
CMS Manual System

Pub. 100-04 Medicare Claims Processing

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

Transmittal 261

Date: JULY 30, 2004

CHANGE REQUEST 3385

I. SUMMARY OF CHANGES: This instruction provides billing requirements for islet cell transplantation for beneficiaries in a National Institutes of Health sponsored clinical trial.

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

IMPLEMENTATION DATE: *October 4, 2004*

Disclaimer for manual changes only: The revision date and transmittal number apply only to the red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will only receive the new/revised information, 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	32/Table of Contents
N	32/70/Billing Requirements for Islet Cell Transplantation for Beneficiaries in a National Institutes of Health (NIH) Clinical Trial
N	32/70.1/Healthcare Common Procedural Coding System (HCPCS) Codes for Carriers
N	32/70.2/Applicable Modifier for Islet Cell Transplant Claims for Carriers
N	32/70.3/Special Billing and Payment Requirements for Carriers
N	32/70.4/Special Billing and Payment Requirements for Intermediaries
N	32/70.5/ Special Billing and Payment Requirements Medicare Advantage (MA) Beneficiaries

III. FUNDING: *Medicare contractors only:

These instructions should be implemented within your current operating budget.

IV. ATTACHMENTS:

X	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

Attachment - Business Requirements

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SUBJECT: Billing and Requirements for Islet Cell Transplantation for Beneficiaries in a National Institutes of Health (NIH) Clinical Trial

I. GENERAL INFORMATION

This instruction provides billing requirements for beneficiaries in an NIH clinical trial. Refer to Publication 100-03 (National Coverage Determinations Manual), section 260.3.1 for complete coverage policy.

A. Background: For services performed/discharges on or after October 1, 2004, Medicare will cover islet cell transplantation for patients with Type I diabetes who are participating in an NIH sponsored clinical trial. The islet cell transplant may be done alone or in combination with a kidney transplant. Islet recipients will also need immunosuppressive therapy to prevent rejection of the transplanted islet cells. Routine follow-up care will be necessary for each trial participant. Refer to Pub 100-03, section 310 for further guidance relative to routine care. All other uses for this service will remain non-covered.

B. Policy: Refer to the Medicare National Coverage Determinations Manual, section 260.3.1 and section 733 of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA) (P.L. 108-173).

C. Provider Education: A provider education article related to this instruction will be available at www.cms.hhs.gov/medlearn/matters shortly after the CR is released. You will receive notification of the article release via the established "medlearn matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site of the provider education article. In addition, the provider education article must be included in your next regularly scheduled bulletin.

II. BUSINESS REQUIREMENTS

"Shall" denotes a mandatory requirement

"Should" denotes an optional requirement

Requirement #	Requirements	Responsibility
3385.1	<p>The Medicare contractor and the Common Working File (CWF) shall accept the following Healthcare Procedural Coding System (HCPCS) Codes and Type of Service (TOS) for islet cell transplants effective for dates of service on and after October 1, 2004.</p> <p>G0341: Percutaneous islet cell transplant, includes portal vein catheterization and infusion</p>	<p>Carrier standard system/(local Part B carrier)/ CWF</p>

	<p>Short descriptor: Percutaneous islet cell trans</p> <p>TOS = 2</p> <p>G0342: Laparoscopy for islet cell transplant, includes portal vein catheterization and infusion</p> <p>Short descriptor: Laparoscopy islet cell trans</p> <p>TOS = 2</p> <p>G0343: Laparotomy for islet cell transplant, includes portal vein catheterization and infusion</p> <p>Short descriptor: Laparotomy islet cell transp</p> <p>TOS = 2</p>	
3385.2	The Medicare contractor shall instruct physicians to bill for NIH clinical trial Medicare beneficiaries using the appropriate procedure code and modifier QV for islet cell transplantation and routine follow up care related to this trial.	Local Part B carriers
3385.3	The new procedure codes will be paid under the Medicare Physician Fee Schedule. (Pricing information will be on the October 2004 update to the MPFSDB.)	Local Part B carriers
3385.4	Medicare contractors shall make payment on behalf of Medicare Advantage (MA) organizations directly to providers of these islet cell transplants in accordance with Medicare payment rules, except that beneficiaries are not responsible for the Part A and Part B deductibles. MA enrollees will be liable for any applicable coinsurance amounts MA organizations have in place for clinical trial benefits.	Local Part B carriers and FIs.
3385.4.1	The contractor shall apply fee-for-service payment for islet cell transplantation and appropriate related items and services for Medicare beneficiaries participating in an NIH-sponsored clinical trial.	Local Part B carriers and FIs
3385.5	The FI shall accept islet cell transplantation procedures when billed on the 11X TOB.	FIs
3385.6	The FI shall pay for islet cell transplantation (ICD-9-CM procedure code 52.85) only for IPPS hospitals participating in the trial. ICD-9-CM diagnosis code V70.7 in the second diagnosis code position. Claims for MA beneficiaries shall also include Condition Code 30, which will allow deductible to not be applied.	FIs/CWF

3385.7	Deductible and co-insurance apply for fee-for service beneficiaries.	Local Part B carriers and FIs
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III. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions: N/A

X-Ref Requirement #	Instructions

B. Design Considerations: N/A

X-Ref Requirement #	Recommendation for Medicare System Requirements

C. Interfaces: N/A

D. Contractor Financial Reporting /Workload Impact: N/A

E. Dependencies: N/A

F. Testing Considerations: N/A

IV. SCHEDULE, CONTACTS, AND FUNDING

<p>Effective Date: October 1, 2004</p> <p>Implementation Date: October 4, 2004</p> <p>Pre-Implementation Contact(s): Yvette Cousar 410-786-2160 (carrier claims processing); Sarah Shirey 410-786-0187 (FI claims processing) and Samantha Richardson 410-786-6939 (coverage policy only)</p> <p>Post-Implementation Contact(s): Appropriate regional office</p>	<p>These instructions shall be implemented within your current operating budget.</p>
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Medicare Claims Processing Manual

Chapter 32 – Billing Requirements for Special Services

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70.5 - Special Billing and Payment Requirements Medicare Advantage (MA) Beneficiaries

70 - Billing Requirements for Islet Cell Transplantation for Beneficiaries in a National Institutes of Health (NIH) Clinical Trial

(Rev. 261, Issued :07-30-04, Effective: 10-01-04, Implementation: 10-04-04)

For services performed on or after October 1, 2004, Medicare will cover islet cell transplantation for patients with Type I diabetes who are participating in an NIH sponsored clinical trial. See Pub 100-04 (National Coverage Determinations Manual) section 260.3.1 for complete coverage policy.

The islet cell transplant may be done alone or in combination with a kidney transplant. Islet recipients will also need immunosuppressant therapy to prevent rejection of the transplanted islet cells. Routine follow-up care will be necessary for each trial patient. See Pub 100-04, section 310 for further guidance relative to routine care. All other uses for service will remain non-covered.

70.1 - Healthcare Common Procedural Coding System (HCPCS) Codes for Carriers

(Rev. 261, Issued :07-30-04, Effective: 10-01-04, Implementation: 10-04-04)

G0341: Percutaneous islet cell transplant, includes portal vein catheterization and infusion

Short Descriptor: Percutaneous islet cell trans

Type of Service: 2

G0342: Laparoscopy for islet cell transplant, includes portal vein catheterization and infusion

Short Descriptor: Laparoscopy islet cell trans

Type of Service: 2

G0343: Laparotomy for islet cell transplant, includes portal vein catheterization and infusion

Short Descriptor: Laparotomy islet cell transp

Type of Service: 2

70.2 - Applicable Modifier for Islet Cell Transplant Claims for Carriers

(Rev. 261, Issued :07-30-04, Effective: 10-01-04, Implementation: 10-04-04)

Carriers shall instruct physicians to bill using the above procedure code(s) with modifier QV for all claims for islet cell transplantation and routine follow-up care related to this service.

70.3 - Special Billing and Payment Requirements for Carriers

(Rev. 261, Issued :07-30-04, Effective: 10-01-04, Implementation: 10-04-04)

Payment and pricing information will be on the October 2004 update of the Medicare Physician Fee Schedule Database (MPFSDB). Pay for islet cell transplants on the basis of the MPFS. Deductible and coinsurance apply for fee-for-service beneficiaries.

70.4 - Special Billing and Payment Requirements for Intermediaries

(Rev. 261, Issued :07-30-04, Effective: 10-01-04, Implementation: 10-04-04)

This procedure (ICD-9-CM procedure code 52.85-heterotransplantation of islet cells of pancreas) is covered for the clinical trial in an inpatient hospital setting. The applicable TOB is 11X. The second diagnosis must be V70.7 (examination of participant or control in clinical research). V70.7 alerts the claims processing system that this is a clinical trial. The procedure is paid under inpatient prospective payment system for hospitals with patients in the trial. Deductible and coinsurance apply for fee-for-service beneficiaries.

All other normal inpatient billing practices apply.

70.5 - Special Billing and Payment Requirements Medicare Advantage (MA) Beneficiaries

(Rev. 261, Issued :07-30-04, Effective: 10-01-04, Implementation: 10-04-04)

CMS will make payment directly on a fee-for service basis for the routine costs of pancreatic islet cell transplants as well as transplantation and appropriate related items and services, for MA beneficiaries participating in an NIH-sponsored clinical trial. MA organizations will not be liable for payment for routine costs of this new clinical trial until MA payments can be appropriately adjusted to take into account the cost of this national coverage decision. Medicare contractors shall make payment on behalf of MA organizations directly to providers of these islet cell transplants in accordance with Medicare payment rules, except that beneficiaries are not responsible for the Part A and Part B deductibles. MA enrollees will be liable for any applicable coinsurance amounts MA organizations have in place for clinical trial benefits.