

514C.26 Approved cancer clinical trials coverage.

1. *Definitions.* For purposes of [this section](#), unless the context otherwise requires:

a. “*Approved cancer clinical trial*” means a scientific study of a new therapy for the treatment of cancer in human beings that meets the requirements set forth in [subsection 3](#) and consists of a scientific plan of treatment that includes specified goals, a rationale and background for the plan, criteria for patient selection, specific directions for administering therapy and monitoring patients, a definition of quantitative measures for determining treatment response, and methods for documenting and treating adverse reactions.

b. “*Institutional review board*” means a board, committee, or other group formally designated by an institution and approved by the national institutes of health, office for protection from research risks, to review, approve the initiation of, and conduct periodic review of biomedical research involving human subjects. “*Institutional review board*” means the same as “institutional review committee” as used in section 520(g) of the federal Food, Drug, and Cosmetic Act, as codified in 21 U.S.C. §301 et seq.

c. (1) “*Routine patient care costs*” means medically necessary services or treatments that are a benefit under a contract or policy providing for third-party payment or prepayment of health or medical expenses that would be covered if the patient were receiving standard cancer treatment.

(2) “*Routine patient care costs*” does not include any of the following:

(a) Costs of any treatments, procedures, drugs, devices, services, or items that are the subject of the approved cancer clinical trial or any other investigational treatments, procedures, drugs, devices, services, or items.

(b) Costs of nonhealth care services that the patient is required to receive as a result of participation in the approved cancer clinical trial.

(c) Costs associated with managing the research that is associated with the approved cancer clinical trial.

(d) Costs that would not be covered by the third-party payment provider if noninvestigational treatments were provided.

(e) Costs of any services, procedures, or tests provided solely to satisfy data collection and analysis needs that are not used in the direct clinical management of the patient participating in an approved cancer clinical trial.

(f) Costs paid for, or not charged for, by the approved cancer clinical trial providers.

(g) Costs for transportation, lodging, food, or other expenses for the patient, a family member, or a companion of the patient that are associated with travel to or from a facility where an approved cancer clinical trial is conducted.

(h) Costs for services, items, or drugs that are eligible for reimbursement from a source other than a patient’s contract or policy providing for third-party payment or prepayment of health or medical expenses, including the sponsor of the approved cancer clinical trial.

(i) Costs associated with approved cancer clinical trials designed exclusively to test toxicity or disease pathophysiology.

(j) Costs of extra treatments, services, procedures, tests, or drugs that would not be performed or administered except for participation in the cancer clinical trial. Nothing in this subparagraph division shall limit payment for treatments, services, procedures, tests, or drugs that are otherwise a covered benefit under subparagraph (1).

d. “*Therapeutic intent*” means that a treatment is aimed at improving a patient’s health outcome relative to either survival or quality of life.

2. *Coverage required.* Notwithstanding the uniformity of treatment requirements of [section 514C.6](#), a policy or contract providing for third-party payment or prepayment of health or medical expenses shall provide coverage benefits for routine patient care costs incurred for cancer treatment in an approved cancer clinical trial to the same extent that such policy or contract provides coverage for treating any other sickness, injury, disease, or condition covered under the policy or contract, if the insured has been referred for such cancer treatment by two physicians who specialize in oncology and the cancer treatment is given pursuant to an approved cancer clinical trial that meets the criteria set forth in [subsection 3](#). Services that are furnished without charge to a participant in the approved

cancer clinical trial are not required to be covered as routine patient care costs pursuant to [this section](#).

3. *Criteria.* Routine patient care costs for cancer treatment given pursuant to an approved cancer clinical trial shall be covered pursuant to [this section](#) if all of the following requirements are met:

a. The treatment is provided with therapeutic intent and is provided pursuant to an approved cancer clinical trial that has been authorized or approved by one of the following:

- (1) The national institutes of health.
- (2) The United States food and drug administration.
- (3) The United States department of defense.
- (4) The United States department of veterans affairs.

b. The proposed treatment has been reviewed and approved by the applicable qualified institutional review board.

c. The available clinical or preclinical data indicate that the treatment that will be provided pursuant to the approved cancer clinical trial will be at least as effective as the standard therapy and is anticipated to constitute an improvement in therapeutic effectiveness for the treatment of the disease in question.

4. *Notice.* As soon as practical after the insured provides written consent to participate in an approved cancer clinical trial, the physician shall provide notice to the third-party payment provider of the insured's intent to participate in an approved cancer clinical trial. Failure to provide such notice to the third-party payment provider shall not be the basis for denying the coverage required under [subsection 2](#).

5. *Applicability.*

a. [This section](#) applies to the following classes of third-party payment provider contracts or policies delivered, issued for delivery, continued, or renewed in this state on or after July 1, 2010:

(1) Individual or group accident and sickness insurance providing coverage on an expense-incurred basis.

(2) An individual or group hospital or medical service contract issued pursuant to [chapter 509](#), [514](#), or [514A](#).

(3) An individual or group health maintenance organization contract regulated under [chapter 514B](#).

(4) Any other entity engaged in the business of insurance, risk transfer, or risk retention, which is subject to the jurisdiction of the commissioner.

(5) A plan established pursuant to [chapter 509A](#) for public employees.

(6) An organized delivery system licensed by the director of public health.

b. [This section](#) shall not apply to accident-only, specified disease, short-term hospital or medical, hospital confinement indemnity, credit, dental, vision, Medicare supplement, long-term care, basic hospital and medical-surgical expense coverage as defined by the commissioner, disability income insurance coverage, coverage issued as a supplement to liability insurance, workers' compensation or similar insurance, or automobile medical payment insurance.

[2010 Acts, ch 1013, §1](#); [2010 Acts, ch 1193, §61](#)