PriorityHealth

MEDICAL POLICY
No. 91606-R4

CLINICAL TRIALS

Effective Date: December 21, 2015	**Review Dates: 12/13, 11/14, 11/15, 11/16, 11/17, 11/18, 2/19**
Date Of Origin: December 11, 2013	**Status: Current**

Note: This policy applies to the Individual Market, fully funded commercial groups and non-grandfathered self-funded groups (verify clinical trial coverage with the individual plan document for self-funded products). For grandfathered self-funded groups that may opt out of PPACA expanded clinical trials coverage, please refer to the *Clinical Trials for Cancer Care Medical Policy #91448*. Please refer to CMS guidelines and Appendix B for Priority Health Medicare coverage.

Summary of Changes

Deletion:

- Pg. 2, Section I. 4.A: Removed advanced care planning assessment requirement for members with Stage IV cancer or other life threatening conditions.
- Pg. 3, Section I. 5: Removed prior authorization requirement for in-network services for commercial plans.
- Removed Appendix A: Advanced Care Planning Assessment, renamed Appendix B: Clinical Trials Coverage Reference Sheet as Appendix A.

I. POLICY/CRITERIA

Coverage for routine patient care costs in a clinical trial may be a covered benefit as defined in the Patient Protection and Affordable Care Act (PPACA) when **all** of the following are met:

1. Member is eligible to participate in an approved clinical trial (see #3 below) according to the trial protocol for treatment of:
    a. Cancer, or
    b. Other life-threatening disease/condition defined as: a terminal illness, or a chronic, life threatening, severely disabling disease that is causing serious clinical deterioration.

2. One of the following:

    A. The referring health care professional is a participating health care provider and has concluded that participation in a trial would be appropriate based upon the conditions described in Section I. 1; **or**

    B. The member or the referring healthcare provider provides medical and scientific information establishing that participation in such trial would be appropriate based on the conditions described in Section I.1.

3. An "approved clinical trial" means a phase I, phase II, phase III, or phase IV clinical trial that is conducted in relation to the prevention, detection, or treatment of cancer or other life-threatening disease or condition and meets one of the following (A or B or C):

   A. Federally funded trials. The study or investigation is approved or funded (which may include funding through in-kind contributions) by one or more of the following:

      i. The National Institutes of Health.

      ii. The Centers for Disease Control and Prevention.

      iii. The Agency for Health Care Research and Quality.

      iv. 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 Veterans Affairs.

      v. A qualified non-governmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants.

      vi. Any of the following if the conditions described in Section I. 2 are met:

         (a) The Department of Veterans Affairs.

         (b) The Department of Defense.

         (c) The Department of Energy.

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

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

4. Additional coverage requirements include:

   A. Copies of pertinent documentation, including the trial protocol and the member's signed informed consent agreement, must be submitted to Priority Health to support the member's request for coverage.

   B. If services can be provided in plan (e.g. labs and imaging studies), then the Plan will pay for those services in-plan only.

C. The Plan will only reimburse for service provided through clinical trials at the fee schedule paid to participating providers. The member may have additional expenses if the physicians and facility providing the services balance bill the member.

D. Depending on the type of clinical trial that a member may be enrolled in, the potential for case management services should be evaluated. Case or payment rates should be negotiated, and out of network payment agreements should be executed for care that is not contracted by the Plan.

E. Out of network services are not covered, unless approved in advance by the health plan.

5. If criteria 1-4 are met, the following coverage applies:

A. **Covered Services**

i. Priority Health will cover the routine patient cost associated with an approved clinical trial and will include all items and services consistent with the coverage provided in the plan (or coverage) that is typically covered for a member who is not enrolled in a clinical trial.

B. **Non-Covered Services**

The following are not covered in connection with an approved clinical trial:

i. The investigational item, device, or service, itself;

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

iii. A service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis.

Note: A Clinical Trials Coverage Reference Sheet (Appendix A) can be found at the end of this policy and reflects coverage for all products.

II. MEDICAL NECESSITY REVIEW

☒ Prior Authorization Required*
☒ Prior Notification Required **
☐ Not Required
☐ Not Applicable

*****Prior Authorization is required for out-of-network services and Medicaid/Healthy Michigan Plan/MICHILD. Fax form available on https://www.priorityhealth.com/provider/manual/auths
****** Prior Notification required for clinical trial services provided by in-network providers via Clear Coverage. **Medicare plans do not require prior authorization.**

Coverage for Self-funded Members — this policy does not apply to most ASO/Self-funded plans. Verify clinical trial coverage with the individual plan document.

III. APPLICATION TO PRODUCTS

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

- **HMO/EPO:** ***This policy applies to insured HMO/EPO plans.***
- **POS:** ***This policy applies to insured POS plans.***
- **PPO:** ***This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.***
- **ASO:** ***For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.***
- **INDIVIDUAL:** ***For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.***
- **MEDICARE:** ***Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, this policy applies.***
- **MEDICAID/HEALTHY MICHIGAN PLAN/MICHILD:** ***For Medicaid/Healthy Michigan Plan/MIChild members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html, the Michigan Medicaid Provider Manual will govern. If there is a discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.***

IV. DESCRIPTION

Clinical trials are conducted in phases. The trials at each phase have a different purpose and help scientists answer different questions:

1. In Phase I trials, researchers test a new drug or treatment in a small group of people (20-80) for the first time to evaluate its safety, determine a safe dosage range, and identify side effects.

2. In Phase II trials, the study drug or treatment is given to a larger group of people (100-300) to see if it is effective and to further evaluate its safety.

3. In Phase III trials, the study drug or treatment is given to large groups of people (1,000-3,000) to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the drug or treatment to be used safely.

4. In Phase IV trials, post marketing studies delineate additional information including the drug's risks, benefits, and optimal use.

V. CODING INFORMATION

ICD-10 Codes:

Z00.6 Encounter for examination for normal comparison and control in clinical research program

Modifiers

Report the appropriate modifier for services reported as part of a clinical trial and include the 8 digit national clinical trial number (NCT.) Do not append modifiers to service lines that are unrelated to the clinical trial protocol.

Q0 Investigational clinical service provided in a clinical research study that is in an approved clinical research study

Q1 Routine clinical service provided in a clinical research study that is in an approved clinical research study

CPT/HCPCS/Revenue Codes:

Reportable, no charge, no payment.

0624 FDA investigational devices

0256 Experimental drugs

Explanatory notes must accompany claims billed with unlisted codes.

Not covered:

G0293 Noncovered surgical procedure(s) using conscious sedation, regional, general, or spinal anesthesia in a Medicare qualifying clinical trial, per day

G0294 Noncovered procedure(s) using either no anesthesia or local anesthesia only, in a Medicare qualifying clinical trial, per day

S9988 Services provided as part of a Phase 1 clinical trial

S9989 Services provided outside of the United States of America (list in addition to code(s) for services(s))

S9990 Services provided as part of a Phase II clinical trial

S9991 Services provided as part of a Phase III clinical trial
S9992 Transportation costs to and from trial location and local transportation costs (e.g., fares for taxicab or bus) for clinical trial participant and one caregiver/companion
S9994 Lodging costs (e.g., hotel charges) for clinical trial participant and one caregiver/companion
S9996 Meals for clinical trial participant and one caregiver/companion

APPENDIX A
CLINICAL TRIALS COVERAGE REFERENCE SHEET***

	Commercial Fully-funded	**Commercial Self-funded**	**Medicare**
Clinical Trials	Routine services* only, use *Clinical Trials Policy #91606*	Non-grandfathered groups: routine services only, use *Clinical Trials Policy #91606* Grandfathered groups opting out of PPACA: use *Clinical Trials for Cancer Policy #91448*	Original Medicare covers routine services for those trials that are Medicare approved. *Submit Medicare EOB with claim for payment of member cost share from PH plan.* If trial is not Medicare approved, there is no coverage under Original Medicare or Priority Health Medicare
IDE (Investigational Device Exemption)Trial: Category A Device	Never covered. Device and all services, including routine services, are not covered Use *Experimental & Investigational Policy #91117.* *Report on claim with $0 or $.01 as charge amount on claim line for device.*	Never covered. Device and all services, including routine services, are not covered. Use *Experimental & Investigational Policy #91117.* *Report on claim with $0 or $.01 as charge amount on claim line.*	Device is never covered. Routine care items and services in CMS-approved Category A IDE studies are covered by Priority Health Medicare. *Report on claim with $0 or $.01 as charge amount on claim line.*
IDE Trial: Category B Device	Routine services only; device not covered. ** Use *Experimental & Investigational Policy #91117.* *Report device on claim with $0 or $.01 as charge amount on claim line for device.*	Device and all services, including routine services, are not covered. ** Use *Experimental & Investigational Policy #91117. Submit claims with $0 or $.01 as charge amount on claim lines related to the trial services.*	All services, including the device, are covered by Priority Health Medicare
Clinical Studies Approved Under	Use *Experimental & Investigational Policy*	Use *Experimental & Investigational Policy*	All care and services are covered by Priority Health

Evidence Development (CED)	*#91117* or other specific medical policy to determine coverage.	*#91117, or other specific medical policy*, and/or individual plan documents to determine coverage.	Medicare per related NCD/LCD.

*Routine patient care costs are items or services that are typically covered benefits when provided outside a clinical trial. The clinical trial protocol may be needed to determine the specific services that are covered and excluded.

** Priority Health may, at its discretion, choose to cover the experimental device if the cost of that device is less than the non-experimental arm of the trial.

***For Medicaid/Healthy Michigan refer to section III "Application to Products"

AMA CPT Copyright Statement:
All Current Procedure Terminology (CPT) codes, descriptions, and other data are copyrighted by the American Medical Association.

This document is for informational purposes only. It is not an authorization, certification, explanation of benefits, or contract. Receipt of benefits is subject to satisfaction of all terms and conditions of coverage. Eligibility and benefit coverage are determined in accordance with the terms of the member's plan in effect as of the date services are rendered. Priority Health's medical policies are developed with the assistance of medical professionals and are based upon a review of published and unpublished information including, but not limited to, current medical literature, guidelines published by public health and health research agencies, and community medical practices in the treatment and diagnosis of disease. Because medical practice, information, and technology are constantly changing, Priority Health reserves the right to review and update its medical policies at its discretion.

Priority Health's medical policies are intended to serve as a resource to the plan. They are not intended to limit the plan's ability to interpret plan language as deemed appropriate. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment they choose to provide.

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