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Reimbursement Policy

Clinical Trials

Policy Number: SCO 4.134
Version Number: 3
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Product Applicability	☐ **All Plan⁺ Products**
Well Sense Health Plan ☐ Well Sense Health Plan	**Boston Medical Center HealthNet Plan** ☐ MassHealth MCO ☐ MassHealth ACO ☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct ☒ Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Policy Summary

The Plan reimburses covered services based on the provider's contractual rates with the Plan and the terms of reimbursement identified within this policy.

Prior-Authorization

Please refer to the Plan's Prior Authorization Requirements Matrix at www.bmchp.org.

⁺ *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

Definitions

Category A Device – an experimental device for which absolute risk of the device type has not been established (that is, initial questions regarding safety and effectiveness have not been resolved) and the FDA is unsure whether the device type can be safe and effective.

Category B Device – a non-experimental/investigational device for which the incremental risk is the primary risk in question (that is, initial questions of safety and effectiveness of that device have been resolved) or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA pre-market approval or clearance for that device type.

Provider Reimbursement

The Plan may reimburse providers for items and services in clinical research studies under (1) Investigation Device Exemption and (2) Coverage with Evidence Development policies. Both policies require the submission of ICD-10 Z00.6 in the primary or secondary position as well as a Q0 or Q1 as appropriate.

As described in The National Coverage Determinations (NCD) for Routine Costs in Clinical Trials (310.1), routine care items and services refers to items and services that are otherwise generally available to Medicare beneficiaries (that is, a benefit category exists, it is not statutorily excluded, and there is not a national non-coverage decision) that are furnished during a clinical study and that would be otherwise furnished even if the beneficiary were not enrolled in a clinical study.

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.

Investigational Device Exemption (IDE) Policy

The Plan reimburses routine costs in CMS-approved Category A IDE studies. The Plan reimburses routine costs, as well as the Category B device under study in CMS-approved Category B IDE studies.

A listing of all CMS-approved Category A IDE studies and Category B IDE studies can be found on the CMS Medicare Coverage Center, Medicare Coverage Related to Investigational Device Exemption (IDE) Studies, Approved IDE Studies webpage.

Category A IDE Studies

Category A IDE devices are considered experimental and are not eligible for reimbursement to any provider; Routine costs of clinical trials involving a Category A IDE device are reimbursed when it is determined that the device is used in the trial for the diagnosis, monitoring, or treatment of an

immediately life-threatening disease or condition. The Category A IDE device shall not be reported on institutional claims since Category A IDE devices are not eligible for payment under Medicare.

Category B IDE Studies
Category B devices are newer generations of proven technologies that have had questions about its safety and effectiveness resolved, and may be reimbursed. If the device is billed under a Category B IDE study, and it meets the billing requirements for IDEs, the device itself and the routine costs associated with its use are eligible for reimbursement.

A listing of all CMS-approved Category A IDE studies and Category B IDE studies will be posted on the CMS Coverage webpage site.

Coverage with Evidence Development (CED)
The Plan may also reimburse for items and services in certain CMS approved Coverage with Evidence Development (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 Medicare Coverage Center, Coverage with Evidence Development webpage.

All other clinical trials are reimbursed by Original Medicare.

Service Limitations

The following Plan reimbursement rules apply:

- Payment for a Category B device may not exceed the Medicare-approved amount for a comparable device that has been already FDA-approved.
- Payment is not made for medical and hospital services that are related to the use of a device that is not covered under Medicare. These non-covered services include all services furnished in preparation for the use of a non-covered device, services furnished contemporaneously with, and necessary to the use of, a non-covered device, and services furnished as necessary after-care that are incident to recovery from the use of the device or from receiving related non-covered services.
- Routine costs in a clinical trial do not include:
  - 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.

Applicable Coding and Billing Guidelines

Applicable coding is listed below, subject to codes being active on the date of service. Because the American Medical Association (AMA), Centers for Medicare & Medicaid Services (CMS), and the U.S.

Department of Health and Human Services may update codes more frequently or at different intervals than Plan policy updates, the list of applicable codes may not be all inclusive. These codes are not intended to be used for coverage determinations.

Split Claim Billing

All related services must be reported on one claim. Subsequent related claims received after the initial claim will be denied. The initial claim must be resubmitted as a replacement claim.

Mandatory Reporting of National Clinical Trial and Investigational Device Exemption Numbers

In accordance with CMS guidelines providers must report the 8 digit clinical trial number on claims for items/services provided in clinical trials/studies/registries or under Coverage with Evidence Development (CED). Provider must also report the 7 digit Investigational Device Exemption (IDE) number for Category B devices.

Providers should follow CMS guidelines for billing clinical trials. The table below provides paper and electronic reporting requirements:

NCT/IDE	**Professional**		**Institutional**	
Reporting	**Paper**	**Electronic**	**Paper**	**Electronic**
National Clinical Trial (NCT) 8-digit Number	CMS-1500: Item 19 (preceded by "CT")	837P: Loop 2300 REF02 (REF01=P4)	CMS-1450: FLs 39-41 (Value Code=D4)	837I: Loop 2300 REF02 (REF01=P4)
Investigational Device Exemption (IDE) 7-digit Number	CMS-1500: Item 23	837P: Loop 2300 REF02 (REF01=LX)	CMS-1450: FL 43 with Revenue code 0624 (FL 42) *(Category B IDE Only)* CMS-1500-Item 23	837I: Loop 2300 REF02 (REF01=LX)

Additional Claim Submission Requirements

All Inpatient and Outpatient Institutional clinical trial claims must report condition code 30 regardless of whether all services are related to the clinical trial or not.

In accordance with CMS guidelines providers must include appropriate diagnosis coding and modifiers, as applicable and listed in the table below:

ICD-10 Code	**Description**	**Instructions**
Z00.6	Encounter for examination for normal comparison and control in clinical research program	Include as Primary or Secondary Diagnosis on all Institutional and Professional clinical trial claims

Modifier	Description	Instructions
Q0	Investigational clinical service provided in a clinical research study that is in an approved clinical research study.	Include on all lines as applicable on Outpatient and Professional claims in the first position
Q1	Routine clinical service provided in a clinical research study that is in an approved clinical research study.	Include on all lines, as applicable, on Outpatient claims in the first position
Condition Code	**Description**	**Instructions**
30	Qualified Clinical Trial	All Inpatient and Outpatient Institutional clinical trial claims must report condition code 30 regardless of whether all services are related to the clinical trial or not

Additional Category B Device Coding Requirements

Institutional providers billing on Inpatient and Outpatient claims for Category B devices must bill with the following requirements:

Institutional Inpatient Claims:

- If the Institution has incurred a charge for the Category B device, providers must bill the Category B IDE number on a 0624 revenue code line with charges in the covered charges field.
- If the Institution has incurred no charge for the Category B IDE device, providers should not bill for the Category B IDE device they have received free-of-charge.

Institutional Outpatient Claims:

- If the Institution has incurred a charge for the Category B IDE device, providers must bill the Category B IDE number on a 0624 revenue code line with charges in the covered charges field, as well as any Category B IDE device HCPCS code and Q0 modifier.
- If the Institution has incurred no charge for the Category B IDE device, providers must report on their Outpatient claim a token charge in the covered field of either $0.00 or $0.01 along with Value code "FD" and one of the appropriate following condition codes:
  - 49 - Replacement of a product earlier than the anticipated lifecycle
  - 50 - Product Replacement for Known Recall of a Product
  - 53 - Initial placement of a medical device provided as part of a clinical trial or free sample

Policy History

Original Approval Date	Original Effective Date	Policy Owner	Approved by
10/7/2015	01/01/2016	Payment Policy	SCO Product Subgroup

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
04/11/2019	Annual Review, New template, now applicability box	07/01/2019	Payment Policy Committee
06/15/2021	Annual Review, No changes	07/01/2021	Payment Policy Committee

Other Applicable Policies

Reimbursement Policies

- General Billing and Coding Guidelines, SCO 4.31
- General Clinical Editing and Payment Accuracy Review Guidelines, SCO 4.108
- Physician and Non Physician Practitioner Services, SCO 4.608

References

- Medicare Benefit Policy Manual Chapter 14 Section 20 and Chapter 16
- Medicare Claims Processing Manual, Chapter 32, Sections 68 and 69
- Medicare Managed Care Manual Chapter 4 - Benefits and Beneficiary Protections
- Medicare National Coverage Determination Manual for Routine Costs in Clinical Trials, Chapter 1, Part 4, Section 310.1
- 42 Code of Federal Regulations (CFR) Subpart B- Medical Services Coverage Decisions That Relate to Health Care Technology
- Pub 100-04 Medicare Claims Processing Transmittal 2955
- National institutes of Health's (NIH) National Library of Medicine (NLM) Clinical Trials registry
- MM8921 – Medicare Coverage of Items and Services in Category A and B Investigational Device Exemption (IDE) Studies
- MM8401 - Mandatory Reporting of an 8-Digit Clinical Trial Number on Claims
- CMS Mandatory Reporting of National Clinical Trial (NCT) Identifier Numbers on Medicare Claims – Q&As
- U.S. Food & Drug Administration (FDA) Drug Approval and Databases
- U.S. Food & Drug Administration (FDA) Device Advice: Medical Device Databases
- Medicare Approved Facilities/Trials/Registries

Disclaimer Information

This Policy provides information about the Plan's reimbursement/claims adjudication processing guidelines. The use of this Policy is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement. Member cost-sharing (deductibles, coinsurance and copayments) may apply – depending on the member's benefit plan. Unless otherwise specified in writing, reimbursement will be made at the lesser of billed charges or the contractual rate of payment. Plan policies may be amended from time to time, at Plan's discretion. Plan policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization guidelines (including NCQA). The Plan reserves the right to conduct Provider audits to ensure compliance with this Policy. If an audit determines that the Provider did not comply with this Policy, the Plan will expect the Provider to refund all payments related to non-compliance. For more information about the Plan's audit policies, refer to the Provider Manual.