

**§4310. Access to clinical trials**

**1. Qualified enrollee.** An enrollee is eligible for coverage for participation in an approved clinical trial if the enrollee meets the following conditions:

A. The enrollee has a life-threatening illness for which no standard treatment is effective; [PL 1999, c. 742, §19 (NEW); PL 1999, c. 742, §21 (AFF).]

B. The enrollee is eligible to participate according to the clinical trial protocol with respect to treatment of such illness; [PL 1999, c. 742, §19 (NEW); PL 1999, c. 742, §21 (AFF).]

C. The enrollee's participation in the trial offers meaningful potential for significant clinical benefit to the enrollee; and [PL 1999, c. 742, §19 (NEW); PL 1999, c. 742, §21 (AFF).]

D. The enrollee's referring physician has concluded that the enrollee's participation in such a trial would be appropriate based upon the satisfaction of the conditions in paragraphs A, B and C. [PL 1999, c. 742, §19 (NEW); PL 1999, c. 742, §21 (AFF).]  
[PL 1999, c. 742, §19 (NEW); PL 1999, c. 742, §21 (AFF).]

**2. Coverage.** A carrier may not deny a qualified enrollee participation in an approved clinical trial or deny, limit or impose additional conditions on the coverage of routine patient costs for items and services furnished in connection with participation in the clinical trial. For the purposes of this section, "routine patient costs" does not include the costs of the tests or measurements conducted primarily for the purpose of the clinical trial involved.  
[PL 1999, c. 742, §19 (NEW); PL 1999, c. 742, §21 (AFF).]

**3. Payment.** A carrier shall provide payment for routine patient costs but is not required to pay for costs of items and services that are reasonably expected to be paid for by the sponsors of an approved clinical trial. In the case of covered items and services, the carrier shall pay participating providers at the agreed upon rate and pay nonparticipating providers at the same rate the carrier would pay for comparable services performed by participating providers.  
[PL 1999, c. 742, §19 (NEW); PL 1999, c. 742, §21 (AFF).]

**4. Approved clinical trial.** For the purposes of this section, "approved clinical trial" means a clinical research study or clinical investigation approved and funded by the federal Department of Health and Human Services, National Institutes of Health or a cooperative group or center of the National Institutes of Health.  
[PL 1999, c. 742, §19 (NEW); PL 1999, c. 742, §21 (AFF).]

**5. Application.** The requirements of this section apply to all individual and group policies, contracts and certificates executed, delivered, issued for delivery, continued or renewed in this State. For purposes of this section, all contracts are deemed to be renewed no later than the next yearly anniversary of the contract date.  
[PL 2003, c. 517, Pt. B, §31 (NEW).]

**SECTION HISTORY**

PL 1999, c. 742, §19 (NEW). PL 1999, c. 742, §21 (AFF). PL 2003, c. 517, §B31 (AMD).

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