

# CENTERS FOR MEDICARE AND MEDICAID (CMS) CLINICAL TRIAL POLICY (CTP)

## Frequently Asked Questions – October 2007

On October 17, 2007 CMS issued its final NCD related to the Clinical Trial Policy. The final policy maintains the current clinical trial policy (issued on July 9, 2007) without imposing any additional conditions of coverage that had been proposed on July 19, 2007. In the October 17, 2007 decision memorandum, CMS cites numerous comments that questioned their authority to establish standards and limitations to coverage for research studies, and recent FDA legislation already creating requirements for clinical trials as its reasons for not changing the current policy.

**Q.** What is the chronology of the proposed and final decisions? It seems there have been a number in a short period of time.

**A.**

September 2000	Clinical Trial Policy issued. General understanding that this policy was for trials such as chemotherapeutic trials and not applicable to device trials.
2006	Policy opened for review.
April 10, 2007	Clinical Trial Policy proposed changes are issued with a 30-day comment period. Decision to be posted on July 9, 2007.
July 9, 2007	Clinical Trial Policy Decision Memorandum issued and, except for two minor revisions, the 2000 Clinical Trial Policy was left intact.
July 19, 2007	Clinical Trial Policy proposed changes requiring each study meet a specific set of 13 standards. Issued with a 30-day comment period. Decision to be posted on October 17, 2007.
October 17, 2007	Decision Memorandum issued maintaining the policy issued on July 9, 2007. It is important to note it is the policy issued on July 9, 2007 that now stands as the reference document going forth.

**Q.** What does CMS's 2007 Clinical Trial Policy impact?

**A.** On July 9, 2007, the Centers for Medicare and Medicaid Services (CMS) posted the Decision Memorandum for the Clinical Trial Policy ("CTP"). CMS issued the national coverage determination in order to preserve the status quo of the policy issued in September 2000 with only two changes implemented in the final policy:

1. Language to make clear that standard of care services "would be covered if they would be covered outside of the clinical research trial;" and
2. Language to include items and services for Coverage with Evidence Development (CED) where additional data is collected as a condition of coverage.

**Q.** So how does this impact coverage or claims submittal for post market trials?

**A.** There is no change to the coverage or billing of services associated with post market trials. Services that would be considered routine and medically necessary and covered if not being performed as a part of a clinical trial should be covered and submitted for payment.

**Q.** Does this include non standard of care protocol induced services too?

**A.** No. Protocol induced services should never be billed to Medicare or any payer. Medtronic's clinical teams work to determine those services that are protocol induced and compensate a physician, via the clinical trial agreement, for their time and effort in rendering these services.

**Q.** Are private payers affected by this?

**A.** No, this is a Medicare policy, applicable to Medicare beneficiaries and is not applicable to private payers, unless the private payers decide to make changes on their own.

**Q.** Are IDE trials impacted by this decision?

**A.** No, IDE trials still follow the requirements of the 1995 Interagency Agreement.

**Q.** Can you provide the Web link to this decision?

**A.** The final decision memorandum and a question and answer sheet developed by CMS can be found at <http://www.cms.hhs.gov/mcd/viewtrackingsheet.asp?id=210>.

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