CLINICAL POLICY AND PROCEDURE MANUAL

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PA.078.CC Clinical Trials

Summary

A clinical trial is a research program conducted with patients to evaluate a new medical treatment, drug, or device. The purpose of clinical trials is to find new and improved methods of treating, preventing, screening for, and diagnosing different diseases and are often used to learn if a new treatment is more effective and/or has less harmful side effects than the standard treatment.

Clinical trials are carefully designed, reviewed and completed, and need to be approved before they can start. People of all ages can take part in clinical trials.

Clinical Criteria

County Care considers routine care costs of members in **Clinical Trials** medically necessary for the following indications:

- The member is a participant in a qualifying clinical trial
- Documentation of 8-digit clinical trial number on items or services provided in clinical trial (Clinical trials that are also an Investigational Device Exemptions (IDE) must document associated IDE number).
- Items, medications or services for which coverage is requested are typically provided to members who are not part of a clinical trial.
- Treatment with the items or services is included in medical record documentation of the provider(s).

Clinical trials also should have the following desirable characteristic:

1. The principal purpose of the trial is to test whether the intervention potentially improves the participants' health outcomes;
2. The trial is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use;
3. The trial does not unjustifiably duplicate existing studies;
4. The trial design is appropriate to answer the research question being asked in the trial;

5. The trial is sponsored by a credible organization or individual capable of executing the proposed trial successfully;
6. The trial is in compliance with Federal regulations relating to the protection of human subjects; and
7. All aspects of the trial are conducted according to the appropriate standards of scientific integrity.

Limitations

Coverage will not include any of the following:

1. The investigational item and/or associated services (including medications) that are rendered in connection with the clinical trial.
2. Items and services provided solely to satisfy data collection and analysis needs and that are not used in a direct clinical management of a patient (e.g., monthly CT scans for a condition usually requiring only a single scan).
3. Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial.
4. Services that are not health care services (e.g., administrative services).
5. Services not routinely provided for the direct clinical management of the patient. The services must not be designed exclusively to test toxicity or disease pathophysiology. It must have therapeutic benefit.
6. Laboratory services and imaging surveillance ordered for the sole purpose of gauging what effect the clinical trial drug is having on the patient's condition.
7. Coverage of routine care costs for members participating in clinical trials at out-of-network facilities is governed by the benefit design of the member's plan.

References

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Routine Costs in a Clinical Trial. Revised: May 16, 2018. https://wayback.archive-it.org/2744/20111021192401/https://www.cms.gov/MLNMattersArticles/downloads/SE0822.pdf

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6. United States of America. Federal Government: Public Law 111-152. Health Care and Education Reconciliation. Enacted: March 30, 2010. http://www.gpo.gov/fdsys/pkg/PLAW-111publ152/pdf/PLAW-111publ152.pdf
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Revision History

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Policy Adopted	03/01/2023
Annual Review, formatting updates	09/14/2023

Disclaimer

CountyCare medical payment and prior authorization policies do not constitute medical advice and are not intended to govern or otherwise influence the practice of medicine. The policies constitute only the reimbursement and coverage guidelines of CountyCare and its affiliated managed care entities. Coverage for services varies for individual members in accordance with the terms and conditions of applicable Certificates of Coverage, Summary Plan Descriptions, or contracts with governing regulatory agencies.

CountyCare reserves the right to review and update the medical payment and prior authorization guidelines in its sole discretion. Notice of such changes, if necessary, shall be provided in accordance with the terms and conditions of provider agreements and any applicable laws or regulations.