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MLN Matters Number: MM5093

Related Change Request (CR) #: 5093

Related CR Release Date: May 19, 2006

Effective Date: April 26, 2006

Related CR Transmittal #: R56NCD and R957CP

Implementation Date: July 3, 2006 for carriers; October 2, 2006 for FIs

Pancreas Transplants Alone (PA)

Note: This article was updated on November 8, 2012, to reflect current Web addresses. This article was revised on October 5, 2006, to include this statement alerting affected providers to review *MLN Matters* article SE0674 for important information regarding the continued hold of affected claims. This article is available at <http://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnmattersarticles/downloads/SE0674.pdf> on the CMS website.

Provider Types Affected

Physicians and providers billing Medicare fiscal intermediaries (FIs) and carriers for PA

Background

Medicare covers whole organ pancreas transplantation when it is performed in conjunction with or after kidney transplantation (*National Coverage Determination (NCD) Manual*, Section 260.3). However, Medicare does not cover PA in diabetes patients without end-stage renal failure because of a lack of sufficient evidence, based in large part on a 1994 Office of Health Technology Assessment report.

Key Points

This article is based on information contained in Change Request (CR) 5093, which informs physicians and providers that, effective for services performed on or after April 26, 2006, Medicare will cover PA for beneficiaries in the following limited circumstances:

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- Facilities must be Medicare-approved for kidney transplantation (Approved centers are found at www.cms.gov/Medicare/End-Stage-Renal-Disease/ESRDGeneralInformation/index.html on the CMS website).
- Patients must have a diagnosis of Type I diabetes:
 - The patient with diabetes must be beta cell autoantibody positive; or
 - The patient must demonstrate insulinopenia, defined as a fasting C-peptide level that is less than or equal to 110% of the lower limit of normal of the laboratory's measurement method. Fasting C-peptide levels will be considered valid only with a concurrently obtained fasting glucose ≤ 225 mg/dL.
- Patients must have a history of medically-uncontrollable labile (brittle) insulin-dependent diabetes mellitus with documented recurrent, severe, acutely life-threatening metabolic complications that require hospitalization.
- These complications include frequent hypoglycemia unawareness or recurring severe ketoacidosis, or recurring severe hypoglycemic attacks.
- Patients must have been optimally and intensively managed by an endocrinologist for at least 12 months with the most medically recognized advanced insulin formulations and delivery systems.
- Patients must have the emotional and mental capacity to understand the significant risks associated with surgery and to effectively manage the lifelong need for immunosuppression.
- Patients must otherwise be suitable candidates for transplantation.

Billing and Claims Processing

- The following ICD-9 CM codes will be recognized by FIs and carriers for pancreas transplantation alone for beneficiaries with type I diabetes when billed with HCPCS 48554:
25001, 25003, 25011, 25013, 25021, 25023, 25031, 25033, 25041, 25043, 25051, 25053, 25061, 25063, 25071, 25073, 25081, 25083, 25091, and 25093.
- Carriers and FIs who receive claims for PA services that were performed in an **unapproved facility** should use the following messages upon the reject or denial:
 - **Medicare Summary Notice MSN Message - MSN code 16.2** (*This service cannot be paid when provided in this location/facility*)

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- **Remittance Advice Message** - Claim Adjustment Reason Code 58
(*Payment adjusted because treatment was deemed by the payer to have been rendered in an inappropriate or invalid place of service*)
- Carriers and FIs who receive claims for PA services that are **not billed using the covered diagnosis/procedure codes listed** above should use the following messages upon the reject or denial:
 - **Medicare Summary Notice MSN Message** - MSN code 15.4 (*The information provided does not support the need for this service or item*)
 - **Remittance Advice Message** – Claim Adjustment Reason Code 50
(These are non-covered services because this is not deemed a 'medical necessity' by the payer)
- Modification of the current coverage policy on pancreas transplants can be found in Publication 100-03, Section 260.3 and claims processing information is located in Publication 100-04, Chapter 3, Section 90.5.1. The location of this information is listed in the *Additional Information* section of this article.

Note: Carriers and FIs will hold any PA claims with dates of service on or after April 26, 2006, until the claims can be processed in their systems. For FIs this date is October 2, 2006, and for carriers the date is July 3, 2006.

Additional Information

The official instructions issued to your Medicare FI or carrier regarding this change can be found at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R56NCD.pdf> for the NCD manual revision and <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R957CP.pdf> for changes to the Medicare Claims Processing Manual.

If you have questions, please contact your Medicare FI or carrier at their toll-free number, which may be found at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html> on the CMS website.

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