

# CMS Manual System

## Pub 100-03 Medicare National Coverage Determinations

Transmittal 56

Department of Health &  
Human Services (DHHS)

Center for Medicare &  
Medicaid Services (CMS)

Date: MAY 19, 2006

Change Request 5093

**SUBJECT: Pancreas Transplants Alone**

**I. SUMMARY OF CHANGES:** Pancreas transplants alone are covered under Medicare in limited circumstances. This revision to section 260.3 of Pub. 100-03 is a national coverage determination (NCD) made under section 1862(a)(1) of the Social Security Act. NCDs are binding on all carriers, fiscal intermediaries, quality improvement organizations, health maintenance organizations, competitive medical plans, health care prepayment plans, the Medicare Appeals Council, and administrative law judges (see 42 CFR 405.1064, effective May 1, 2005). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an administrative law judge may not review an NCD. (See 1869(f)(1)(A)(i) of the Social Security Act.

### NEW/REVISED MATERIAL

**EFFECTIVE DATE: April 26, 2006**

**IMPLEMENTATION DATE: No later than July 3, 2006 for Carriers. October 2, 2006 for FIs.**

*Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.*

### II. CHANGES IN MANUAL INSTRUCTIONS:

**R = REVISED, N = NEW, D = DELETE**

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	1/Table of Contents
R	1/260.3/Pancreas Transplants (Effective April 26, 2006)

### III. FUNDING:

**No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2006 operating budgets.**

**IV. ATTACHMENTS:**

Manual Instruction

*\*Unless otherwise specified, the effective date is the date of service.*

**Medicare National Coverage  
Determinations Manual**  
**Chapter 1, Part 4 (Sections 200 – 310.1)**  
**Coverage Determinations**

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260.3 - Pancreas Transplants *(Effective April 26, 2006)*

## **260.3 - Pancreas Transplants (*Effective April 26, 2006*)**

*(Rev.56, Issued: 05-19-06, Effective: 04-26-06, Implementation: 07-03-06 Carriers/10-02-06 FIs)*

### **A. General**

Pancreas transplantation is performed to induce an insulin-independent, euglycemic state in diabetic patients. The procedure is generally limited to those patients with severe secondary complications of diabetes, including kidney failure. However, pancreas transplantation is sometimes performed on patients with labile diabetes and hypoglycemic unawareness.

### **B. Nationally Covered Indications**

*Effective for services performed on or after July 1, 1999, whole organ pancreas transplantation is nationally covered by Medicare when performed simultaneous with or after a kidney transplant. If the pancreas transplant occurs after the kidney transplant, immunosuppressive therapy begins with the date of discharge from the inpatient stay for the pancreas transplant.*

*Effective for services performed on or after April 26, 2006, pancreas transplants alone (PA) are reasonable and necessary for Medicare beneficiaries in the following limited circumstances:*

- 1. PA will be limited to those facilities that are Medicare-approved for kidney transplantation. (Approved centers can be found at [http://www.cms.hhs.gov/ESRDGeneralInformation/02\\_Data.asp#TopOfPage](http://www.cms.hhs.gov/ESRDGeneralInformation/02_Data.asp#TopOfPage).)*
- 2. Patients must have a diagnosis of type I diabetes:*
  - o Patient with diabetes must be beta cell autoantibody positive; or*
  - o 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 only be considered valid with a concurrently obtained fasting glucose  $\leq$ 225 mg/dL;*
- 3. 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. Aforementioned complications include frequent hypoglycemia unawareness or recurring severe ketoacidosis, or recurring severe hypoglycemic attacks;*

*4. 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;*

*5. 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; and,*

*6. Patients must otherwise be a suitable candidate for transplantation.*

**C. Nationally Non-Covered Indications**

The following procedure *is* not considered reasonable and necessary within the meaning of section 1862(a)(1)(A) of the Social Security Act:

1. Transplantation of partial pancreatic tissue or islet cells (except in the context of a clinical trial (see section 260.3.1 of the *National Coverage Determinations Manual*)).

**D. Other**

Not applicable.

(This NCD last reviewed *April 2006*.)