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# CMS Manual System

## Pub. 100-03 Medicare National Coverage Determinations

Department of Health &  
Human Services (DHHS)  
Centers for Medicare &  
Medicaid Services (CMS)

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Transmittal 18

Date: JULY 30, 2004

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CHANGE REQUEST 3385

**I. SUMMARY OF CHANGES:** Section 733 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 mandates that the Centers for Medicare & Medicaid Services cover the costs of the transplantation of pancreatic islet cell, but only in the context of an NIH-sponsored clinical trial.

**NEW MATERIAL - EFFECTIVE DATE: October 1, 2004**

**\*IMPLEMENTATION DATE: October 4, 2004**

(This revision to §260.3, and addition of §260.3.1, of Pub. 100-03 is a national coverage determination (NCD). NCDs are binding on all carriers, fiscal intermediaries, quality improvement organizations, health maintenance organizations, competitive medical plans, and health care prepayment plans. Under 42 CFR 422.256(b), an NCD that expands coverage is also binding on Medicare Advantage Organizations. In addition, an administrative law judge may not review an NCD. (See §1869(f)(1)(A)(i) of the Social Security Act.)

*Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. 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 = DELETED)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	1/Table of Contents
R	1/260.3/Pancreas Transplants (Effective July 1, 1999)
N	1/260.3.1/Islet Cell Transplantation in the Context of a Clinical Trial (Effective October 1, 2004)

## \*III. FUNDING:

These instructions shall be implemented within your current operating budget.

**IV. ATTACHMENTS:**

	<b>Business Requirements</b>
<b>X</b>	<b>Manual Instruction</b>
	<b>Confidential Requirements</b>
	<b>One-Time Notification</b>
	<b>Recurring Update Notification</b>

**\*Medicare contractors only**

# Medicare National Coverage Determinations Manual

## Chapter 1 - Coverage Determinations

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### Table of Contents

*(Rev. 18, Issued 07-30-04)*

*260.3.1 – Islet Cell Transplantation in the Context of a Clinical Trial  
(Effective October 1, 2004)*

## 260.3 - Pancreas Transplants (Effective July 1, 1999)

*(Rev. 18, Issued 07-30-04, Effective: 10-01-04, Implementation: 10-04-04)*

### *CIM 35-82*

#### *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.

*Medicare has had a long-standing policy of not covering pancreas transplantation, as the safety and effectiveness of the procedure had not been demonstrated. The Office of Health Technology Assessment performed an assessment of pancreas-kidney transplantation in 1994. It found reasonable graft survival outcomes for patients receiving either simultaneous pancreas-kidney transplantation or pancreas-after-kidney transplantation.*

#### *B. Nationally Covered Indications*

*CMS determines that whole organ pancreas transplantation will be nationally covered by Medicare only when performed simultaneous with or after a kidney transplant. If the pancreas transplant occurs after the kidney transplant, immunosuppressive therapy will begin with the date of discharge from the inpatient stay for the pancreas transplant.*

#### *C. Nationally Noncovered Indications*

*CMS determines that the following procedures are not considered reasonable and necessary within the meaning of section 1862(a)(1)(A) of the Social Security Act:*

*1. Pancreas transplantation for diabetic patients who have not experienced end-stage renal failure secondary to diabetes.*

*2. Transplantation of partial pancreatic tissue or islet cells (except in the context of a clinical trial (see section 260.3.1 of the NCD Manual)).*

#### *D. Other*

*Not applicable.*

*(This NCD last reviewed July 2004.)*

### ***260.3.1 - Islet Cell Transplantation in the Context of A Clinical Trial (Effective October 1, 2004)***

***(Rev. 18, Issued 07-30-04, Effective: 10-01-04, Implementation: 10-04-04)***

#### ***A. General***

*As a result of section 733 of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (P.L. 108-173), The Secretary of the Department of Health and Human Services, acting through the National Institute of Diabetes and Digestive and Kidney Disorders, shall conduct a clinical investigation of pancreatic islet cell transplantation that includes Medicare beneficiaries.*

*The transplant is performed on patients with Type I diabetes. A typical islet cell transplant requires over 500,000 islet cells, but varies depending on the recipient's weight. One of the desired patient outcomes is insulin independence. Elimination of clinically significant hypoglycemia episodes and improved glucose control are other important patient outcomes*

*One or more pancreata are obtained from donor(s). The islets must be removed within hours after the recovery of the donor pancreas to ensure viability. The islet cells are transplanted by injection into the portal vein of the recipient either using direct visualization, guided ultrasound or percutaneously. The islet cell transplant may be performed alone, in combination with a kidney transplant, or after a kidney transplant. Islet recipients require immunosuppressant therapy to prevent rejection of the transplanted islet cells. Routine follow-up care is necessary for each trial participant.*

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

*Medicare will pay for the routine costs, as well as transplantation and appropriate related items and services, for Medicare beneficiaries participating in a National Institutes of Health (NIH)-sponsored clinical trial(s). The term `routine costs' means reasonable and necessary routine patient care costs, including immunosuppressive drugs and other follow-up care, as defined in section 310.1 of the NCD Manual.*

*Specifically, Medicare will cover transplantation of pancreatic islet cells, the insulin producing cells of the pancreas. Coverage will include the costs of acquisition and delivery of the pancreatic islet cells, as well as clinically necessary inpatient and outpatient medical care and immunosuppressants.*

#### ***C. Nationally Noncovered Indications***

*Partial pancreatic tissue transplantation or islet cell transplantation performed outside the context of a clinical trial continues to be noncovered.*

D. Other

*Not applicable.*

*(This NCD last reviewed July 2004.)*