Health and Human Services and sets out the responsibilities of the institution and the procedures that will be used by the institution to protect human subjects.

"NCI" means the National Cancer Institute.

"NIH" means the National Institutes of Health.

"Patient cost" means the cost of a medically necessary health care service that is incurred as a result of the treatment being provided to the member for purposes of a clinical trial. "Patient cost" does not include (i) the cost of nonhealth care services that a patient may be required to receive as a result of the treatment being provided for purposes of a clinical trial, (ii) costs associated with managing the research associated with the clinical trial, or (iii) the cost of the investigational drug or device.

D. Coverage for patient costs incurred during clinical trials for treatment studies on cancer shall be provided if the treatment is being conducted in a Phase II, Phase III, or Phase IV clinical trial. Such treatment may, however, be provided on a case-by-case basis if the treatment is being provided in a Phase I clinical trial.

E. The treatment described in subsection D shall be provided by a clinical trial approved by:

1. The National Cancer Institute;

2. An NCI cooperative group or an NCI center;

3. The FDA in the form of an investigational new drug application;

4. The federal Department of Veterans Affairs; or

5. An institutional review board of an institution in the Commonwealth that has a multiple project assurance contract approved by the Office of Protection from Research Risks of the NCI.

F. The facility and personnel providing the treatment shall be capable of doing so by virtue of their experience, training, and expertise.

G. Coverage under this section shall apply only if:

1. There is no clearly superior, noninvestigational treatment alternative;

2. The available clinical or preclinical data provides a reasonable expectation that the treatment will be at least as effective as the noninvestigatonal alternative; and

3. The member and the physician or health care provider who provides services to the member under the insurance policy, subscription contract or health care plan conclude that the member's participation in the clinical trial would be appropriate, pursuant to procedures established by the insurer, corporation or health maintenance organization and as disclosed in the policy and evidence of coverage.

H. The provisions of this section shall not apply to short-term travel, accident-only, limited or specified disease policies or contracts designed for issuance to persons eligible for coverage under Title XVIII of the Social Security Act, known as Medicare, or any other similar coverage under state or governmental plans or to short-term nonrenewable policies of not more than six months' duration.

(1999, cc. 643, 649.)

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§ 38.2-3419. Additional mandated coverage made optional to group policy or contract holder.

Any new or existing group policy or contract holder for whom coverage under an accident and sickness insurance policy is issued or renewed by an insurer or for whom coverage under a contract is issued or renewed by a corporation licensed pursuant to Chapter 42 (§ 38.2-4200 et seq.) of this title, shall be given the option to purchase any coverage, benefits or services first mandated under this chapter on or after July 1, 1982, provided that all mandated coverages as of June 30, 1982, will not be affected.

(1982, c. 577, § 38.1-348.14; 1986, c. 562.)