

(7) (i) "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 the clinical trial.

(ii) "Patient cost" does not include:

1. the cost of an investigational drug or device;
2. 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 the clinical trial;
3. costs associated with managing the research associated with the clinical trial; or
4. costs that would not be covered under the patient's policy, plan, or contract for noninvestigational treatments.

(b) This section applies to:

(1) insurers and nonprofit health service plans that provide hospital, medical, surgical, or pharmaceutical benefits to individuals or groups on an expense-incurred basis under a health insurance policy or contract issued or delivered in the State; and

(2) health maintenance organizations that provide hospital, medical, surgical, or pharmaceutical benefits to individuals or groups under contracts that are issued or delivered in the State.

(c) This section does not apply to a policy, plan, or contract paid for under Title XVIII or Title XIX of the Social Security Act.

(d) A policy, plan, or contract subject to this section shall provide coverage for patient cost to a member in a clinical trial, as a result of:

- (1) treatment provided for a life-threatening condition; or
- (2) prevention, early detection, and treatment studies on cancer.

(e) The coverage under subsection (d) of this section shall be required if:

(1) (i) the treatment is being provided or the studies are being conducted in a Phase I, Phase II, Phase III, or Phase IV clinical trial for cancer; or

(ii) the treatment is being provided in a PHASE I, Phase II, Phase III, or Phase IV clinical trial for any other life-threatening condition;

(2) the treatment is being provided in a clinical trial approved by:

- (i) one of the National Institutes of Health;
- (ii) an NIH cooperative group or an NIH center;
- (iii) the FDA in the form of an investigational new drug application;