



North Carolina
State Health Plan
FOR TEACHERS AND STATE EMPLOYEES



Coverage for Clinical Trials

Board of Trustees Meeting

February 5, 2016

A Division of the Department of State Treasurer

ACA Coverage of Approved Clinical Trials

- Under the Affordable Care Act (ACA), group health plans and health insurance issuers offering individual or group health insurance products are required to provide coverage of **routine patient costs** associated with approved clinical trials.
- For plan years beginning on or after January 1, 2014, the plan or issuer is prohibited, under federal law, from doing any of the following:
 1. Denying the **qualified individual** participation in an approved clinical trial.
 2. Denying or limiting, or imposing additional conditions on, the coverage of routine patient costs for items or services furnished in connection with participation in the approved clinical trial.
 3. Discrimination against the individual on the basis of the individual's participation in the **approved clinical trial**.

ACA Coverage of Approved Clinical Trials

- **Qualified individual:** An individual who is enrolled or participating in a health plan or coverage and who is eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of cancer or another life-threatening disease or condition. There must be a determination that the individual's participation in the approved clinical trial is appropriate to treat the disease or condition.
- **Routine patient costs:** Generally includes all items and services consistent with the coverage provided under the plan for a qualified individual who is not enrolled in a clinical trial. However, the following costs are not required to be covered:
 1. The cost of an investigational item, device, or service.
 2. The cost of items and services provided solely to satisfy data collection and analysis needs that are not used in direct clinical management.
 3. The cost for a service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis.

ACA Coverage of Approved Clinical Trials

- **Approved clinical trial:** A phase I, II, III, or IV clinical trial that is conducted in relation to the prevention, detection, or treatment of cancer or other life-threatening disease or condition and is one of the following:
 1. A federally funded or approved trial.
 2. A clinical trial conducted under an FDA investigational new drug application.
 3. A drug trial that is exempt from the requirement of an FDA investigational new drug application.

Current Coverage under Grandfathered Plans

- Under the Traditional 70/30 Plan and Enhanced 80/20 Plan the following is covered:
 - Participation in clinical trials phases II, III, and IV.
 - Only covers medically necessary costs of health services associated with the trials and only to the extent costs are not funded by other resources.
 - Member must meet all protocol requirements and provide informed consent.
 - Must involve a life-threatening medical condition with services that are medically indicated and preferable for that member compared to non-investigational alternatives.

Current Coverage under Grandfathered Plans

- The clinical trial must:
 - Involve determinations by treating physicians, relevant scientific data and opinions of relevant medical specialists.
 - Be approved by centers or groups funded by the National Institutes of Health, the Food and Drug Administration, the Centers for Disease Control and Prevention, the Agency for Health Care Research and Quality, the Department of Defense or the Department of Veteran Affairs.
 - Be conducted in a setting and by personnel of high expertise based on training, experience and patient volume.
- Exclusions:
 - Non-health care services, such as services provided for data collection and analysis.
 - Investigational drugs and devices and services that are not for the direct clinical management of the patient.

Cost of Expanding Coverage to Phase I Trials

- The Segal Company has advised plans that the cost of covering clinical trials as required under the ACA is approximately 0.45% of total claims (i.e. medical and pharmacy combined), with phase I costs usually accounting for 10% or less of the projected costs of all phases.
- Since the Plan already covers participation in clinical trial phases II, III, and IV under the Traditional 70/30 and Enhanced 80/20 plans, the cost of expanding coverage to include phase I trials is estimated to be \$1 million annually.

Recommendation

Plan staff recommends that the Board of Trustees approve the coverage of approved clinical trials consistent with ACA requirements for our grandfathered plans: Traditional 70/30 and Enhanced 80/20

If approved, this benefit change can be implemented for CY 2016 (effective January 1, 2016).