Clinical Trials

Policy Number:	**M011011296**
Effective Date:	**10/11/2001**
Sponsoring Department:	**Health Care Services**
Impacted Department(s):	**Health Care Services**

Type of Policy: ☒ Internal ☒ External

Data Classification: ☐Confidential ☐Restricted ☒Public

Applies to (Line of Business):

☐ Corporate (All)
☒ State Products, if yes which plan(s): ☒MediSource; ☒ MediSource Connect ☒Child Health Plus; ☒ Essential Plan
☒ Medicare, if yes, which plan(s): ☒MAPD; ☐PDP; ☒ISNP; ☒CSNP
☒ Commercial, if yes, which type: ☒Large Group; ☒Small Group; ☒Individual
☒ Self-Funded Services *(Refer to specific Summary Plan Descriptions (SPDs) to determine any pre-authorization or pre-certification requirements and coverage limitations. In the event of any conflict between this policy and the SPD of a Self-Funded Plan, the SPD shall supersede the policy.)*

Excluded Products within the Selected Lines of Business (LOB)

Applicable to Vendors? Yes ☐ No☒

Purpose and Applicability:

To set forth the criteria for coverage and member participation in a **clinical trial** under each Line of Business.

Policy:

Commercial and Self-Funded:

A. Criteria: (Applicable to all Approved Clinical Trials)

Independent Health covers medically necessary **Routine Patient Costs** of a **Qualified Individual** participating in an Approved Clinical Trial consistent with Public Health Service Act §2709 effective for plan years commencing on or after January 1, 2014.
Note – please refer to Definitions section for Routine Patient Costs definition.

B. Covered for Approved Clinical Trials
- The Routine Patient Costs of care provided to a Qualified Individual enrolled in an Approved Clinical Trial;
- The routine costs of treating any side effects and/or complications associated with the Approved Clinical Trial.
  Note: please refer to Independent Health policy titled Provider Billing, Payment, and Reporting Rules and Requirements for Serious Reportable Adverse Events, Never Events, and Hospital-Acquired Conditions.

C. Not covered for Approved Clinical Trials
- Items and services available free from the clinical trial sponsor.
- Services identified as investigational clinical services provided in an approved clinical research study.
- The actual device, equipment, or drug that is being studied.
- Items and services that are provided solely to satisfy data collection and analysis needs that are not used in direct clinical management of the patient.
- Services that are clearly inconsistent with the widely accepted and established standards of care for a particular disease or condition.
- Services or items that would not be covered if the member was not enrolled in a clinical trial
- Services that are specifically excluded by the member's benefits.
- Transportation, lodging and meals associated with a clinical trial.

D. Clinical Trial Facilities Notification Requirement:
- Facilities must notify Independent Health of a member's participation by forwarding the following clinical trial information:
  - Clinical trial protocol including Approved Clinical trial number, member information and medical history
  - Clinical trial sponsor budget
  - Protocol billing grid/treatment calendar
  - National Clinical Trial (NCT) identifier to be included on any claim submission.

E. Limitations
- All coverage policies relating to routine care for members not in clinical trials will also apply to routine care for members in clinical trials.
- Subject to paragraph F below, all applicable plan limitations for coverage of network care will apply to routine cost for Qualified Individuals in Approved Clinical Trials.
- Benefits for Clinical Trials do not include:
  - The Experimental or Investigational Service(s) or item that is used in the clinical trial is not covered, except for the following:

- Certain **Category B Devices**. Only certain FDA-designated Category B Devices are covered. In order to be covered, all of the following criteria must be met:
    - The device must be used within the context of an FDA-approved clinical trial.
    - The device must be used according to the clinical trial's approved protocols.
    - Must fall under a covered benefit category and must not be excluded by law, regulation or current Medicare coverage guidelines.
    - The device is medically necessary for the member, and the amount, duration and frequency of use or application of the service is medically appropriate.
    - The device is furnished in a setting appropriate to the member's medical needs and condition.

F. Network Providers

Independent Health may require the Qualified Individual to participate in the Approved Clinical Trial through a participating provider if the provider will accept the individual as a participant in the trial. **NOTE:** When an individual is participating in an Approved Clinical Trial, coverage for out-of-network or non-participating provider(s) is approved if there is no network provider with the expertise required to administer the Approved Clinical Trial. However, for services that can be provided within the network by available, qualified participating providers (e.g., laboratory and diagnostic services or physician, practitioner, or provider services), Independent Health requires the individual to use such participating providers unless the individual's plan has out of network benefits. A Qualified Individual that has out of network benefits may participate in an Approved Clinical Trial conducted outside the state or service area in which the individual resides and will encounter higher member liability in accordance with the terms of their plan.

G. Nondiscrimination

Independent Health does not deny a qualified individual participation in an approved clinical trial with respect to cancer or another Life-threatening Disease or Condition and does not discriminate against an individual on the basis of their participation in a clinical approved trial.

Medicare Advantage:

Original (fee-for-service) Medicare covers the routine costs of Medicare approved clinical trials in accordance with Medicare's national coverage determination and local coverage articles.

Medicare covers the routine costs of Medicare qualifying clinical trials for all Medicare enrollees, including those enrolled in Independent Health's Medicare Advantage plans, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participating in qualifying clinical trials.

Trials that are deemed to be automatically qualifying are:

- Trials funded by NIH, CDC, AHRQ, CMS, DOD, and VA;
- Trials supported by centers or cooperative groups that are funded by NIH, CDC, AHRQ, CMS, DOD, and VA;

- Trials conducted under an investigational new drug application (IND) reviewed by the FDA; or
- IND exempt drug trials under 21 CFR 312.2(b)(1) will be deemed automatically qualified until the self-certification process is in place.

Other clinical trials that do not fall into the above categories must meet the following three requirements to receive Medicare coverage:

- The trial must evaluate an item or service that falls within a Medicare benefit category
- The trial must not be designed exclusively to test toxicity or disease pathophysiology. It must have a therapeutic intent
- Trials of therapeutic interventions must enroll patients with diagnosed disease, not healthy volunteers

Note: Trials of diagnostic interventions may enroll healthy patients as a control group.

In addition to the three requirements referenced above qualifying clinical trials should have the following desirable characteristics:

- Tests whether the intervention potentially improves the participants' health outcomes
- Is well supported by available scientific literature, or is intended to clarify the health outcomes of interventions already in common clinical use
- Does not unjustifiably duplicate existing studies
- Design is appropriate to answer the research question
- Is sponsored by a credible organization or individual
- Is compliant with Federal regulations on protection of human subjects
- All aspects are conducted according to the appropriate standards of scientific integrity

Covered routine costs include:

1. Items or services that are typically provided absent a clinical trial;

2. Items or services required solely for the provision of the investigation item or service (e.g., administration of a non-covered chemotherapeutic agent) the clinically appropriate monitoring of the effects of the item or service; or the prevention of complications;

3. Items or services needed for reasonable and necessary care arising from the provision of an investigation item or service in particular, for the diagnosis or treatment of complications;

Routine costs do not include:

1. The investigational item or service, itself unless otherwise covered outside of the clinical trial;

2. Items and services provided solely to satisfy data collection and analysis needs that are not used in the direct clinical management of the patient; and

3. Items and services customarily provided by the research sponsors free-of-charge for any enrollee in the trial.

For noncovered items and services, including items and services for which Medicare payment is statutorily prohibited; Medicare only covers the treatment of complications arising from the delivery of the noncovered item or service and unrelated reasonable and necessary care. (Refer to

MCM 2300.1 and MIM 3101.) However, if the item or service is not covered by virtue of a national noncoverage policy in the Coverage Issues Manual and is the focus of a qualifying clinical trial, the routine costs of the clinical trial (as defined above) will be covered by Medicare but the noncovered item or service, itself, will not.

Independent Health pays the enrollee the difference between original Medicare cost-sharing incurred for qualified clinical trial items and services and the enrollee's Independent Health Medicare Advantage in-network cost-sharing for the same category of items and services otherwise covered by the plan. To be eligible for reimbursement, enrollees (or providers acting on their behalf) must notify Independent Health that they have received qualified clinical trial services and provide documentation of the cost-sharing incurred, such as a provider bill. Independent Health may also seek the Medicare Advantage enrollee's original Medicare cost-sharing information directly from clinical trial providers.

Independent Health Medicare Advantage enrollees are free to participate in any qualifying clinical trial that is open to beneficiaries in original Medicare. Authorization from Independent Health is not required in order to join a clinical trial. However, it is recommended that an enrollee notifies the Independent Health resource coordination department before joining a clinical trial in order to maintain a record of all health care services rendered.

A clinical trial provider does not have to be Independent Health network provider. However, health services unrelated to the clinical trial must be rendered by an Independent Health Medicare Advantage provider, unless the Medicare Advantage member's contract permits otherwise.

Original Medicare will pay for many Clinical Trial related claims. Independent Health Medicare Advantage, however, pays for Clinical Trial related claims classified as Coverage with Evidence Development (CED)/ Investigational Device Exemption (IDE) Studies for Cat B/ Data Collections:

- Coverage with Evidence Development-In National Coverage Determinations (NCDs) requiring Coverage with Evidence Development (CED), original Medicare covers items and services in CMS-approved CED studies. Medicare Advantage Organizations are responsible for payment of items and services in CMS-approved CED studies.

Medicare Advantage members' cost share will be no greater than the cost share listed in the member's **Evidence of Coverage** (EOC).

- Investigational Device Exemption-Medicare Advantage Organizations are responsible for payment of routine care items and services in CMS-approved Category A and Category B IDE Investigational Device Exemption (IDE) Studies; however, the MAO is only responsible for payment of the CMS approved Category B devices. Institutional providers shall submit claims for the routine costs of a clinical trial involving a Category A IDE device billing to original Medicare since the Category A IDE device itself is considered experimental and, therefore is not eligible for payment.
- Data Collection System-Patients Enrolled in a CMS Qualifying Data Collection System registry. Providers shall use modifier Q0 to identify patients whose data is submitted to a data collection system.

MediSource and MediSource Connect:

Independent Health will cover routine patient costs for MediSource and MediSource Connect members enrolled in a clinical trial per the guidance below:

Per the CMS, Mandatory Medicaid Coverage of Routine Patient Costs Furnished in Connection with Participation in Qualifying Clinical Trials guidance effective immediately, the Medicaid Attestation Form on the Appropriateness of Qualified Clinical Trial, located at: https://www.medicaid.gov/resources-for-states/downloads/medicaid-attest-form.docx , must be submitted for each Medicaid member enrolled in a qualifying clinical trial for whom Medicaid reimbursement is requested, prior to providing treatment in the trial. For each trial participant who is enrolled in either NYS Medicaid fee-for-service (FFS) or Medicaid Managed Care (MMC), the form must be completed, in full, and must be:

1) signed by the clinical trial's Principal Investigator (PI);

2) signed by the member's Health Care Provider; and

3) submitted via the Secure File Transfer Application in the Health Commerce System to "Medicaid Clinical Trial."

Once a completed form is received, the NYS Department of Health will review the attestation and make a coverage determination within 72 hours of its electronic submission. Notification of the coverage determination will be sent electronically to the submitter within 72 hours.

Child Health Plus

Only certain clinical trials will be considered for Child Health Plus members if deemed appropriate by a physician that must be a licensed, board-certified or board eligible physician qualified to practice in the area appropriate to treat the member's life-threatening or disabling condition or disease. If an external appeal is filed by a member and the External Appeal Agent overturns Independent Health's decision that a service is not medically necessary or approves coverage of an experimental or investigational treatment, Independent Health will provide coverage subject to the other terms and conditions of this Child Health Plus Contract. Please note that if the External Appeal Agent approves coverage of an experimental or investigational treatment that is part of a clinical trial, Independent Health will only cover the costs of services required to provide treatment to you according to the design of the trial. Independent Health shall not be responsible for the costs of investigational drugs or devices, the costs of non-health care services, the costs of managing research, or costs which would not be covered under this Subscriber Contract for non-experimental or non-investigational treatments provided in such clinical trial.

Essential Plan:

Essential plan covers the routine patient costs for a member's participation in an approved clinical trial and such coverage shall not be subject to utilization review if the member is:

- Eligible to participate in an approved clinical trial to treat either cancer or other Life-threatening Disease or Condition; and

- Referred by a participating provider who has concluded that the member's participation in the approved clinical trial would be appropriate.

All other clinical trials, including when the member does not have cancer or other Life-threatening Disease or Condition, may be subject to the Utilization Review and External Appeal sections of this Contract.

Essential Plan does not cover:

- The costs of the investigational drugs or devices;
- The costs of non-health services required for the member to receive the treatment;
- The costs of managing the research; or
- Costs that would not be covered for non-investigational treatments provided in the clinical trial.

An "approved clinical trial" means a phase I, II III, or IV clinical trial that is:

- A federally funded or approved trial;
- Conducted under an investigational drug application reviewed by the federal Food and Drug Administration; or
- A drug trial that is exempt from having to make an investigational new drug application.

An evaluation of the peer-reviewed scientific literature, including but not limited to subscription materials, has provided Independent Health the basis for its medical necessity coverage outlined above.

Pre-Authorization Required? Yes ☐ No☐ Other☒

Self-funded products require pre-authorization.

Commercial, MediSource, MediSource Connect, Medicare Advantage, Child Health Plus, and Essential Plan members are not required to obtain pre-authorization in order to participate in a clinical trial.

Commercial members' and Essential Plan members' coverage for routine costs associated with participation in an approved clinical trial for treatment of cancer or another Life-threatening Disease are not subject to utilization management if such members are referred by a participating provider who has concluded that the member's participation in the approved clinical trial would be appropriate.

Definitions

Approved Clinical Trial (note – this definition only applies to Commercial members): means a phase I, phase II, phase III, or phase IV clinical trial that is :

1. Being conducted in relation to the prevention, detection or treatment for Cancer or other life-threatening disease or condition;
   Note: a "life-threatening disease or condition" is one from which the likelihood of death is probable unless the course of the disease or condition is interrupted.

2. Being conducted in relation to the detection or treatment of non-life threatening:
   o Cardiovascular disease (cardiac/stroke),

o Surgical musculoskeletal disorders of the spine, hip and knees; and/or
o Other Clinical Trials: Certain plans may allow Clinical Trials relating to other diseases or disorders which are not life-threatening.

3. The clinical trial must have a written protocol that describes a scientifically sound study that has been approved by all relevant institutional review boards (IRBs) before participants are enrolled in the trial. We may, at any time, request documentation about the trial.

4. Federally funded trial – The study or investigation is approved or funded by one or more of the following:

    - The National Institutes of Health
    - The Centers for Disease Control and Prevention
    - The Agency for Health Care Research and Quality
    - The Centers for Medicare & Medicaid Services
    - Cooperative group or center of any of the entities described in clauses (i)through (iv) or the Department of Defense or the Department of Veteran Affairs
    - A qualified non-governmental research entity identified in the guidelines issued by the National Institutes of Health for Center support grants
    - Any of the following if conditions described in paragraph (2) are met:
    - The Department of Veteran Affairs
    - The Department of Defense
    - The Department of Energy.

5. The study or investigation is conducted under an investigational new drug application reviewed by the U.S Food and Drug Administration.

6. The study or investigation is a drug trial that is exempt from having such an investigational new drug application.

Category B Devices as determined by the FDA, are non-experimental and/or investigational devices where the incremental risk is the primary risk in question (i.e., underlying questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA approval for that device type. (CFR, 1995)

Conditions for Departments – The condition described in this paragraph, for a study or investigation conducted by a department, are that the study or investigation has been reviewed and approved through a system peer review that the Secretary determines:

1. To be comparable to the system of peer reviewed studies and investigations used by the National Institutes of Health, and
2. Assures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review.

Evidence of Coverage is a document that describes in detail the health care benefits covered by the health plan.

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.

Qualified Individual means a person who is:

1. Covered under the plan, and
2. Eligible to participate in an approved clinical trial according to the trial protocol based upon:
    - The individual was referred to the approved clinical trial by an in-network health care professional who has concluded that the individual's participation would be appropriate because the individual is eligible for the trial according to its protocol, or
    - The individual provides the plan with medical and scientific information that establishes that participation would be appropriate because the individual is eligible for the trial according to its protocol.

Routine Patient Costs (applies to Commercial, Self-Funded, Medicare Advantage and State Products) include:

1. Items and/or services that would be provided if there were no clinical trial (e.g., conventional care such as hospital services, room and board, physician services, office visits, laboratory, and diagnostic tests);
2. Items and/or services required to administer the item or service being investigated (e.g., administration of a chemotherapy drug being tested);
3. Clinical monitoring of the effects of the item and/or service being investigated;
4. Items and/or services for the prevention of complications; and
5. Other reasonable and necessary items and/or services arising from the trial (e.g., the diagnosis or treatment of complications).

Routine costs do not include:

1. The investigational item or service, itself unless otherwise covered outside of the clinical trial

2. Items and services provided solely to satisfy data collection and analysis needs that are not used in the direct clinical management of the patient; and

3. Items and services customarily provided by the research sponsors free-of-charge for any enrollee in the trial

References

Related Policies, Processes and Other Documents

Experimental or Investigational Treatment Utilization Review Decisions, policy no. M20150623055

Provider Billing, Payment, and Reporting Rules and Requirements for Serious Reportable Adverse Events, Never Events, and Hospital-Acquired Conditions. Policy number M100301774

Non-Regulatory references

Independent Health 2017 Evidence of Coverage. Section F p. 27.

Independent Health 2017 Subscriber Contract-Essential Plan.

National Institutes of Health (NIH) [web page] NIH Clinical Research Trials and You. Reviewed October 3, 2022. Available at: http://www.nih.gov/health/clinicaltrials/basics.htm Accessed November 12, 2023

National Institutes of Health National Cancer Institute (NCI) [web site]. Cancer Clinical Trials. Updated September 6, 2019. Available at: https://www.cancer.gov/about-cancer/treatment/clinical-center Accessed November 12, 2023

Regulatory References

42 U.S.C. §300gg-8 (also referred to as Public Health Service Act §2709, as added by the Affordable Care Act).

Centers for Medicare and Medicaid (CMS) [web site]. National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1). Available at: https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=1&ncdver=2&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York+-+Entire+State&KeyWord=trial&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAABAAAAAAAA%3d%3d& Accessed November 12, 2023

Centers for Medicare and Medicaid (CMS) [web site]. Local Coverage Article (LCA) Clinical Trials – Medical Policy Article (A52840). Available at: https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=52840&ver=2&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York+-+Entire+State&KeyWord=trial&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAABAAAAAAAA%3d%3d& Accessed November 12, 2023

Centers for Medicare and Medicaid [web site]. Mandatory Medicaid Coverage of Routine Patient Costs Furnished in Connection with Participation in Qualifying Clinical Trials. SMD#21-005. April 13, 2022. Available at https://www.medicaid.gov/federal-policy-guidance/downloads/smd21005.pdf . Accessed November 12, 2023.

Medicaid Managed Care/Family Health Plus/HIV Special Needs Plan Model Contract, March 1, 2019, Appendix K, Section 36.

Medicare Managed Care Manual, Chapter 4, Section 10.2.2 and 10.7.

New York State Department of Health, Division of Managed Care Response to Coverage Question (CovQuest). December 2014.

New York State Medicaid Update [web site]; Volume 38; Number 8; July 2022: p. 8-9. Available at: https://www.health.ny.gov/health_care/medicaid/program/update/2022/docs/mu_no8_jul22_pr.pdf . Accessed November 12, 2023.

Patient Protection and Affordable Care Act, 42 U.S.C. § 10103(c) (2010)

This policy contains medical necessity criteria that apply for this service. Please note that payment for covered services is subject to eligibility criteria, contract exclusions and the limitations noted in the member's contract at the time the services are rendered.

Version Control

Signature / Approval on File? Yes ☒ No ☐

Revision Date	Owner	Notes
1/1/2024	Health Care Services	Revised
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8/1/2011	Medical Management	Revised
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01/01/2010	Medical Management	Revised
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