

Clinical Trials and Stem Cell Transplant

Since the full implementation of the Affordable Care Act (ACA) in 2014, patients have expanded access to life-saving stem cell transplants. Many transplants in the United States are performed as clinical trials through the Blood and Marrow Clinical Trials Network. Section 2709 of the ACA expands access to our patient population by requiring almost all payers to cover *routine costs* of *approved* clinical trials for the treatment of cancer or other life-threatening diseases. Medicaid and [grandfathered plans](#) do not have to comply with this provision of the ACA.

Routine Costs

Routine costs include all services and treatment that would be covered if the patient were not in the trial. Unfortunately, routine costs of the clinical trial **do not** include the investigational items or devices.

Approved Clinical Trials

Approved clinical trials are Phase I, II, III and IV trials that must be approved or funded by one of the following organizations:

- National Institutes of Health
- National Cancer Institute
- Center for Disease Control and Prevention
- Agency for Health Care Research and Quality
- Centers for Medicare and Medicaid Services
- Food and Drug Administration

Note to Transplant Centers: If a patient at your Center is denied coverage for a clinical trial, please ensure that the patient is eligible for the trial, that it is an approved clinical trial and contact their payer for further information. The American Society of Clinical Oncology has developed a "[Clinical Trial Attestation Form](#)" that Centers can use with their payers to clarify patient and trial eligibility under the new ACA standard.

The NMDP has partnered with payers to develop a [standard authorization request](#) form to highlight key information items that payers need to process your request. It is recommended you use this form in conjunction with supplying a copy of the clinical trial protocol and a brief, (2-3 sentence) easy-to-understand explanation of the study's purpose.

Resources

[Federal Clinical Trial Listing](#)

[Blood & Marrow Transplant Clinical Trials Network](#) (BMT CTN)