Clinical Trials
Payment Policy

Policy

Blue Cross Blue Shield of Massachusetts (Blue Cross*) reimburses contracted health care providers for covered, medically necessary services for qualified individuals during approved clinical trials in accordance with state and federal mandates for coverage of clinical trials.

For non-grandfathered health plans that renewed on or after January 1, 2014, Section 2709 of the Patient Protection and Affordable Care Act (ACA) requires group or individual coverage for qualified individuals to participate in an approved clinical trial with respect to the treatment of a life-threatening disease or condition.

Some self-insured accounts may not offer benefits for clinical trials. It’s important that providers check member benefits and eligibility before performing services.

General Benefit Information

Services and subsequent payment are based on the member’s benefit plan and provider Agreement. Providers and their office staff may use our electronic technologies to verify effective dates and member copayments before initiating services. Please visit our eTools page to access links that provide information on member eligibility and benefits. Member liability may include, but is not limited to, copayments, deductibles, and co-insurance, and will be applied depending upon the member’s benefit plan.

Certain services may require prior authorization or referral. Please refer to the member’s subscriber certificate for more information and Authorization Requirements by Product.

Payment Information

Blue Cross reimburses health care providers based on:

- Network provider reimbursement or contracted rates
- Member benefits

Claims are subject to payment edits, which Blue Cross updates regularly.

Blue Cross clinical trials definition:
The term approved clinical trial is defined in the federal statute as a Phase I, Phase II, Phase III, or Phase IV clinical trial that is conducted in relation to the prevention, detection, or treatment of life-threatening diseases or conditions, and meets one of the following conditions:

- A federally funded or approved trial:
  - National Institutes of Health (NIH) (which includes organizations under NIH, such as the National Cancer Institute, NCI) and organizations funded by the NIH or NCI (such as academic institutions, designated cancer centers, and cooperative groups)
  - Centers for Disease Control and Prevention (CDC)
  - Agency for Health Care Research and Quality (AHRQ)
  - Centers for Medicare and Medicaid Services (CMS)
  - Department of Defense, Department of Veterans Affairs, or the Department of Energy if the trial is subject to unbiased, scientific review by experts, similar to NIH requirements
- A clinical trial conducted under an FDA investigational new drug application
- A drug trial that is exempt from the requirement of an FDA investigational new drug application

Blue Cross does not reimburse:

- Items and services available free from the clinical trial sponsor
- Services identified as investigational clinical services provided in an approved clinical research study
- The actual device, equipment, or drug that is being studied
- Items and services that are provided solely to satisfy data collection and analysis needs that are not used in direct clinical management of the patient
• Services that are clearly inconsistent with the widely accepted and established standards of care for a particular disease or condition
• Services or items that would not be covered if the member was not enrolled in a clinical trial
• Services that are specifically excluded by the member’s benefits
• Transportation, lodging and meals associated with a clinical trial

General information:
• Plans are not required to provide benefits for routine patient care services provided outside of the plan’s network area unless out-of-network benefits are provided under the plan. Members who have out-of-network benefits may be subject to a higher cost-share. Blue Cross may require members who do not have an out-of-network benefit to participate in the trial through an in-network provider only if the clinical trial is offered by an in-network provider.
• A qualified individual is someone who is eligible to participate in an approved clinical trial according to the trial protocol. Either the individual’s doctor must have concluded that participation is appropriate, or the participant must have provided medical and scientific information establishing that their participation is appropriate.
• A life-threatening disease or condition is any disease or condition from which the likelihood of death is probable unless the course of the disease is interrupted.
• Investigational drugs and devices. Please refer to the member’s subscriber certificate for additional information about reimbursement of investigational drugs and devices.
• Routine patient costs associated with the individual’s participation in a clinical trial means all medically necessary health care provided to the individual for purposes of the trial, consistent with a plan’s medical coverage, and services that would be covered for those not enrolled in clinical trials. Such services include those rendered by a physician, diagnostic or laboratory tests, and other services provided during the course of treatment for a condition or one of its complications that are consistent with the usual and customary standard of care.
• Refer to the Massachusetts General Laws for criteria of state-approved clinical trials. For Massachusetts products under MGL Ch. 175 Section 110L(c) and (d), with respect to Phase II, III, or IV clinical trials only, a trial is approved by a qualified institutional review board (IRB) as defined in the statute.

Billing Information

Specific billing guidelines:
• The absence or presence of a procedure code on the grid does not guarantee or imply coverage or reimbursement and is subject to change
• All clinical trial claims must include the Z00.6 diagnosis code
• All lines of a clinical trial office or outpatient claim must include the modifier Q0 or Q1
• All clinical trial claims should include the clinical trial number (Effective September 1, 2018):

For CMS-1500 professional claims:

<table>
<thead>
<tr>
<th>Paper claims</th>
<th>Electronic claims (837P)</th>
<th>Both paper and electronic</th>
</tr>
</thead>
</table>
| • Enter the 8-digit clinical trial number in field 19 preceded by ‘CT’ | • Enter the 8-digit clinical trial number in loop 2300 REF02 (REF01=P4). Do not precede with ‘CT’ on electronic claims. | Use:  
  • ICD-10 diagnosis code  
    Z00.6  
  • Modifier Q0 and/or Q1 as appropriate (outpatient claims only) |

For CMS-1450 facility claims:

<table>
<thead>
<tr>
<th>Paper claims</th>
<th>Electronic claims (837I)</th>
<th>Both paper and electronic</th>
</tr>
</thead>
</table>
| • Place the 8-digit clinical trial number in the amount field in form locator 39-41, value code D4, | • Report the 8-digit clinical trial number in loop 2300 REF02 (REF01=P4). | Use:  
  • Condition code 30  
  • ICD-10 diagnosis code  
    Z00.6  
  • Modifier Q0 and/or Q1 as appropriate (outpatient claims only) |

• For Medicare Advantage clinical trial related claims (other than IDE and Clinical Evidence Development), submit first to Original Medicare, and then submit to us with the Medicare Explanation of Member Benefits.
• Have the following items available in the patient’s medical record (this should be available upon request):
  o Trial name
  o Sponsor
  o Sponsor-assigned protocol number
  o Analysis of billing coverage by service, device or item (coverage analysis grid)
  o Informed consent

<table>
<thead>
<tr>
<th>Code</th>
<th>Service description</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Z00.6</td>
<td>Encounter for examination for normal comparison and control in clinical research program</td>
<td>Report following primary diagnosis. Must be reported on all clinical trial claims</td>
</tr>
</tbody>
</table>

**Modifiers**

<table>
<thead>
<tr>
<th>Code</th>
<th>Service description</th>
<th>Comments</th>
</tr>
</thead>
</table>
| Q0 | Investigational clinical service provided in a clinical research study that is in an approved clinical research study | • If billing with other modifiers, use Q0 or Q1 in the second or subsequent modifier fields
• Modifier Q0 is not reimbursed
• Clinical trial claim lines without one of these modifiers will deny |
| Q1 | Routine clinical service provided in a clinical research study that is in an approved clinical research study | |

**Condition codes**

<table>
<thead>
<tr>
<th>Code</th>
<th>Service description</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>30</td>
<td>Non-research services provided to all patients, including managed care enrollees, enrolled in a qualified clinical trial</td>
<td></td>
</tr>
<tr>
<td>53</td>
<td>The initial placement of a medical device provided as part of a clinical trial or a free sample</td>
<td></td>
</tr>
</tbody>
</table>

**HCPCS**

<table>
<thead>
<tr>
<th>Code</th>
<th>Service description</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>S9988</td>
<td>Services provided as part of a phase I clinical trial</td>
<td>Not reimbursed</td>
</tr>
<tr>
<td>S9990</td>
<td>Services provided as part of a phase II clinical trial</td>
<td></td>
</tr>
<tr>
<td>S9991</td>
<td>Services provided as part of a phase III clinical trial</td>
<td></td>
</tr>
<tr>
<td>S9992</td>
<td>Transportation costs to and from trial location and local transportation costs (examples: fares for taxicab or bus) for clinical trial participant and one caregiver/companion</td>
<td></td>
</tr>
<tr>
<td>S9994</td>
<td>Lodging costs (example: hotel charges) for clinical trial participant and one caregiver/companion</td>
<td></td>
</tr>
<tr>
<td>S9996</td>
<td>Meals for clinical trial participant and one caregiver/companion</td>
<td></td>
</tr>
</tbody>
</table>

• When submitting claims for reimbursement, report all services with:
  o Up-to-date industry-standard procedure and diagnosis codes
  o Modifiers that affect payment in the first modifier field, followed by informational modifiers

**Billing scenario:**

A patient goes to a hospital outpatient department for chemotherapy with a drug, Bevacizumab, which is undergoing a clinical trial for an expanded use with a non-standard dose of 350 units or 1500 mg.

• The drugs is supplied by the trial sponsor.
• The patient also receives a simple radiation therapy treatment on the same day at the same facility that is not part of the trial.
• A comprehensive metabolic panel was drawn.
Billing example:

<table>
<thead>
<tr>
<th>Revenue code</th>
<th>HCPCS</th>
<th>Description</th>
<th>Modifier</th>
<th>Diagnosis (secondary)</th>
</tr>
</thead>
<tbody>
<tr>
<td>335</td>
<td>96413</td>
<td>Chemotherapy administration</td>
<td>Q1</td>
<td>Z00.6</td>
</tr>
<tr>
<td>636</td>
<td>J9035</td>
<td>Bevacizumab <em>(bill with appropriate units)</em></td>
<td>Q0</td>
<td>Z00.6</td>
</tr>
<tr>
<td>333</td>
<td>77402</td>
<td>Radiation</td>
<td>Q1</td>
<td>Z00.6</td>
</tr>
<tr>
<td>301</td>
<td>80053</td>
<td>Metabolic panel</td>
<td>Q1</td>
<td>Z00.6</td>
</tr>
</tbody>
</table>

- Bill the **clinical trial number** in FL 39-41 (paper) or **Loop 2300 REF02** (electronic)
- Report **condition code 30** in FL18

Related Policies

See the payment policy relating to the specific service rendered.

Related Policies

<table>
<thead>
<tr>
<th>Date</th>
<th>Change Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>05/05/2014</td>
<td>Documentation of existing policy</td>
</tr>
<tr>
<td>07/13/2015</td>
<td>Annual review; template update</td>
</tr>
<tr>
<td>09/30/2016</td>
<td>Annual review; template update; inclusion of detailed documentation on existing policy and specific billing guidelines</td>
</tr>
<tr>
<td>09/30/2017</td>
<td>Annual review; edits for clarity in the coding grid</td>
</tr>
<tr>
<td>05/01/2018</td>
<td>Annual review; billing guideline edits for clarity; addition of documentation requirements</td>
</tr>
</tbody>
</table>

This document is designed for informational purposes only and is not an authorization, an explanation of benefits, or a contract. Receipt of benefits is subject to satisfaction of all terms and conditions of the coverage. Medical technology is constantly changing, and we reserve the right to review and update our policies periodically.

Payment policies are intended to assist providers in obtaining Blue Cross Blue Shield of Massachusetts’ payment information. Payment policy determines the rationale by which a submitted claim for service is processed and paid. Payment policy formulation takes into consideration a variety of factors, including: the terms of the participating provider’s contract; scope of benefits included in a given member’s benefit plan; clinical rationale, industry-standard procedure code edits, and industry-standard coding conventions.