Reimbursement Policy

Clinical Trials

Policy Number: 4.134  
Version Number: 6  
Version Effective Date: 07/01/2015

Product Applicability  □ All Plan Products

Well Sense Health Plan
☐ New Hampshire Medicaid  
☐ NH Health Protection Program

Boston Medical Center HealthNet Plan
☒ MassHealth  
☒ Qualified Health Plans/ConnectorCare/Employer Choice Direct

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.
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 patient’s diagnosis, is consistent with the study protocol for the clinical trial, and would be covered if the patient did not participate in the clinical trial.

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.

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 of 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, even if the drug or device has been approved for use in the qualified clinical trial
• 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

*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.
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.

All services billed as patient care services must be submitted using the below coding specifications.

<table>
<thead>
<tr>
<th>ICD-9 Code</th>
<th>Description</th>
<th>Reimbursement Term</th>
</tr>
</thead>
<tbody>
<tr>
<td>V70.7</td>
<td>Examination of participant in clinical trial</td>
<td>Used to identify patients enrolled in a clinical trial. Must be present in the 2nd position of any claim submitted that includes charges for a clinical trial related fee.</td>
</tr>
</tbody>
</table>

Effective for dates of service on or after October 1, 2015

<table>
<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>200.6</td>
<td>Encounter for examination for normal comparison and control in clinical research program</td>
</tr>
</tbody>
</table>

Policy History

<table>
<thead>
<tr>
<th>Original Approval Date</th>
<th>Original Effective Date</th>
<th>Policy Owner</th>
<th>Approved by</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/02/2009</td>
<td>01/01/2010</td>
<td>Payment Policy</td>
<td>Payment Policy Committee</td>
</tr>
</tbody>
</table>

Policy Revisions History

<table>
<thead>
<tr>
<th>Review Date</th>
<th>Summary of Revisions</th>
<th>Revision Effective Date</th>
<th>Approved by</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/04/2011</td>
<td>Deleted applicable plan products, responsibility and accountability, and definitions; added coverage statement; updated applicable coding, references, and formatting.</td>
<td>10/04/2011</td>
<td>Payment Policy Committee</td>
</tr>
<tr>
<td>12/02/2013</td>
<td>Updated template, product applicability section, and references for BMC HealthNet Plan Qualified Health Plans, including ConnectorCare</td>
<td>12/02/2013</td>
<td>Payment Policy Committee</td>
</tr>
</tbody>
</table>

*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.
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.

### Policy Revisions History

<table>
<thead>
<tr>
<th>Date</th>
<th>Revision</th>
<th>Date</th>
<th>Committee</th>
</tr>
</thead>
<tbody>
<tr>
<td>01/15/2014</td>
<td>Added ICD-10 Diagnosis Coding</td>
<td>01/15/2014</td>
<td>Payment Policy Committee</td>
</tr>
<tr>
<td>06/16/2014</td>
<td>Removed clinical trial criteria; added reference to medical policy</td>
<td>06/16/2014</td>
<td>Payment Policy Committee</td>
</tr>
<tr>
<td>05/12/2015</td>
<td>Annual review, new template</td>
<td>07/01/2015</td>
<td>Payment Policy Committee</td>
</tr>
</tbody>
</table>

### Next Review Date

2017

### 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
- Physician and Non Physician Practitioner Services, 4.608

#### Medical Policies
- Clinical Trials, OCA 3.192
- Experimental and Investigational Treatment, OCA 3.12

### References

- Chapter 257 of the Acts of 2002
- Contract between The Office of Health and Human Services (EOHHS), and Boston Medical Center HealthNet Plan MassHealth
- Form of Contract between the Commonwealth Health Insurance Connector Authority and Boston Medical Center HealthNet Plan
- BMC HealthNet Plan Qualified Health Plans, including ConnectorCare Evidence of Coverage

*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.*
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.

*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.*