CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 1192	**Date: MARCH 2, 2007**
	Change Request 5505

Subject: Payment and Billing for Islet Isolation Add-On in National Institutes of Health (NIH) Clinical Trial

I. SUMMARY OF CHANGES: 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 an NIH sponsored clinical trial. The islet cell transplant may be done alone or in combination with a kidney transplant. As part of this trial, Medicare will also pay an add-on of $18,848.00 for islet isolation services. This payment will be in addition to the final inpatient prospective payment system (IPPS) amount for this hospital stay.

New / Revised Material
Effective Date: October 1, 2004
Implementation Date: April 2, 2007

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	32/70.4/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 2007 operating budgets.

IV. ATTACHMENTS:

Recurring Update Notification

Manual Instruction

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

Attachment – Recurring Update Notification

Pub. 100-04	Transmittal: 1192	Date: March 2, 2007	Change Request: 5505

SUBJECT: Payment and Billing for Islet Isolation Add-On in National Institutes of Health (NIH) Clinical Trial

Effective Date: **October 1, 2004**

Implementation Date: April 2, 2007

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 an NIH sponsored clinical trial. The islet cell transplant may be done alone or in combination with a kidney transplant. As part of this trial, Medicare will also pay an add-on of $18,848.00 for islet isolation services. This payment will be in addition to the final inpatient prospective payment system (IPPS) amount for this hospital stay. Should two infusions occur during the same hospital stay, two add-on payments for isolation of the islet cells can be made along with the final IPPS payment.

B. Policy: Medicare will pay IPPS hospitals participating in the trial for claims billed with ICD-9-CM procedure code 52.85 (All transplantation of cells of Islets of Langerhaus) and a secondary diagnoses code (claim positions 2-9) of V70.7 (Examination of participant in clinical trial). The IPPS Pricer program will pay the add-on based on the number of times procedure code 52.85 appears (note that Medicare will not pay more than two add-ons per discharge). Hospitals participating in the trial shall report in the Organ Acquisition revenue center (0810, 0811, 0812, 0813, or 0819), charges for pre-transplant items and services related to the acquisition and delivery of pancreatic islet cell transplantation. There should not be any donor charges associated because islet cells are acquired from a cadaveric pancreas. Like other Medicare covered organ transplants, these charges are subtracted from the total charges on the claim and paid as a pass-through. Pancreata procured for islet cell transplant are not included in the IPPS payment. They are paid on a reasonable cost basis. This is a pass-through cost for which interim payments may be made.

Hospitals paid under Periodic Interim Payments (PIP) will receive this add-on in addition to their PIP payment.

Refer to Medicare National Coverage Determinations Manual (Pub. 100-03, Chapter 1, Part 4, § 260.3.1), § 733 of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA) (P.L 108-173), the August 11, 2004 Federal Register, and the Medicare Claims Processing Manual (Pub. 100-04, Chapter 32, § 70) for background.

II. BUSINESS REQUIREMENTS TABLE

Use "Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)							
		A/B	DME	FI	CAR	DME	RHH	Shared-System Maintainers	OTHER

								FISS	MCS	VMS	CWF	
5505.1	Contractors shall install and pay claims with IPPS Pricer Version 07.3. (Recurring item R20715).	X		X				X				

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A/B MAC	DME MAC	FI	CARRIER	DME RC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
5505.2	A provider education article related to this instruction will be available at http://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 one week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. 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.	X		X								

IV. SUPPORTING INFORMATION

A. For any recommendations and supporting information associated with listed requirements, use the box below:

Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
5505.1	The IPPS Pricer shall output the islet isolation add-on payment in the same field used for the new technology add-on in order to minimize claims processing system changes. The add-on will also populate Value Code 77.
5505.1	The IPPS Pricer shall ensure that only a maximum of two add-ons shall be paid per claim.
5505.1	The IPPS Pricer shall ensure that a claim can be paid either a new technology add-on or an islet isolation

X-Ref Requirement Number	Recommendations or other supporting information:
	add-on, but not both.

B. For all other recommendations and supporting information, use the space below: Note that although Medicare began covering this trial for discharges on or after October 1, 2004, patients are not expected to participate in the trial until mid-2007.

Hospitals shall locate their islet isolation add-on payment in the same field as their new technology add-on their Remittance Advice. The add-on will also be present in their final PPS payment.

V. CONTACTS

Pre-Implementation Contact(s): Sarah Shirey-Losso at (410) 786-0187

Post-Implementation Contact(s): Appropriate Regional Office

VI. FUNDING

A. *For TITLE XVIII Contractors*, use only one of the following statements:
No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2007 operating budgets.

B. *For Medicare Administrative Contractors (MAC)*, use only one of the following statements:

The contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the Statement of Work (SOW). The contractor is not obligated to incur costs in excess of the amounts specified in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

70.4 - Special Billing and Payment Requirements for Intermediaries

(Rev.1192, Issued: 03-02-07, Effective: 10-01-04, Implementation: 04-02-07)

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. *A* second*ary diagnoses (diagnoses positions 2 – 9) of* V70.7 (examination of participant or control in clinical research) *must be* present 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.

Inpatient hospitals participating in this trial are entitled to an add-on payment of $18,848.00 for islet isolation services. This amount is in addition to the final IPPS payment made to the hospital. Should two infusions occur during the same hospital stay, Medicare will pay for two add-ons for isolation of the islet cells, but never for more than two add-ons for a hospital stay.

Inpatient hospitals shall report charges for organ acquisition in Revenue Code 0810, 0811, 0812, 0813, or 0819. This includes charges for the pre-transplant items and services related to the acquisition and delivery of the pancreatic islet cell transplants. As is Medicare's policy with other organ transplants, Medicare contractors deduct acquisition charges prior to processing through the IPPS Pricer. Pancreata procured for islet cell transplant are not included in the prospective payment. They are paid on a reasonable cost basis. This is a pass-through cost for which interim payments may be made.

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.