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New Healthcare Common Procedure Coding System (HCPCS) Modifiers When Billing for Patient Care in Clinical Research Studies

Key Words

MM5805, CR5805, R1418CP, HCPCS, Clinical, Research

Provider Types Affected

Physicians, providers, and suppliers who bill Medicare Carriers, Fiscal Intermediaries (FIs), including Regional Home Health Intermediaries (RHHIs), Part A/B Medicare Administrative Contractors (A/B MACs) and Durable Medical Equipment MACs (DME MACs) for services provided to Medicare beneficiaries in clinical research studies

Key Points

- The effective date of the instruction is January 1, 2008.
- The implementation date is no later than April 7, 2008.
- The Centers for Medicare & Medicaid Services (CMS) is discontinuing the QA (FDA Investigational Device Exemption), QR (Item or Service Provided in a Medicare Specified Study), and QV (Item or Service Provided as Routine Care in a Medicare Qualifying Clinical Trial) HCPCS modifiers as of December 31, 2007.
- CMS is also creating two new modifiers that will be used solely to differentiate between routine and investigational clinical services.
- These new modifiers will be included in the 2008 Annual HCPCS Update and are effective for dates of service on and after January 1, 2008:
 - **Q0** - Investigational clinical service provided in a clinical research study that is in an approved clinical research study. Q0 replaces QA and QR.
 - **Q1** - Routine clinical service provided in a clinical research study that is in an approved clinical research study. Q1 replaces QV.
- Providers should use these two new modifiers as follows:
 - Investigational clinical services are defined as those items and services that are being investigated as an objective within the study. Investigational clinical services may include items or services that are approved, unapproved, or otherwise covered (or not covered) under Medicare.

- Routine clinical services are defined as those items and services that are covered for Medicare beneficiaries outside of the clinical research study.
- Routine clinical services are used for the direct patient management within the study and do not meet the definition of investigational clinical services.
- Routine clinical services may include items or services required solely for the provision of the investigational clinical services (e.g., administration of a chemotherapeutic agent), clinically appropriate monitoring, whether or not required by the investigational clinical service (e.g., blood tests to measure tumor markers), and items or services required for the prevention, diagnosis, or treatment of research related adverse events (e.g., blood levels of various parameters to measure kidney function).
- Medicare contractors will not search their files to adjust affected claims processed prior to implementation of this change, but they will adjust such claims that providers bring to their attention.

Note: If a Category A or B investigational device is used on the clinical trial, providers should continue to include the Investigational Device Exemption (IDE) number in item 23 of the CMS-1500 claim form or the electronic equivalent. Also, the Medicare contractor will validate the IDE number when it appears on the claim with the Q0 modifier. If the IDE number does not meet validation criteria, the claim will be returned as unprocessable.

Important Links

The related MLN Matters article can be found at

<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5805.pdf> on the CMS website.

The official instruction (CR5805) regarding this change may be viewed at

<http://www.cms.hhs.gov/Transmittals/downloads/R1418CP.pdf> on the CMS website.

If providers have questions regarding this issue, they may contact their Medicare Carrier, A/B MAC, FI, DME MAC, or RHHI at their toll-free number, which may be found at

<http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip> on the CMS website.