



EFFECTIVE DATE: 11 | 15 | 2016
POLICY LAST UPDATED: 08 | 21 | 2018

OVERVIEW

This documents the coverage and payment guidelines for BlueCHIP for Medicare members participating in approved clinical trials.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

BlueCHIP for Medicare

Blue Cross & Blue Shield of Rhode Island (BCBSRI) follows the Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations (NCD) and coverage guidelines for clinical trials. Refer to the reference section for Medicare coverage and billing guidelines for clinical trials. See the related BCBSRI policy for BlueCHIP for Medicare National and Local Coverage Determinations.

Original Medicare (also referred to as Medicare “fee for service”) covers most of the routine costs for BlueCHIP for Medicare members participating in qualified Medicare clinical trials. Qualified Medicare clinical trials are found at www.clinicaltrials.gov.

For clinical trial related claims that are not the responsibility of the Medicare Advantage plans according to CMS instructions, submit first to Original Medicare, and then submit the claim to BCBSRI with the Medicare Explanation of Member Benefits. BCBSRI is responsible for the difference in the member cost sharing for Original Medicare and the member’s Medicare Advantage cost sharing. If the Medicare Advantage cost share is higher than Original Medicare, then BCBSRI will not make a payment.

It is the responsibility of the billing provider to validate when claims are submitted to BCBSRI for BlueCHIP for Medicare members versus Original Medicare. Refer to the instructions found on the CMS website for correct claims submissions:

Medicare Coverage Related to Investigational Device Exemption (IDE) Studies

Category A and B IDE study review requests, along with the list of CMS-approved studies is available on the CMS Coverage Website found here: [Medicare Coverage IDE](#).

Clinical Trials with Coverage of Evidence Development (CED):

CMS Coverage Website found here:

[Medicare Coverage with Evidence Development](#)

The member’s medical records must document that services are medically necessary and all CMS requirements are met. Blue Cross Blue Shield of Rhode Island maintains the right to audit the services provided to our members, regardless of the participation status of the provider. All documentation must be available to BCBSRI upon request. Failure to produce the requested information may result in denial or retraction of payment.

Please refer to the member's BlueCHiP for Medicare Evidence of Coverage (EOC) for specific language regarding clinical trials or research studies.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage for coverage of clinical research studies.

BACKGROUND

Clinical trials (or clinical research studies) are scientific investigations of treatment alternatives designed to help compare the safety and efficacy of new, untested, or non-standard treatments to standard currently accepted treatments. Clinical trials are intended to improve clinicians' knowledge about a treatment and to improve clinical outcomes for future members. Improvement of health outcomes for members enrolled in clinical trials is a desirable but secondary consideration.

According to the Medicare National Coverage Determination 310.1, Medicare covers the routine costs of qualifying clinical trials, as such costs are defined below, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. All other Medicare rules apply.

Routine costs of a clinical trial include all items and services that are otherwise generally available to Medicare beneficiaries (i.e., there exists a benefit category, it is not statutorily excluded, and there is not a national non-coverage decision) that are provided in either the experimental or the control arms of a clinical trial except:

- The investigational item or service, itself unless otherwise covered outside of the clinical trial;
- Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan); and
- Items and services customarily provided by the research sponsors free-of-charge for any enrollee in the trial.

Routine costs in clinical trials include:

- Items or services that are typically provided absent a clinical trial (e.g., conventional care);
- Items or services required solely for the provision of the investigational item or service (e.g., administration of a noncovered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and
- 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.

CODING

BlueCHiP for Medicare

The following modifiers are used for clinical trial services:

- Q0** Investigational clinical service provided in a clinical research study that is in an approved clinical study
- Q1** Routine clinical service provided in a clinical research study that is in an approved clinical research study

To ensure correct claims processing, report the following:

- ICD-10 diagnosis code:
Z00.6 Encounter for examination for normal comparison and control in clinical research program
- The 8 digit National Clinical Trial (NCT) Identifier Number

RELATED POLICIES

BlueCHiP for Medicare National and Local Coverage Determinations
Autologous Platelet-Derived Growth Factors

Image-Guided Minimally Invasive Lumbar Decompression IG-MLD for Spinal Stenosis
Islet Cell Transplant
Transcatheter Mitral Valve Repair

PUBLISHED

Provider Update, November 2018

Provider Update, February 2018

Provider Update, January 2017

REFERENCES

1. CMS.gov Centers for Medicare and Medicaid Services National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1) Accessed Nov 2016 <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=1&ncdver=2&bc=BAABAAAAAAAA>
2. CMS.gov Centers for Medicare and Medicaid Services Coverage with Evidence Development: <https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/>
3. CMS.gov Centers for Medicare and Medicaid Services Medicare Coverage Related to Investigational Device Exemption (IDE) Studies <https://www.cms.gov/Medicare/Coverage/IDE/index.html>
4. Medicare Managed Care Manual Chapter 4 - Benefits and Beneficiary Protections 10.7 – Clinical Trials Accessed Oct 2017 <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c04.pdf>
5. Medicare Benefit Policy Manual Chapter 14 - Medical Devices Accessed Oct 2017 <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c14.pdf>
6. DEPARTMENT OF HEALTH AND HUMAN SERVICES Centers for Medicare & Medicaid Services MLN Matters® Number: MM8401 Mandatory Reporting of an 8-Digit Clinical Trial Number on Claims <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM8401.pdf>

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