



EFFECTIVE DATE: 11 | 15 | 2016
POLICY LAST UPDATED: 02 | 17 | 2021

OVERVIEW

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

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

Medicare Advantage Plans

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 Medicare Advantage Plans National and Local Coverage Determinations.

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

Clinical Trials that qualify for coverage under the Clinical Trials Policy (CTP):

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. Claims should first be submitted with the Medicare contractor that processes fee-for-service claims, and then submit the claim to BCBSRI with the Medicare Explanation of Member Benefits.

Investigational device exemption (IDE) studies:

Category A IDE studies - BCBSRI reimburses coverage of routine services only related to Category A IDE studies.

Category B IDE studies - BCBSRI covers devices and services related to Category B IDE studies, unless the Category B device is paid for by the trial sponsor. Category B investigational devices must be used in the context of an FDA-approved trial.

Approved IDE studies are posted on the CMS IDE webpage: [Medicare Coverage IDE Studies](#)

Clinical Trials approved under Coverage with Evidence Development (CED):

For National Coverage Determinations (NCD’s) requiring CED, BCBSRI will reimburse items and services in CMS-approved CED studies unless CMS determines that the significant cost threshold is exceeded for that item or service.

Approved CED studies are posted on the CMS CED webpage:

[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 Medicare Advantage Plan Evidence of Coverage (EOC) for specific language regarding clinical trials or research studies.

Type of Clinical Trial	Where to Submit Claims
IDE (Category A and Category B)	BCBSRI
Clinical Trials that Qualify for Coverage Under a Specific NCD	BCBSRI unless CMS determines that the significant cost threshold is exceeded.
Clinical Trials that Qualify for Coverage under the Clinical Trial Policy (CTP)	Fee-for-Service MAC

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.

Billing Requirements:

Investigational Device Exemption (IDE) Studies:

A. Institutional Inpatient and Outpatient Billing in Category A IDE Studies

Routine Care Items and Services

Institutional providers shall submit claims only for routine care items and services in Category A IDE studies approved by CMS (or its designated entity) and listed on the CMS coverage website, by billing according to the clinical trial billing instructions found at 69.6, Chapter 32 of the Medicare Claims Processing Manual. *The category A IDE device are not eligible for payment under Medicare.*

B. Institutional Inpatient Billing in Category B IDE studies

Routine Care Items and Services

Institutional providers shall submit claims for the routine care items and services in Category B IDE studies approved by CMS (or its designated entity) and listed on the CMS coverage website, by billing according to the clinical trial billing instructions found at 69.6, Chapter 32 of the Medicare Claims Processing Manual.

Category B Device

Institutional providers must bill the Category B IDE number on a 0624 revenue code line with charges in the covered charges field. Hospital inpatient providers should not bill for the Category B IDE device if receiving the device free-of-charge.

C. Institutional Outpatient Billing for Items and Services in Category B IDE studies

Routine Care Items and Services

Institutional providers shall submit claims for the routine care items and services in Category B IDE studies approved by CMS (or its designated entity) and listed on the CMS coverage website, by billing according to the clinical trial billing instructions found at 69.6, Chapter 32 of the Medicare Claims Processing Manual. *The category A IDE device are not eligible for payment under Medicare.*

Category B Device

On a 0624 revenue code line, institutional providers must bill the following for Category B IDE devices for which they incur a cost:

- Category B IDE device HCPCS code, if applicable
- Appropriate HCPCS Modifier, Q0 or Q1
- Category B IDE number
- Charges for the device billed as covered charges

NOTE: If the category B IDE device is provided at no cost, providers must report a token charge of .01 in the covered charge field along with the applicable HCPCS modifier (i.e., modifier – FB) appended to the procedure code.

D. Practitioner Billing in Category A IDE Studies

Routine Care Items and Services

Practitioners shall submit claims only for routine care items and services in Category A IDE studies approved by CMS (or its designated entity) and listed on the CMS coverage website, by billing according to the clinical trial billing instructions found at 69.6, Chapter 32 of the Medicare Claims Processing Manual. *The category A IDE device shall not be reported on practitioner claims since Category A IDE devices are not eligible for payment under Medicare.*

E. Practitioner Billing in Category B IDE Studies

Routine Care Items and Services

Practitioners shall submit claims only for routine care items and services in Category B IDE studies approved by CMS (or its designated entity) and listed on the CMS coverage website, by billing according to the clinical trial billing instructions found at 69.6, Chapter 32 of the Medicare Claims Processing Manual.

CLINICAL TRIALS (Approved under Coverage with Evidence Development CED):

Effective January 1, 2014 CMS mandated the reporting of a clinical trial number on claims for items/services provided in clinical trials/studies/registries, or under CED.

A. Practitioners/Suppliers

- CMS-1500 paper form – place in Field 19 (preceded by ‘CT’); OR
- 837 P – Loop 2300, REF02, REF01=P4 (do not use ‘CT’ on the electronic claim)

In addition to the clinical trial number, claims shall include:

- ICD-10 diagnosis code Z00.6 (in either the primary/secondary positions)
- HCPCS modifier Q0 or Q1 as appropriate:
 - 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

B. Institutional Providers

- CMS-1450 paper form value code ‘D4’
- 837 INSTITUTIONAL CLAIM FORMAT-Loop 2300 REF02 (REF01=P4)

In addition to the clinical trial number, claims shall include:

- ICD-10 diagnosis code Z00.6 (in either the primary/secondary positions)
- Inpatient claims must contain condition code 30 (regardless of whether all services are related to the clinical trial or not).

HCPCS modifier Q0 or Q1 as appropriate (Outpatient claims only):

- 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.

CODING

See billing requirements above for details.

Note: claims filed without the required documentation will be returned to the provider for missing information.

RELATED POLICIES

Medicare Advantage Plans 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, April 2021
Provider Update, November 2020
Provider Update, August 2019
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)
<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
<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c04.pdf>
5. Medicare Benefit Policy Manual Chapter 14 - Medical Devices <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>
7. Medicare Claims Processing Manual Chapter 32 – Billing Requirements for Special Services
<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c32.pdf>
8. Medicare National Coverage Determinations Manual Chapter 1, Part 1 (Sections 10 – 80.12) Coverage Determinations
https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/ncd103c1_Part1.pdf

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