



Related MLN Matters Article #: MM3705

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Infusion Pumps: C-Peptide Levels as a Criterion for Use

Key Words

C-Peptide, Levels, Testing, Requirement, CR3705, MM3705, R27NCD, R513CP, Insulinopenia, 84681, 86337, CPT, Code, Coverage, CSII, Diabetes, Renal, Creatinine

Provider Types Affected

Physicians, suppliers, and providers providing continuous subcutaneous insulin infusion and related drugs/supplies in the treatment of diabetic patients in the home setting and billing Medicare carriers or Fiscal Intermediaries (FIs)

Key Points

- The effective date of the instruction is December 17, 2004.
- The implementation date is February 18, 2005.
- Effective for services performed on or after December 17, 2004, in addition to meeting criterion A or B, the beneficiary with diabetes must be insulinopenic per the fasting C-peptide testing requirement or, as an alternative, must be beta cell autoantibody positive.
- Insulinopenia is defined as a fasting C-peptide level that is less than or equal to 110 percent of the lower limit of normal of the laboratory's measurement method.
- For patients with renal insufficiency and a creatinine clearance (actual or calculated from age, gender, weight, and serum creatinine) ≤ 50 ml/minute, insulinopenia is defined as a fasting C-peptide level that is less than or equal to 200 percent of the lower limit of normal of the laboratory's measurement method.
- Fasting C-peptide levels will only be considered valid when a concurrently obtained fasting glucose is ≤ 225 mg/dL.
- Levels need only be documented once in the patient's medical records.
- Coverage of all other uses of CSII that adheres with the Category B investigational device exemption clinical trials regulation (42 CFR 405.201) or routine cost under the clinical trials policy (*Medicare NCD Manual* Chapter 1, Part 4, Section 310.1) will continue.

- Those billing for these services should note that Medicare carriers will accept, effective for services on or after December 17, 2004, Current Procedural Terminology (CPT) code 84681 (C-peptide) or CPT code 86337 (insulin antibodies) when diagnosis codes 250.00-250.93 are also reported on a claim.

Important Links

The related MLN Matters article can be found at

<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM3705.pdf> on the CMS website.

Affected providers may find the official instruction issued to their Medicare carrier/intermediary regarding this change at <http://www.cms.hhs.gov/transmittals/downloads/R513CP.pdf> and

<http://www.cms.hhs.gov/Transmittals/downloads/R27NCD.pdf> on the CMS website.