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Related MLN Matters Article #: MM5719

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Medicare Clinical Trial Policy

Key Words

MM5719, CR5719, R74NCD, Clinical, Trial

Provider Types Affected

All physicians, providers, and suppliers who submit claims related to clinical trials to Medicare carriers, Part A/B Medicare Administrative Contractors (A/B MACs), Durable Medical Equipment MACs (DME MACs), Fiscal Intermediaries (FIs), and Regional Home Health Intermediaries (RHHIs)

Key Points

- The effective date of the instruction is July 9, 2007.
- The implementation date is October 9, 2007.
- On June 7, 2000, the President of the United States issued an executive memorandum directing the Secretary of Health and Human Services to "explicitly authorize [Medicare] payment for routine patient care costs and costs due to medical complications associated with participation in clinical trials."
- In keeping with the President's directive, the Centers for Medicare & Medicaid Services (CMS) engaged in defining the routine costs of clinical trials and identifying the clinical trials for which payment for such routine costs should be made.
- On September 19, 2000, CMS implemented its initial clinical trial policy through the National Coverage Determination (NCD) process.
- On July 10, 2006, CMS opened a reconsideration of its NCD on clinical trials in the *NCD Manual,* Section 310.1.
- Change Request (CR) 5719 communicates the findings resulting from that analysis.

Changes Made by CR5719

- CR5719 implements two changes to the 2000 clinical trial policy by:
  - Modifying the language describing coverage of an investigational item/service in the context of a clinical trial, and
  - Adopting coverage with evidence development.
- The remainder of the 2000 clinical trials policy continues without change.
- CR5719 states that for items and services furnished on and after July 9, 2007, the routine costs of a clinical trial include 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.
- The investigational item or service itself is excluded, unless otherwise covered outside of the clinical trial.
- In addition, the NCD is revised to add coverage with evidence development (CED).
- CED is for items and services in clinical research trials for which there is some evidence of significant medical benefit, but for which there is insufficient evidence to support a “reasonable and necessary” determination.
- CED is determined through the NCD process, and conditional upon meeting standards of patient safety and clinical evidence and standards for items and services not otherwise covered that would be considered "reasonable and necessary" in the context of a clinical trial.
- Coverage determined under CED is implemented via subsequent NCDs, CRs, and MLN Matters articles specific to the coverage issue.

Important Links

The related MLN Matters article can be found at *http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5719.pdf* on the CMS website.

The official instruction (CR5719) regarding this change may be viewed at *http://www.cms.hhs.gov/transmittals/downloads/R74NCD.pdf* on the CMS website.

If providers have questions regarding this issue, they may contact their Medicare FI, carrier, DME MAC, RHHI or A/B MAC at their toll-free number, which may be found at *http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip* on the CMS website.