

Clinical trial Applies to:



**Blue Cross
Blue Shield**
of Michigan

A nonprofit corporation and independent licensee
of the Blue Cross and Blue Shield Association

Medicare Plus BlueSM PPO Medicare Plus BlueSM Group PPO Both

Clinical trial

Clinical trials are research studies designed to evaluate the safety and effectiveness of medical care. They are key to understanding the appropriate use of medical interventions of all types and informing payers about what services to cover.

A clinical trial is one of the final stages of a research process that helps doctors and researchers see if a new approach works and if it is safe. They may also be used to compare different treatments for the same condition to see which treatment is better, or to test new uses for existing treatments.

Original Medicare

Original Medicare offers the option to join some clinical trials for the diagnosis and treatment of illnesses. If a member joins a covered clinical trial, Original Medicare will pay for routine costs of qualifying clinical trial services as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. Routine costs of a clinical trial include all items and services that are otherwise generally available to Medicare beneficiaries that are provided in either the experimental or the control arms of a clinical trial.

Medicare Plus Blue

Medicare Plus Blue plans provide at least the same level of benefit coverage as Original Medicare (Part A and Part B) and provide enhanced benefits beyond the scope of Original Medicare within a single health care plan. This flexibility allows BCBSM to offer enriched plans by using Original Medicare as the base program and adding desired benefit options.

Coverage for the additional benefit of the 20 percent coinsurance for clinical trials is provided to members under all individual Medicare Plus Blue PPO, standard and custom Medicare Plus Blue Group PPO plans. The member's cost-sharing and other coverage conditions are determined by the group.

BCBSM Clinical trial policy – specified oncology clinical trials

Specified oncology clinical trials services that are not covered by original Medicare for stages II, III and IV breast cancer and all stages of ovarian cancer should be submitted to BCBSM Medicare Plus Blue.

Specified Oncology Clinical Trials covers bone marrow and peripheral blood stem cell transplants, their related services and FDA-approved antineoplastic drugs to treat stages II, III and IV breast cancer and all stages of ovarian cancer when they are provided pursuant to an approved phase II or III clinical trial. All services must be pre-approved and performed in a designated cancer center. A designated cancer center is a site approved by the National Cancer Institute as a cancer center, comprehensive cancer center, clinical cancer center or an affiliate of one of these centers.

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Medicare Plus Blue pays for Autologous and Allogeneic transplants. In an autologous transplant, stem cells are collected from the patient themselves, harvested, frozen and stored, then given back to the patient after intensive therapy. An autologous stem cell transplant is different from an Allogeneic stem cell transplant, which uses stem cells from a matching donor.

Autologous Transplants:

- Infusion of colony stimulating growth factors
- Harvesting (including peripheral blood stem cell phereses) and storage of bone marrow and / or peripheral blood stem cells
- Purging or positive stem cell selection of bone marrow or blood stem cells
- High dose chemotherapy and or total body irradiation
- Infusion of bone marrow and or peripheral blood stem cells
- Hospitalization

Allogeneic Transplants:

- Blood tests to evaluate donors (if not covered by the potential donor's insurance)
- Search of the National Bone Marrow Donor Program Registry for a donor. A search will begin only when the need for a donor is established
- Infusion of colony stimulating growth factors
- Harvesting (including peripheral blood stem cell pheresis) and storage of the donor's bone marrow, peripheral blood stem cells, and or umbilical cord blood (We will cover harvesting and storage even if it is not covered by the donor's insurance.)
- High dose chemotherapy and or total body irradiation
- Infusion of bone marrow, peripheral blood stem cells, and or umbilical cord blood
- T-cell depleted infusion
- Donor lymphocyte infusion
- Hospitalization

BCBSM Clinical trial policy – routine clinical trials

Autologous islet cell transplantation for chronic pancreatitis that is not a benefit for Original Medicare is a payable benefit for all individual Medicare Plus Blue PPO, standard and custom Medicare Plus Blue Group PPO plans. The safety and effectiveness of autologous islet cell transplantation after a total or near total pancreatectomy have been established. It may be considered useful in preventing insulin dependent diabetes.

Pancreatitis is an inflammation of the pancreas which may cause severe pain, nausea and vomiting. The only relief from this pain may be the removal of the pancreas. The islets of Langerhans within the pancreas produce insulin. With the removal of the pancreas it is a certainty that the patient will become an insulin-dependent diabetic. During the removal of the pancreas these islets are removed and reinserted into the portal vein of the liver where they can function to produce insulin. It has been established that autologous transplant of these islets is safe and effective and may prevent the patient from becoming an insulin dependent diabetic.

Criteria for a pancreatectomy with islet cell autotransplant include but are not limited to the following:

- Patients who need total pancreatectomy or partial pancreatectomy when a completion pancreatectomy might be required in the future
- Non-diabetic at the time of pancreatectomy or if diabetic, mild diabetes with c-peptide present as an indication of beta cell function
- Patients with pancreatitis, or benign disease of the pancreas

Exclusion:

- Cancer of the pancreas

Conditions for payment

The table below specifies payment conditions for clinical trials.

Conditions for payment	
Eligible provider	Consistent with Original Medicare
Payable locations	Consistent with Original Medicare, designated cancer center
Frequency	Consistent with Original Medicare
CPT/HCPCS codes	Restrictions apply
Diagnosis restrictions	
Age restrictions	Consistent with Original Medicare

Reimbursement

Medicare Plus Blue plan's maximum allowed amounts for clinical trials benefit is consistent with Original Medicare. The provider will be paid the lesser of this allowed amount or the provider's charge, minus the member's cost-share. This represents payment in full and providers are not allowed to balance bill the member for the difference between the allowed amount and the charge.

Member cost-sharing

- Medicare Plus Blue providers should collect the applicable cost-sharing from the member at the time of the service when possible. Cost-sharing refers to a flat-dollar copayment, a percentage coinsurance or a deductible. You can only collect the appropriate Medicare Plus Blue cost-sharing amounts from the member.
- If the member elects to receive a noncovered service, he or she is responsible for the entire charge associated with the noncovered service.

For detailed information about Medicare Plus Blue member's benefits and cost-share, providers may verify member benefits via web-DENIS or call CAREN at 1-866-309-1719.

Billing instructions for members

1. Bill services on the CMS 1500 (8/05) claim form, UB-04 or the 837 equivalent claim.
2. Use the Medicare Advantage PPO unique billing requirements.
3. Report CPT/HCPCS codes and diagnosis codes to the highest level of specificity.
4. Report your National Provider Identifier number on all claims.
5. Submit claims to your local BCBS plan.
6. Use electronic billing:
 - a. Michigan providers
 - A copy of the ANSI ASC X12N 837 and 835 Institutional Health Care Claim and Health Care Claim Payment/Advice (BCBSM Electronic Data Interchange (EDI) Institutional 837/835 Companion Document) is available at: bcbsm.com/pdf/837_835_institutional_companion.pdf
 - A copy of the BCBSM EDI Professional 837/835 Companion Document is available at: bcbsm.com/pdf/systems_resources_prof_837_835.pdf
 - b. Providers outside of Michigan should contact their local BCBS plan.

Additional billing instructions

1. Providers must include the Medicare Clinical Trial Registration number on all requests and claims submitted.