Reimbursement Policy

Clinical Trials

Policy Number: SCO 4.134
Version Number: 1
Version Effective Date: 01/01/2016

Product Applicability

- All Plan* Products

<table>
<thead>
<tr>
<th>Well Sense Health Plan</th>
<th>Boston Medical Center HealthNet Plan</th>
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<tr>
<td>□ New Hampshire Medicaid</td>
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<td>□ NH Health Protection Program</td>
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<td>□ MassHealth</td>
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<tr>
<td>□ Qualified Health Plans/ConnectorCare/Employer Choice Direct</td>
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<tr>
<td>X Senior Care Options</td>
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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 (initial questions regarding safety and effectiveness have not been resolved) and the FDA is not sure whether the device type is safe and effective.

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

Routine Costs in Clinical Trials – as described in The National Coverage Determinations (NCD) for Routine Costs in Clinical Trials (310.1), routine costs are 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 and 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 non-covered 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.

Provider Reimbursement

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 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 Coverage webpage site located at: http://www.cms.hhs.gov/center/coverage.asp and published in the Federal Register.

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 Coverage with Evidence Development webpage at http://www.cms.gov/Medicare/Coverage/Coverage-with-EvidenceDevelopment/index.html. Billing instructions are issued for each NCD.

All other clinical trials are reimbursed by Original Medicare.

Category A IDE studies
- Category A IDE devices are considered experimental and are not eligible for payment.

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• 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.

• Institutional providers (inpatient and outpatient) should not bill for Category A IDE devices.

• Professional providers are required to report the IDE number in Item 23 (or the electronic equivalent) on the CMS 1500 claims form although no payment will be made.

**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.

• Institutional providers must report the category B IDE number on a 0624 revenue code line with charges in the covered charges field.

• Professional providers must report the category B IDE number in Item 23 (or the electronic equivalent) on the CMS 1500 claims form.

**Service Limitations**

• Payment for a Category B device may not exceed the Medicare-approved amount for a comparable device that has been already FDA-approved.

• 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 Clinical Trial Number**

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).

Providers should follow CMS guidelines for billing clinical trials.

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<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
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<tr>
<td>Z00.6</td>
<td>Encounter for examination for normal comparison and control in clinical research program</td>
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<tr>
<th>Modifier</th>
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<tbody>
<tr>
<td>Q0</td>
<td>Investigational clinical service provided in a clinical research study that is in an approved clinical research study.</td>
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<tr>
<td>Q1</td>
<td>Routine clinical service provided in a clinical research study that is in an approved clinical research study.</td>
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**Policy History**

<table>
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<th>Original Approval Date</th>
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<th>Policy Owner</th>
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<tr>
<td>10/7/2015</td>
<td>01/01/2016</td>
<td>Payment Policy</td>
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**Policy Revisions History**

<table>
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<th>Summary of Revisions</th>
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**Next Review Date**

2017

**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 - Medical Devices
• Medicare Claims Processing Manual, chapter 32
• Medicare Managed Care Manual Chapter 4 - Benefits and Beneficiary Protections
• Medicare NCD for Routine Costs in Clinical Trials (310.1). July 9, 2007.
• Pub 100-04 Medicare Claims Processing Transmittal 2955

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.

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