INDIANA HEALTH COVERAGE PROGRAMS

PROVIDER REFERENCE MODULE

Clinical Trials

LIBRARY REFERENCE NUMBER: PROMOD00060
PUBLISHED: OCTOBER 8, 2020
POLICIES AND PROCEDURES AS OF SEPTEMBER 1, 2020
VERSION: 3.0

Revision History

Version	Date	Reason for Revisions	Completed By
1.0	Policies and procedures as of October 1, 2018 Published: June 4, 2019	New document	FSSA and DXC
2.0	Policies and procedures as of December 1, 2019 Published: January 30, 2020	Scheduled review	FSSA and DXC
3.0	Policies and procedures as of September 1, 2020 Published: October 8, 2020	Scheduled review: • Corrected full name of NIDDK in the *Requirements for Qualifying Clinical Trials* section	FSSA and Gainwell

Table of Contents

> *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 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.

Medicare has established guidelines to cover the routine costs of qualifying clinical trials, as well as reasonable and necessary items and services used to diagnose and treat complications arising from beneficiaries' participation in all clinical trials. The Indiana Health Coverage Programs (IHCP) has accepted Medicare's established guidelines to reimburse for routine costs and complications of clinical trials.

> *Note: Medicare defines an experimental item or service as for "research use only" or for "investigational use only." The terms "experimental" and "investigational" are described under the same definition and have the same coverage guidelines. Thus, in this module, "experimental" and "investigational" are used interchangeably.*

Covered and Noncovered Services

The IHCP covers the routine costs of qualifying clinical trials (as defined in the *Requirements for Qualifying Clinical Trials* section), as well as reasonable and necessary items and services used to diagnose and treat complications arising from the participation in all clinical trials.

For specific prior authorization requirements for a particular procedure or treatment, see the appropriate provider reference module.

Routine Costs

Routine costs of a clinical trial include all items and services provided in either the experimental or the control arms of the trial that are available to IHCP members (that is, 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 be considered investigational and therefore not 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.

Requirements for Qualifying Clinical Trials

For the IHCP to cover the routine costs involved in clinical trials, the clinical trial must meet all the following requirements:

- The subject or purpose of the trial must be the evaluation of an item or service that would be covered under IAC guidelines. The items or service being investigated must not be a noncovered item or service as listed under any of the following:
  - *405 IAC 5-10-5*
  - *405 IAC 5-19-18*
  - *405 IAC 5-24-3*
  - *405 IAC 5-29-1*
  - *405 IAC 5-30-3*
- If a clinical trial has a single objective, it must have a therapeutic intent. If a clinical trial has multiple objectives, the *primary* objective must have a therapeutic intent. It must have some potential to improve a subject's condition, such as prolongation of life, shrinkage of a tumor, or improved quality of life, even though cure or dramatic improvement may not necessarily be effected. The trial cannot be designed exclusively to test toxicity or disease pathology.
- Trials of therapeutic intervention must enroll only members with diagnosed diseases, rather than healthy members. Trials including diagnostic interventions may enroll healthy members to have a proper control group.
- The clinical trial must be deemed "automatically qualified" under Medicare guidelines. The following clinical trials are deemed automatically qualified:
  - Trials funded by any 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)
    - Department of Defense (DOD)
    - Veterans Administration (VA)
  - Trials supported by centers or cooperative groups funded by the NIH, CDC, AHRQ, CMS, DOD, or VA, including but not limited to the following:
    - Food and Drug Administration (FDA)
    - National Heart, Lung, and Blood Institute (NHLBI)
    - National Human Genome Research Institute (NHGRI)
    - National Cancer Institute (NCI)
    - National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
    - National Institute of Mental Health (NIMH)
  - Trials conducted under an Investigational New Drug (IND) application reviewed by the FDA
  - Drug trials that are exempt from the IND application process under *Code of Federal Regulations 21 CFR 312.2 (b)(1)*