INDIANA HEALTH COVERAGE PROGRAMS

PROVIDER REFERENCE MODULE

Clinical Trials

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Revision History

Version	Date	Reason for Revisions	Completed By
1.0	Policies and procedures as of Oct. 1, 2018 Published: June 4, 2019	New document	FSSA and DXC
2.0	Policies and procedures as of Dec. 1, 2019 Published: Jan. 30, 2020	Scheduled review	FSSA and DXC
3.0	Policies and procedures as of Sept. 1, 2020 Published: Oct. 8, 2020	Scheduled review	FSSA and Gainwell
4.0	Policies and procedures as of Oct. 1, 2021 Published: Jan. 27, 2022	Scheduled review	FSSA and Gainwell
5.0	Policies and procedures as of March 1, 2023 Published: April 25, 2023	Scheduled review: • Reorganized and edited text as needed for clarity • Updated the *Introduction* section • Updated the *Requirements for Qualifying Clinical Trials* section • Updated the *Routine (Covered) and Nonroutine (Noncovered) Costs for Clinical Trials* section and updated the introductory text in the *Routine Costs* subsection • Added the *Coverage Determination and Prior Authorization* section	FSSA and Gainwell

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*Note: The information in this module applies to Indiana Health Coverage Programs (IHCP) services provided under the **fee-for-service (FFS)** delivery system. For information about services provided through the **managed care** delivery system – including Healthy Indiana Plan (HIP), Hoosier Care Connect or Hoosier Healthwise services – providers must contact the member's managed care entity (MCE) or refer to the MCE provider manual. MCE contact information is included in the IHCP Quick Reference Guide at in.gov/medicaid/providers.*

For updates to information in this module, see IHCP Banner Pages and IHCP Bulletins at in.gov/medicaid/providers.

Introduction

A clinical trial is a research study among human volunteers to answer specific health questions. Clinical trials are performed to find new ways of using known treatments and to determine whether new drugs, devices and procedures are safe and effective for general use.

In compliance with Section 210 of the *Consolidated Appropriations Act of 2021*, the Indiana Health Coverage Programs (IHCP) covers the routine costs of qualifying clinical trials to the extent that the item or service would otherwise be covered for the member when not participating in the qualifying clinical trial. This coverage includes any item or service provided to prevent, diagnose, monitor or treat complications resulting from participation. This policy applies to items and services furnished to Medicaid members who are participating in a qualifying clinical trial for dates of service on and after Jan. 1, 2022.

Requirements for Qualifying Clinical Trials

A qualifying clinical trial is defined as a clinical trial in any clinical phase of development that is conducted in relation to the prevention, detection or treatment of any serious or life-threatening disease or condition that meets any of the following criteria:

- The study or investigation is approved, conducted or supported (which may include funding) by one or more of the following:
  - National Institutes of Health (NIH)
  - Centers for Disease Control and Prevention (CDC)
  - Agency for Healthcare Research and Quality (AHRQ)
  - Centers for Medicare & Medicaid Services (CMS)
  - A cooperative group or center of any of the entities described above, the Department of Defense or Department of Veterans Affairs
  - A qualified nongovernmental research entity identified in the guidelines issued by the NIH for center support grants
- The clinical trial 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 NIH, which assures unbiased review of the highest scientific standards by qualified individuals with no interest in the outcome of the review. The clinical trial is approved or funded by one or more of the following:
  - Department of Veterans Affairs
  - Department of Defense
  - Department of Energy

- The clinical trial is conducted pursuant to an investigational new drug exemption under section 335(i) of Title 21 or an exemption for a biological product undergoing investigation under section 262(a)(3) of this title.
- The clinical trial is a drug trial that is exempt from having such an investigational new drug application.

Routine (Covered) and Nonroutine (Noncovered) Costs for Clinical Trials

This section provides a breakdown of clinical trial routine costs that are covered and nonroutine costs that are not covered.

Routine Costs

Routine costs that must be covered for an IHCP member participating in a qualifying clinical trial are any item or service provided to the individual under the qualifying clinical trial (including any item or service provided to prevent, diagnose, monitor or treat complications resulting from participation in the qualifying clinical trial), to the extent that the provision of such items or services to the member would otherwise be covered outside the course of participation. In other words, there exists a benefit category, and the item or service is not listed as a noncovered service in the *Indiana Administrative Code* (IAC).

Items or services already covered by the IHCP will be considered routine costs according to existing coverage rules and regulations, even if the item or service is the investigational item or service. The IHCP policy on clinical trials will not render these investigational items or services noncovered.

Items and services considered routine costs in clinical trials, and thus reimbursable, include the following:

- Items and services that would otherwise be covered by the program if they were not provided in the context of a clinical trial. Examples include the following:
  - Nursing/staffing fees
  - Patient monitoring and evaluation
  - Durable medical equipment (DME)
  - Intravenous (IV) and catheter line placement
- Items or services required for the administration and provision of the investigational item or service. Examples include the following:
  - Administration fee for an investigational chemotherapeutic agent
  - Equipment and ancillary staffing for the implantation of an investigational device
  - Provision of a nebulizer to administer an investigational drug
  - Room and board as part of a hospital stay required as part of the clinical trial
- Items required for the clinically appropriate monitoring of the effects of the investigational item or service. Examples include the following:
  - Electrocardiograms (ECGs)
  - Electroencephalograms (EEGs)
  - Blood pressure monitoring
- Items and services required for the prevention of complications – for example, the cost of an antinausea drug for an investigational chemotherapeutic agent.
- Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service – in particular, for the diagnosis or treatment of complications. An example is the treatment of pneumonia caused by an investigational lung procedure.

Nonroutine Costs (Noncovered)

Items not considered routine costs in a clinical trial, and thus not covered by the IHCP, include the following:

- The investigational items or services, unless otherwise covered outside the clinical trial. If the investigational item or service is currently covered only for certain medical conditions and is being tested for use outside the scope of coverage, the item or service will not be reimbursable.
- Items and services provided solely to satisfy data collection and analysis needs, and not used in the direct clinical management of the patient. Examples include the following:
  - Monthly computed tomography (CT) scans for a condition usually requiring only a single CT scan
  - Weekly blood draws not needed to monitor side effects
  - Quarterly Pap smears for a condition usually requiring yearly Pap smears
- Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial.

Coverage Determination and Prior Authorization

Effective for dates of service on or after Jan. 1, 2022, IHCP coverage determinations for costs related to a clinical trial will be:

- Expedited and completed within 72 hours
- Made without limitation on the geographic location or network affiliation of the healthcare provider treating the individual or the principal investigator of the qualifying clinical trial
- Based on attestation regarding the appropriateness of the qualifying clinical trial by the healthcare provider and principal investigator using the following form and kept on file by the provider:
  - *Medicaid Attestation Form on the Appropriateness of the Qualified Clinical Trial* (link will download Word file of form)
- Completed without any requirement of submission of the protocols of the qualifying clinical trial, or any other documentation that may be proprietary or determined by the Department of Health and Human Services (HHS) Secretary to be burdensome to provide

Not all services and costs associated with a clinical trial require prior authorization (PA). All PA requirements that apply to services provided outside of a clinical trial apply to routine services within a clinical trial. For specific PA requirements for a particular procedure or treatment, see the appropriate provider reference module, accessible from the *IHCP Provider Reference Modules* page at in.gov/medicaid/providers.