



EFFECTIVE DATE: 11 | 15 | 2016
POLICY LAST UPDATED: 12 | 05 | 2017

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 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.

All claims for services as part of a clinical trial must be submitted to Original Medicare first. 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.

The “Physician/Provider Special Handling Claim Request Form” attached here details the current billing process for clinical trial services for BlueCHiP for Medicare members:



Special Handling
Form for Clinical Trials

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

Note: If you are treating a BlueCHiP for Medicare member as part of a CMS-approved study, Original Medicare is to be billed first for the Clinical Trial Services. After Medicare has paid on the claim then you may file with the Medicare Advantage plan for the difference in payment that would have been received if the member was not taking part in a CMS-approved study.

Please refer to the special claims handling process detailed in the “Physician/Provider Special Handling Claim Request Form” for the current billing process for BlueCHiP for Medicare members only. The Special Handling process requires these attachments:

- Paper UB 04 or CMS 1500 Claim Form with applicable Clinical Trial Modifier
- Original Medicare Explanation of Benefits (EOB) (Note: Claims submitted without the Medicare EOB will be denied to submit to Medicare primary first)
- CMS Clinical Trial Identification Number



Special Handling
Form for Clinical Trials

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 as the primary diagnosis:
Z00.6 Encounter for examination for normal comparison and control in clinical research program

RELATED POLICIES

BlueCHiP for Medicare National and Local Coverage Determinations

PUBLISHED

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?NCID=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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