IHCP *bulletin*

INDIANA HEALTH COVERAGE PROGRAMS BT202286 OCTOBER 4, 2022

IHCP updates clinical trial policy

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 enrollee when not participating in the qualifying clinical trial. This 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 beneficiaries who are participating in a qualifying clinical trial on and after Jan. 1, 2022.

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
  - Centers for Disease Control and Prevention
  - Agency for Healthcare Research and Quality
  - Centers for Medicare & Medicaid Services
  - 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 National Institutes of Health 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 National Institutes of Health, 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 costs

Routine costs that must be covered for a beneficiary 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 beneficiary 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 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.

Coverage determinations and prior authorization

Coverage determinations shall be:

- Expedited and completed within 72 hours.
- Made without limitation on the geographic location or network affiliation of the healthcare provider treating such 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. This policy change applies to all IHCP programs, subject to limitations established for certain benefit plans.

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