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Reimbursement Policy

Clinical Trials

Policy Number: 4.134
Version Number: 8
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Product Applicability	☐ **All Plan⁺ Products**
Well Sense Health Plan	**Boston Medical Center HealthNet Plan**
☐ Well Sense Health 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

Routine Patient Care Services – health care item or service that is furnished to an individual enrolled in a qualified clinical trial, which is consistent with the usual and customary standard of care for someone with the member's diagnosis, is consistent with the study protocol for the clinical trial, and would be covered if the member did not participate in the clinical trial.

Qualified Clinical Trial – a clinical trial that meets all of the following conditions:

- The clinical trial is intended to treat cancer in a patient who has been so diagnosed.
- The clinical trial has been peer reviewed and is approved by 1 of the United States National Institutes of Health, a cooperative group or center of the National Institutes of Health, a qualified nongovernmental research entity identified in guidelines issued by the National Institutes of Health for center support grants, the United States Food and Drug Administration pursuant to an investigational new drug exemption, the United States Departments of Defense or Veterans Affairs, or, with respect to Phase II, III and IV clinical trials only, a qualified institutional review board.
- The facility and personnel conducting the clinical trial are capable of doing so by virtue of their experience and training and treat a sufficient volume of patients to maintain that expertise.
- With respect to Phase I clinical trials, the facility shall be an academic medical center or an affiliated facility, and the clinicians conducting the trial shall have staff privileges at said academic medical center.
- The patient meets the patient selection criteria enunciated in the study protocol for participation in the clinical trial.
- The patient has provided informed consent for participation in the clinical trial in a manner that is consistent with current legal and ethical standards.
- The available clinical or pre-clinical data provide a reasonable expectation that the patient's participation in the clinical trial will provide a medical benefit that is commensurate with the risks of participation in the clinical trial.
- The clinical trial does not unjustifiably duplicate existing studies.
- The clinical trial must have a therapeutic intent and must, to some extent, assess the effect of the intervention on the patient

Category A – an experimental device refers to a device for which "absolute risk" of the device type has not been established (that is, initial questions of 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 will reimburse providers for routine patient care services based on the contractual terms applicable at the time the service or product is provided. The terms of reimbursement for routine patient care services will be based on existing rules of reimbursement in effect on the date of service, including all clinical editing and coverage limits.

Only FDA approved Category B Investigational Device Exemption (IDE) devices are eligible for reimbursement. FDA Approved Category A devices are not reimbursable.

The Plan reimburses routine patient care related to both Category A and Category B IDE studies.

Service Limitations

Reimbursement of routine patient care services will be limited to the same extent such services are limited when rendered for non-clinical trial purposes.

For the purposes of reimbursement, routine patient care services do **not** include **any** the following:

- The facility fees and professional fees directly attributed to clinic visits for the purpose of evaluating a member's eligibility for participation in a clinical trial;
- An investigational drug or device that has been approved for use in the qualified clinical trial, whether or not the Food and Drug Administration has approved the drug or device for use in treating the patient's particular condition, to the extent it is not paid for by the manufacturer, distributer, or provider;
- Non-health care services that a member may be required to receive as a result of being enrolled in the qualified clinical trial;
- Costs associated with managing the research associated with the qualified clinical trial;
- Costs that would not be covered for non-investigational treatments;
- Any item, service or cost that is reimbursed or otherwise furnished by the sponsor of the clinical trial;
- The costs of services which are inconsistent with widely accepted and established national or regional standards of care;
- The costs of services which are provided primarily to meet the needs of the trial, including, but not limited to: tests, measurements and other services which are typically covered but which are being provided at a greater frequency, intensity or duration according to the trial protocol;
- Services or costs that are not covered, as defined by the MassHealth contract in effect at the time of review.

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.

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

Providers must include appropriate diagnosis coding, modifiers and condition code, 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 item or 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 or second 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 or second 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 (i.e. $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
10/02/2009	01/01/2010	Payment Policy	Payment Policy Committee

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
10/04/2011	Deleted applicable plan products, responsibility and accountability, and definitions; added coverage statement; updated applicable coding, references, and formatting.	10/04/2011	Payment Policy Committee
12/02/2013	Updated template, product applicability section, and references for BMC HealthNet Plan Qualified Health Plans, including ConnectorCare	12/02/2013	Payment Policy Committee
01/15/2014	Added ICD-10 Diagnosis Coding	01/15/2014	Payment Policy Committee
06/16/2014	Removed clinical trial criteria; added reference to medical policy	06/16/2014	Payment Policy Committee
05/12/2015	Annual review, new template	07/01/2015	Payment Policy Committee
04/16/2019	Annual Review, New template and logo box; added billing requirement for NCT and IDE number, modifier, condition code	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, 4.31
- General Clinical Editing and Payment Accuracy Review Guidelines, 4.108
- Inpatient Hospital, 4.112
- Outpatient Hospital, 4.17
- Non-Reimbursed Codes, 4.48
- Physician and Non Physician Practitioner Services, 4.608

Medical Policies

- Clinical Trials, OCA 3.192

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- Experimental and Investigational Treatment, OCA 3.12

References

- Massachusetts General Legislature: Chapter 257 of the Acts of 2002
- Medicare National Coverage Determination Manual for Routine Costs in Clinical Trials, Chapter 1, Part 4, Section 310.1
- Medicare Claims Processing Manual, Chapter 32, Sections 68 and 69
- 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
- Massachusetts General Legislature (M.G.L.) Chapter 175: Section 110L. Clinical Trials.
- National institutes of Health's (NIH) National Library of Medicine (NLM) Clinical Trials registry
- U.S. Food & Drug Administration (FDA) Drug Approval and Databases
- U.S. Food & Drug Administration (FDA) Device Advice: Medical Device Databases
- BMC HealthNet Plan Qualified Health Plans, including ConnectorCare Evidence of Coverage

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.