CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 986	**Date: JUNE 16, 2006**
	Change Request 5140

Subject: Payment for Islet Cell Transplantation in NIH-Sponsored Clinical Trials

I. SUMMARY OF CHANGES: This instruction provides notification of an update of the modifier used for claims for islet cell transplantation in NIH-sponsored clinical trials. Effective for services on or after May 1, 2006, contractors shall accept claims using the QR rather than the QV modifier. The Claims Processing Manual, Publication 100-04, Chapter 32, § 70 has been updated to reflect this change.

New / Revised Material
Effective Date: May 1, 2006
Implementation Date: July 31, 2006

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: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	Chapter / Section / Subsection / Title
R	32/70/ Billing Requirements for Islet Cell Transplantation for Beneficiaries in a National Institutes of Health (NIH) Clinical Trial
R	32/70.2/Applicable Modifier for Islet Cell Transplant Claims for Carriers
R	32/70.4/Special Billing and Payment Requirements for Intermediaries

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:

Business Requirements
Manual Instruction

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

Attachment - Business Requirements

Pub. 100-04	Transmittal: 986	Date: June 16, 2006	Change Request 5140

SUBJECT: Payment for Islet Cell Transplantation in NIH-Sponsored Clinical Trials

I. GENERAL INFORMATION

A. Background: For services performed/ discharges on or after October 1, 2004, Medicare covers islet cell transplantation for patients with Type I diabetes who are participating in a NIH-sponsored clinical trial. The islet cell transplantation may be done alone or in combination with a kidney transplantation. Regarding payment for islet cell transplantation for patients participating in a clinical trial, modifier QR shall be used instead of modifier QV.

B. Policy: Refer to the Medicare National Determinations Manual, § 260.3.1 and § 733 of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA) (P.L. 108-173) and the Medicare Claims Processing Manual (Publication 100-4, Chapter 32, § 70).

II. BUSINESS REQUIREMENTS

"Shall" denotes a mandatory requirement
"Should" denotes an optional requirement

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
5140.1	Effective for services on or after May 1, 2006, contractors shall accept the QR modifier for islet cell transplantation done in conjunction with an NIH-sponsored clinical trial.			X						
5140.1.1	Effective for services on or after May 1, 2006, contractors shall not accept the QV modifier for islet cell transplantation when done in conjunction with an NIH-sponsored clinical trial.			X						
5140.1.2	Effective for services on or after May 1, 2006, contractors shall accept the QR modifier for islet cell transplantation follow up care when performed in an outpatient department of a hospital when the transplant was done in conjunction with an NIH-sponsored clinical	X								

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
	trial, and when billed on type of bill 13X or 85X.									
5140.2	Contractors shall notify providers of this change for services performed on or after May 1, 2006.	X		X						
5140.3	Contractors shall be advised and comply with these changes for islet cell transplantation mentioned in Publication 100-04, Chapter 32, § 70.2.	X		X						
5140.4	Contractors need not search their files to either retract payment for claims already paid or to retroactively pay claims. However, contractors shall adjust claims brought to their attention.			X						

III. PROVIDER EDUCATION

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
5140.5	A provider education article related to this instruction will be available at www.cms.hhs.gov/MLNMattersArticles shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within 1 week of the availability of the provider education article. In addition, the provider									

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
	education article shall be included in your next regularly scheduled bulletin and incorporated into any educational events on this topic. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.									

IV. 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

V. SCHEDULE, CONTACTS, AND FUNDING

Effective Date*: May 1, 2006 **Implementation Date:** July 31, 2006 **Pre-Implementation Contact(s):** Coverage: Susan Harrison at susan.harrison@cms.hhs.gov or 410-786-1806 Carrier: Yvette Cousar at yvette.cousar@cms.hhs.gov or 410-786-2160 Intermediary: Valeri Ritter at Valeri.ritter@cms.hhs.gov or 410-786-8652 **Post-Implementation Contact(s):** Regional Office	**No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2006 operating budgets.**

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Medicare Claims Processing Manual

Chapter 32 – Billing Requirements for Special Services

Table of Contents
(Rev.986, 06-16-06)

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

(Rev.986, Issued: 06-16-06, Effective: 05-01-06, Implementation: 07-31-06)

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 islet cell* service*s* will remain non-covered.

70.2 - Applicable Modifier for Islet Cell Transplant Claims for Carriers

(Rev.986, Issued: 06-16-06, Effective: 05-01-06, Implementation: 07-31-06)

Carriers shall instruct physicians to bill using the above procedure code(s) with modifier Q*R (Item or service provided in a Medicare-specified study)* for all claims for islet cell transplantation and routine follow-up care related to this service.

70.4 - Special Billing and Payment Requirements for Intermediaries

(Rev.986, Issued: 06-16-06, Effective: 05-01-06, Implementation: 07-31-06)

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) *along with condition code 30 (qualifying clinical trial).* V70.7 *and condition code 30* 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.

Effective for services on or after May 1, 2006, contractors shall accept the QR modifier for islet cell transplantation follow up care when performed in an outpatient department of a hospital when the transplant was done in conjunction with an NIH-sponsored clinical trial, and when billed on type of bill 13X or 85X.

All other normal inpatient billing practices apply.