Administrative Policy

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Clinical Trials

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Related Coverage Resources

PURPOSE
Administrative Policies are intended to provide further information about the administration of ***standard*** *Cigna benefit plans. In the event of a conflict, a customer's benefit plan document* ***always supersedes*** *the information in an Administrative Policy. Coverage determinations require consideration of 1) the terms of the applicable benefit plan document; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Administrative Policies and; 4) the specific facts of the particular situation. Administrative Policies relate exclusively to the administration of health benefit plans. Administrative Policies are not recommendations for treatment and should never be used as treatment guidelines.*

Administrative Policy

Coverage is subject to the terms, conditions and limitations of the applicable benefit plan and may be subject to state regulations.

Standard benefit plans administered by Cigna cover Routine Patient Care Costs/Services related to a clinical trial for a Qualified Individual consistent with the Families First Affordable Care Act (ACA) requirements. The individual must be eligible to participate according to the trial protocol and EITHER of the following conditions must be met:

- the referring health care professional is a participating health care provider and has concluded that the individual's participation in such trial would be appropriate, or
- the individual provides medical and scientific information establishing that the individual's participation in the qualified trial would be appropriate

AND the trial is a phase I, phase II, phase III or phase IV clinical trial conducted in relation to the prevention, detection or treatment of cancer or other life-threatening disease or condition that meets ANY of the following criteria:

- Federally funded trial: The study of investigation is approved or funded (which may include funding through in-kind contributions) by one or more of the following:
  - National Institutes of Health (NIH)
  - Centers for Disease Control and Prevention (CDC)
  - Agency for Health Care Research and Quality (AHRQ)
  - Centers for Medicare and Medicaid Services (CMS)
  - A cooperative group or center of any of the entities described above or the Department of Defense (DOD) or the Department of Veterans Affairs (VA)
  - A qualified non-governmental research entity identified in NIH guidelines for center support grants
  - ANY of the following:
    - Department of Defense
    - Department of Veterans Affairs
    - Department of Energy

      if BOTH of the following conditions are met:
    - study or investigation has been reviewed and approved through a system of peer review comparable to the system of peer review of studies and investigations used by the National Institutes of Health
    - assures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review.
- The study or investigation is conducted under an investigational new drug application reviewed by the Food and Drug Administration.
- The study or investigation is a drug trial that is exempt from having such an investigational new drug application.

The following services associated with a clinical trial are not covered:

- services that are not considered routine patient care costs/services, including the following:
  - the investigational drug, device, item, or service itself
  - an item or service that is provided solely to satisfy data collection and analysis needs
  - an item or service that is not used in the direct clinical management of the individual
  - a service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis
- an item or service provided by the research sponsors free of charge for any person enrolled in the trial
- travel and transportation expenses unless otherwise covered under the plan, including, but not limited to the following:
  - fees for personal vehicle, rental car, taxi, medical van, ambulance, commercial airline, train
  - mileage reimbursement for driving a personal vehicle
  - lodging
  - meals
- routine patient costs obtained out-of-network when non-network benefits do not exist under the plan

General Background

For plan years beginning on or after January 1, 2014, the Affordable Care Act (ACA) requires individual policies and non-grandfathered group health plans to cover Routine Patient Care

Costs/Services related to an approved clinical trial for a qualified individual. According to the ACA, for plan years beginning on or after 1/1/2014, a group health plan or health insurance issuer:

- may not deny a qualified individual participation in an Approved Clinical Trial
- may not discriminate against a qualified individual on the basis of the individual's participation in a clinical trial
- must provide coverage of Routine Patient Care Costs/Services

Routine Patient Care Costs/Services: Routine Patient Care Costs/Services are costs associated with the provision of health care items and services including drugs, items, devices and services otherwise covered by Cigna for a covered individual who is not enrolled in a clinical trial. In addition, Routine Patient Care Costs/Services include:

- services required for the clinically appropriate monitoring of the investigational drug, device, item or service
- services provided for the prevention of complications arising from the provision of the investigational drug, device, item or service
- reasonable and necessary care arising from the provision of the investigational drug, device, item or service, including the diagnosis and treatment of complications.

Examples of Routine Patient Care Costs/Services include radiological services, laboratory services, intravenous therapy, anesthesia services, hospital services, physician services, office visits, room and board, and medical supplies that typically would be covered under the plan for an individual who is not enrolled in a clinical trial.

Routine Patient Care Costs/Services do not include the investigational item, device or service itself. Also not included is an item, device, or service:

- that is provided free of charge by the research sponsors
- which is used to satisfy data collection and analysis needs
- not used to direct clinical management of the patient
- obtained out-of-network when non-network benefits do not exist under the plan
- that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis.

Qualified Individual: A qualified individual is a participant or beneficiary in a health plan or with coverage who is eligible to participate in an approved clinical trial according to the trial protocol with respect to the prevention, detection or treatment of cancer or other life threatening disease or condition.

For in-network only benefit plans, Cigna may require Qualified Individuals to participate in a clinical trial through participating health care professionals if a participating health care professional will accept the individual as a participant in the trial. However if the Approved Clinical Trial is conducted outside the resident state of the Qualified Individual, coverage for Routine Patient Care Costs/Services will be allowed.

Life-Threatening Disease or Condition: As defined by ACA the term 'life-threatening disease or condition' means "any disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted." An individual may qualify to participate in a clinical trial based on a referral from a health care professional participating in the trial or by providing medical and scientific information establishing that participation would be appropriate.

Clinical Trial Phases: The Food and Drug Administration (FDA) has established categories for describing the clinical trial of a drug based on the study's characteristics, such as the objective and number of participants:

- Phase I: Studies that are usually conducted with healthy volunteers and that emphasize safety. The goal is to find out what the drug's most frequent and serious adverse events are and, often, how the drug is metabolized and excreted.
- Phase II: Studies that gather preliminary data on effectiveness (whether the drug works in people who have a certain disease or condition). For example, participants receiving the drug may be compared with similar participants receiving a different treatment, usually an inactive substance (called a placebo) or a different drug. Safety continues to be evaluated, and short-term adverse events are studied.
- Phase III: Studies that gather more information about safety and effectiveness by studying different populations and different dosages and by using the drug in combination with other drugs.
- Phase IV: Studies occurring after FDA has approved a drug for marketing. These including postmarket requirement and commitment studies that are required of or agreed to by the sponsor. These studies gather additional information about a drug's safety, efficacy, or optimal use (National Institutes of Health [NIH], 2021).

In-network benefit level: Coverage level applied when care is provided to a Cigna customer by a doctor, certified nurse-midwife, hospital, clinic, or laboratory that is contracted with Cigna to provide health care services.

Out-of-network benefit level: Coverage level applied when care is provided to a Cigna customer by a doctor, certified nurse-midwife, hospital, clinic, or laboratory that is not contracted with Cigna to provide health care services, who does not participate in the network associated with the customer's Cigna plan, and only when a customer's health benefit plan allows out-of-network services.

Coding Information

Notes:

1. This list of codes may not be all-inclusive.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Eligible for Coverage:

HCPCS Codes	Description
S9988	Services provided as part of a phase I clinical trial
S9990	Services provided as part of a phase II clinical trial
S9991	Services provided as part of a phase III clinical trial

ICD-10-CM Diagnosis Codes	Description
Z00.6	Encounter for examination for normal comparison and control in clinical research program

Considered Not Covered:

HCPCS Codes	Description
S9992	Transportation costs to and from trial location and local transportation costs (e.g., fares for taxicab or bus) for clinical trial participant and one caregiver/companion
S9994	Lodging costs (e.g., hotel charges) for clinical trial participant and one caregiver/companion
S9996	Meals for clinical trial participant and one caregiver/companion

References

1. Centers for Medicare and Medicaid. National coverage determination for routine costs in clinical trials (301.1). 2007 Oct 9. Accessed November 7, 2023. Available at URL address: http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=1&ncdver=2&bc=BAABAAAAAAAA&

2. US Department of Health and Human Services. HHS.gov/HealthCare. About the Affordable Care Act. Content last reviewed on March 17, 2022. Accessed November 7, 2023. Available at URL address: http://www.hhs.gov/healthcare/rights/index.html

3. US National Institutes of Health. ClinicalTrials.gov. Accessed November 7, 2023. Available at URL address: http://clinicaltrials.gov/ct2/home

4. The Patient Protection and Affordable Care Act. Accessed November 7, 2023. Available at URL address: https://www.govinfo.gov/content/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf