

CMS Guidance Document	Department of Health & Human Services (DHHS)
Pub. 100-04-Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Executive Guidance Number 0057	Date: September 6, 2007
Planned Web Site Address http://www.cms.hhs.gov/manuals/	Release planned: September 20, 2007

PROGRAM AREA: Billing Transplant Services & Renal Transplantation and Related Services

SUBJECT: New Web Site for Approved Transplant Centers

APPLIES TO: Hospitals & Physicians

I. SUMMARY OF DOCUMENT: On March 30, 2007 the Department of Health and Human Services (DHHS) established regulation authorizing the survey and certification of transplant programs. The Centers for Medicare and Medicaid Services (CMS) is the Federal agency responsible for monitoring compliance with the Medicare conditions of participation. All hospital transplant programs covered by the regulation, whether currently approved by CMS or seeking initial approval, must submit a request for approval under the new regulations to CMS by December 26, 2007 (180 days from the effective date of the regulation.)

II. CHANGES IN POLICY INSTRUCTIONS:

STATUS: R=REVISED, N=NEW, D=DELETED.

Status	CHAPTER/SECTION/SUBSECTION/TITLE
R	3/90/Billing Transplant Services
R	3/90/1/Kidney Transplants-General
R	3/90/1.2/Billing for Kidney Transplants and Acquisition Services
R	3/90/2/Heart Transplants
R	3/90/4/Liver Transplants
R	3/90/4.2/Billing for Liver Transplants and Acquisition Services
R	3/90/5/Pancreas Transplants Kidney Transplants
R	3/90/5.1/Pancreas Transplant Alone (PA)
R	3/90/6/Intestinal and Multi-Visceral Transplants
R	8/120/Renal Transplantation and Related Services

III. CLEARANCES:

Clearance & Point of Contact (POC)	Name/Telephone/Component
Senior Official Clearance	Liz Richter (410)786-0550 CMM
Agency POC	Sarah Shirey-Losso (410) 786-8652 CMM/PBG/DICP

IV. TYPE (Check appropriate boxes for type of guidance)

	Audit Guide
X	Change Request
	HPMS
	Joint Signature Memorandum/Technical Director Letter
	Manual Transmittal/Non-Change Request
	State Medicaid Director Letters
	Other

V. STATUTORY OR REGULATORY AUTHORITY: All transplant hospitals will be recertified under the final rule, **Federal Register** / Vol. 72, No. 61 / Friday, March 30, 2007, / Rules and Regulations.

Attachment - Business Requirements

Pub. 100-04	Transmittal:	Date:	Change Request: 5724
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SUBJECT: New Web Site for Approved Transplant Centers

Effective Date: June 28, 2007

Implementation Date: 30 days from issuance

I. GENERAL INFORMATION

A. Background: On March 30, 2007, the Department of Health and Human Services (DHHS) established regulation authorizing the survey and certification of transplant programs. The Centers for Medicare & Medicaid Services (CMS) is the Federal agency responsible for monitoring compliance with the Medicare conditions of participation. All hospital transplant programs covered by the regulation, whether currently approved by CMS or seeking initial approval, must submit a request for approval under the new regulations to CMS by December 26, 2007, (180 days from the effective date of the regulation).

CMS will review the submitted information and conduct onsite surveys as necessary to determine compliance with the conditions of participation. Programs must be in compliance with the conditions of participation to continue Medicare approval or to receive initial approval for participation. Those programs that were already Medicare approved for participation at the time of the effective date of the regulation will continue to be covered under National Coverage Decisions or ESRD conditions for coverage (as applicable) until they are notified in writing by CMS of their approval or denial under the new regulations.

B. Policy: Effective June 28, 2007, Medicare approved transplant centers for all Medicare approved transplant programs will be listed at the following Web site:

http://www.cms.hhs.gov/CertificationandCompliance/20_Transplant.asp#TopOfPage

Medicare contractors and providers should note that the new CMS Certification Number (CCN) series 9800-9899, established via Transmittal 25 (CR 5490) of Pub. 100-07 on April 20, 2007 is not for billing. Providers are not to bill with the CCN number.

II. BUSINESS REQUIREMENTS TABLE

“Shall” denotes a mandatory requirement

Number	Requirement	Responsibility (place an “X” in each applicable column)										
		A / B M A C	D M E M A C	F I	C A R R I E R	D M E R C	R H H I	Shared-System Maintainers				OTHER
								F I S S	M C S	V M S	C W F	
5724.1	Contractors shall note that Medicare approved transplant centers can be found at the above Web site.	X		X	X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an “X” in each applicable column)										
		A / B M A C	D M E M A C	F I	C A R R I E R	D M E R C	R H I	Shared-System Maintainers				OTHER
								F I S S	M C S	V M S	C W F	
5724.2	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 1 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	X							

IV. SUPPORTING INFORMATION

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

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
5724.1	This CR shall not change Medicare Contractor processes for the processing of transplant claims.

B. For all other recommendations and supporting information, use this space: N/A

V. CONTACTS

Pre-Implementation Contact(s): Survey & Certification: Karen Tritz at (410) 786-8021; Claims Processing: Sarah Shirey-Losso at (410) 786-0187

Post-Implementation Contact(s): CMS Regional Office

VI. FUNDING

A. For Fiscal Intermediaries, Carriers, and the Durable Medical Equipment Regional Carrier (DMERC):

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):

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 allotted 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.

90 - Billing Transplant Services

(Rev.)

Medicare covers the following organ transplants: kidney, heart, lung, heart/lung, liver, pancreas, pancreas/kidney, and intestinal/multi-visceral. Medicare also covers stem cell transplants for certain conditions.

On March 30, 2007, the Department of Health and Human Services (DHHS) established a regulation authorizing the survey and certification of organ transplant programs. The Centers for Medicare & Medicaid Services (CMS) is the Federal agency responsible for monitoring compliance with the Medicare conditions of participation. All hospital transplant programs covered by the regulation (does not include stem cell transplants), whether currently approved by CMS or seeking initial approval, must submit a request for approval under the new regulations to CMS by December 26, 2007 (180 days from the effective date of the regulation.)

http://www.cms.hhs.gov/CertificationandCompliance/20_Transplant.asp#TopOfPage

Transplant hospitals should review the above Web site and send applications to the following address:

*Centers for Medicare and Medicaid Services
Survey and Certification Group
7500 Security Blvd.
Mailstop: S2-12-25
Baltimore, MD 21244*

90.1 - Kidney Transplant - General

(Rev.)

A3-3612, HO-E414

A major treatment for patients with ESRD is kidney transplantation. This involves removing a kidney, usually from a living relative of the patient or from an unrelated person who has died, and surgically placing the kidney into the patient. After the beneficiary receives a kidney transplant, Medicare pays the transplant hospital for the transplant and appropriate standard acquisition charges. Special provisions apply to payment. *For the list of approved Medicare certified transplant facilities, refer to the following Web site:*

http://www.cms.hhs.gov/CertificationandCompliance/20_Transplant.asp#TopOfPage

A transplant hospital may acquire cadaver kidneys by:

- Excising kidneys from cadavers in its own hospital; and

- Arrangements with a freestanding organ procurement organization (*OPO*) that provides cadaver kidneys to any transplant hospital *or by a hospital based OPO*.

A transplant hospital that is also a certified organ procurement organization may acquire cadaver kidneys by:

- Having its organ procurement team excise kidneys from cadavers in other hospitals;
- Arrangements with participating community hospitals, whether they excise kidneys on a regular or irregular basis; and
- Arrangements with an organ procurement organization that services the transplant hospital as a member of a network.

When the transplant hospital also excises the cadaver kidney, the cost of the procedure is included in its kidney acquisition costs and is considered in arriving at its standard cadaver kidney acquisition charge. When the transplant hospital excises a kidney to provide another hospital, it may use its standard cadaver kidney acquisition charge or its standard detailed departmental charges to bill that hospital.

When the excising hospital is not a transplant hospital, it bills its customary charges for services used in excising the cadaver kidney to the transplant hospital or organ procurement agency.

If the transplanting hospital's organ procurement team excises the cadaver kidney at another hospital, the cost of operating such a team is included in the transplanting hospital's kidney acquisition costs, along with the reasonable charges billed by the other hospital of its services.

90.1.2 - Billing for Kidney Transplant and Acquisition Services **(Rev.)**

Applicable standard kidney acquisition charges are identified separately in FL 42 by revenue code 0811 (Living Donor Kidney Acquisition) or 0812 (Cadaver Donor Kidney Acquisition). Where interim bills are submitted, the standard acquisition charge appears on the billing form for the period during which the transplant took place. This charge is in addition to the hospital's charges for services rendered directly to the Medicare recipient.

The *contractor* deducts kidney acquisition charges for PPS hospitals for processing through Pricer. These costs, incurred by approved kidney transplant hospitals, are **not** included in the prospective payment DRG 302 (kidney transplant). They are paid on a reasonable cost basis. Interim payment is paid as a "pass through" item. (See the Provider Reimbursement Manual, Part 1, §2802 B.8.) The *contractor* includes kidney acquisition charges under the appropriate revenue code in CWF.

Bill Review Procedures

The Medicare Code Editor (MCE) creates a Limited Coverage edit for procedure code 55.69 (kidney transplant). Where this procedure code is identified by MCE, the contractor checks the provider number to determine if the provider is an approved transplant center, and checks the effective approval date. The contractor shall also determine if the facility is certified for adults and/or pediatric transplants dependent upon the patient's age. If payment is appropriate (i.e., the center is approved and the service is on or after the approval date) it overrides the limited coverage edit.

90.2 - Heart Transplants **(Rev.)**

A3-3613, HO-416

Cardiac transplantation is covered under Medicare when performed in a facility which is approved by Medicare as meeting institutional coverage criteria. On April 6, 1987, CMS Ruling 87-1, "Criteria for Medicare Coverage of Heart Transplants" was published in the "Federal Register." For Medicare coverage purposes, heart transplants are medically reasonable and necessary when performed in facilities that meet these criteria. If a hospital wishes to bill Medicare for heart transplants, it must submit an application and documentation, showing its ongoing compliance with each criterion.

If a **contractor** has any questions concerning the effective or approval dates of its hospitals, it should contact its RO.

For a complete list of **approved** transplant centers, visit:

http://www.cms.hhs.gov/CertificationandCompliance/20_Transplant.asp#TopOfPage

A. Effective Dates

The effective date of coverage for heart transplants performed at facilities applying after July 6, 1987, is the date the facility receives approval as a heart transplant facility. Coverage is effective for discharges October 17, 1986 for facilities that would have qualified and that applied by July 6, 1987. *All transplant hospitals will be recertified under the final rule, **Federal Register** / Vol. 72, No. 61 / Friday, March 30, 2007, / Rules and Regulations.*

The CMS informs each hospital of its effective date in an approval letter.

B. Drugs

Medicare Part B covers immunosuppressive drugs following a covered transplant in an approved facility.

C. Noncovered Transplants

Medicare will **not** cover transplants or re-transplants in facilities that have not been approved as meeting the facility criteria. If a beneficiary is admitted for and receives a heart transplant from a hospital that is not approved, physicians' services, and inpatient services associated with the transplantation procedure are not covered.

If a beneficiary received a heart transplant from a hospital while it was not an approved facility and later requires services as a result of the noncovered transplant, the services are covered when they are reasonable and necessary in all other respects.

D. Charges for Heart Acquisition Services

The excising hospital bills the *OPO, who in turn bills* the transplant (implant) hospital for applicable services. It should not submit a bill to *its contractor*. The transplant hospital must keep an itemized statement that identifies the services rendered, the charges, the person receiving the service (donor/recipient), and whether this person is a potential transplant donor or recipient. These charges are reflected in the transplant hospital's heart acquisition cost center and are used in determining its standard charge for acquiring a donor's heart. The standard charge is not a charge representing the acquisition cost of a specific heart; rather, it reflects the average cost associated with each type of heart acquisition. Also, it is an all inclusive charge for all services required in acquisition of a heart, i.e., tissue typing, post-operative evaluation, etc.

E. Bill Review Procedures

The *contractor* takes the following actions to process heart transplant bills. It may accomplish them manually or modify its MCE and Grouper interface programs to handle the processing.

1. Change *in* MCE Interface

The MCE creates a Limited Coverage edit for procedure code 37.51 (heart transplant). Where this procedure code is identified by MCE, the *contractor* checks the provider number to determine if the provider is an approved transplant center, and checks the effective approval date. *The contractor shall also determine if the facility is certified for adults and/or pediatric transplants dependent upon the patient's age.* If payment is appropriate (i.e., the center is approved and the service is on or after the approval date) it overrides the limited coverage edit.

2. Handling Heart Transplant Billings From Nonapproved Hospitals

Where a heart transplant and covered services are provided by a nonapproved hospital, the bill data processed through Grouper and Pricer must exclude transplant procedure codes and related charges.

90.4 - Liver Transplants

(Rev.)

A. Background

For Medicare coverage purposes, liver transplants are considered medically reasonable and necessary for specified conditions when performed in facilities that meet specific criteria.

To review the current list of approved Liver Transplant Centers, see http://www.cms.hhs.gov/CertificationandCompliance/20_Transplant.asp#TopOfPage

90.4.2 - Billing for Liver Transplant and Acquisition Services

(Rev.)

Form CMS-1450 or its electronic equivalent is completed, in accordance with instructions in Chapter 25 for the beneficiary who receives a covered liver transplant. Applicable standard liver acquisition charges are identified separately in FL 42 by revenue code 0817 (Donor-Liver). Where interim bills are submitted, the standard acquisition charge appears on the billing form for the period during which the transplant took place. This charge is in addition to the hospital's charge for services furnished directly to the Medicare recipient.

The **contractor** deducts liver acquisition charges for **IPPS** hospitals prior to processing through Pricer. Costs of liver acquisition incurred by approved liver transplant facilities are **not** included in prospective payment DRG 480 (Liver Transplant). They are paid on a reasonable cost basis. This item is a "pass-through" cost for which interim payments are made. (See the Provider Reimbursement Manual, Part 1, §2802 B.8.) The **contractor** includes liver acquisition charges under revenue code 0817 in the HUIP record that it sends to CWF and the QIO.

A. Bill Review Procedures

The **contractor** takes the following actions to process liver transplant bills.

1. Operative Report

The **contractor** requires the operative report with all claims for liver transplants, or sends a development request to the hospital for each liver transplant with a diagnosis code for a covered condition.

2. MCE Interface

The MCE creates *a limited coverage edit* for procedure codes 50.51 and 50.59 (liver transplant). Where one of these procedure codes is identified by the MCE, the *contractor shall* check the provider number and effective date to determine if the provider is an approved liver transplant facility at the time of the transplant, *and the contractor shall also determine if the facility is certified for adults and/or pediatric transplants dependent upon the patient's age*. If yes, the claim is suspended for review of the operative report to determine whether the beneficiary has at least one of the covered conditions when the diagnosis code is for a covered condition. If payment is appropriate (i.e., the facility is approved, the service is furnished on or after the approval date, and the beneficiary has a covered condition), the *contractor* sends the claim to Grouper and Pricer.

If none of the diagnoses codes are for a covered condition, or if the provider is not an approved liver transplant facility, the *contractor* denies the claim.

NOTE: Some non-covered conditions are included in the covered diagnostic codes. (The diagnostic codes are broader than the covered conditions. For example, primary biliary cirrhosis is a covered condition, secondary biliary cirrhosis is not a covered condition. Both primary and secondary biliary cirrhosis have the same **diagnosis** code ICD 9 571.6) Do not pay for noncovered conditions.

3. Grouper

If the bill shows a discharge date before March 8, 1990, the procedure is not covered. If the discharge date is March 8, 1990 or later, the *contractor* processes the bill through Grouper and Pricer. If the discharge date is after March 7, 1990, and before October 1, 1990, Grouper assigns DRG 191 or 192. The *contractor* sends the bill to Pricer with review code 08. Pricer overlays DRG 191 or 192 with DRG 480 and the weights and thresholds for DRG 480 to price the bill. If the discharge date is after September 30, 1990, Grouper assigns DRG 480 and Pricer is able to price without using review code 08.

4. Liver Transplant Billing From Non-approved Hospitals

Where a liver transplant and covered services are provided by a non-approved hospital, the bill data processed through Grouper and Pricer must exclude transplant procedure codes and related charges.

When CMS approves a hospital to furnish liver transplant services, it informs the hospital of the effective date in the approval letter. The *contractor* will receive a copy of the letter.

90.5 - Pancreas Transplants Kidney Transplants (Rev.)

A. Background

Effective July 1, 1999, Medicare covered pancreas transplantation when performed simultaneously with or following a kidney transplant (ICD-9-CM procedure code 55.69). 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 policy of not covering pancreas transplantation. The Office of Health Technology Assessment performed an assessment on pancreas-kidney transplantation in 1994. They found reasonable graft survival outcomes for patients receiving either simultaneous pancreas-kidney (SPK) transplantation or pancreas after kidney (PAK) transplantation. *For a list of facilities approved to perform SPK or PAK, refer to the following Web site:*
http://www.cms.hhs.gov/CertificationandCompliance/20_Transplant.asp#TopOfPage

B. Billing for Pancreas Transplants

There are no special provisions related to managed care participants. Managed care plans are required to provide all Medicare covered services. Medicare does not restrict which hospitals or physicians may perform pancreas transplantation.

The transplant procedure and revenue code 0360 for the operating room are paid under these codes. Procedures must be reported using the current ICD-9-CM procedure codes for pancreas and kidney transplants. Providers must place at least one of the following transplant procedure codes on the claim:

- 52.80 Transplant of pancreas
- 52.82 Homotransplant of pancreas

The Medicare Code Editor (MCE) has been updated to include 52.80 and 52.82 as *limited coverage* procedures. *The contractor must determine if the facility is approved for the transplant and certified for either pediatric or adult transplants dependent upon the age of the patient.*

Effective October 1, 2000, ICD-9-CM code 52.83 was moved in the MCE to non-covered. The *contractor* must override any deny edit on claims that came in with 52.82 prior to October 1, 2000 and adjust, as 52.82 is the correct code.

If the discharge date is July 1, 1999, or later: the *contractor* processes the bill through Grouper and Pricer.

Pancreas transplantation is reasonable and necessary for the following diagnosis codes. However, since this is not an all-inclusive list, the contractor is permitted to determine if any additional diagnosis codes will be covered for this procedure.

Diabetes Diagnosis Codes

250.00	Diabetes mellitus without mention of complication, type II (non-insulin dependent) (NIDDM) (adult onset) or unspecified type, not stated as uncontrolled.
250.01	Diabetes mellitus without mention of complication, type I (insulin dependent) (IDDM) (juvenile), not stated as uncontrolled.
250.02	Diabetes mellitus without mention of complication, type II (non-insulin dependent) (NIDDM) (adult onset) or unspecified type, uncontrolled.
250.03	Diabetes mellitus without mention of complication, type I (insulin dependent) (IDDM) (juvenile), uncontrolled.
250.1X	Diabetes with ketoacidosis
250.2X	Diabetes with hyperosmolarity
250.3X	Diabetes with coma
250.4X	Diabetes with renal manifestations
250.5X	Diabetes with ophthalmic manifestations
250.6X	Diabetes with neurological manifestations
250.7X	Diabetes with peripheral circulatory disorders
250.8X	Diabetes with other specified manifestations
250.9X	Diabetes with unspecified complication

NOTE: X=0-3

- Hypertensive Renal Diagnosis Codes:

403.01	Malignant hypertensive renal disease, with renal failure
403.11	Benign hypertensive renal disease, with renal failure
403.91	Unspecified hypertensive renal disease, with renal failure
404.02	Malignant hypertensive heart and renal disease, with renal failure
404.03	Malignant hypertensive heart and renal disease, with congestive heart failure or renal failure
404.12	Benign hypertensive heart and renal disease, with renal failure
404.13	Benign hypertensive heart and renal disease, with congestive heart failure or renal failure
404.92	Unspecified hypertensive heart and renal disease, with renal failure
404.93	Unspecified hypertensive heart and renal disease, with congestive heart failure or renal failure
585.1 - 585.6, 585.9	Chronic Renal Failure Code

NOTE: If a patient had a kidney transplant that was successful, the patient no longer has chronic kidney failure, therefore it would be inappropriate for the provider to bill 585.1 - 585.6, 585.9 on such a patient. In these cases one of the following V-codes should be present on the claim or in the beneficiary's history.

The provider uses the following V-codes only when a kidney transplant was performed before the pancreas transplant:

V42.0 Organ or tissue replaced by transplant kidney

V43.89 Organ tissue replaced by other means, kidney or pancreas

NOTE: If a kidney and pancreas transplants are performed simultaneously, the claim should contain a diabetes diagnosis code and a renal failure code or one of the hypertensive renal failure diagnosis codes. The claim should also contain two transplant procedure codes. If the claim is for a pancreas transplant only, the claim should contain a diabetes diagnosis code and a V-code to indicate a previous kidney transplant. If the V-code is not on the claim for the pancreas transplant, the *contractor* will search the beneficiary's claim history for a V-code.

C. Drugs

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.

D. Charges for Pancreas Acquisition Services

A separate organ acquisition cost center has been established for pancreas transplantation. The Medicare cost report will include a separate line to account for pancreas transplantation costs. The 42 CFR 412.2(e)(4) was changed to include pancreas in the list of organ acquisition costs that are paid on a reasonable cost basis.

Acquisition costs for pancreas transplantation as well as kidney transplants will occur in Revenue Center 081X. The *contractor* overrides any claims that suspend due to repetition of revenue code 081X on the same claim if the patient had a simultaneous kidney/pancreas transplant. It pays for acquisition costs for both kidney and pancreas organs if transplants are performed simultaneously. It will not pay for more than two organ acquisitions on the same claim.

E. Medicare Summary Notices (MSN) and Remittance Advice Messages

If the provider submits a claim for simultaneous pancreas kidney transplantation or pancreas transplantation following a kidney transplant, and omits one of the appropriate diagnosis/procedure codes, the *contractor* rejects the claim, using the following MSN:

- MSN 16.32, "Medicare does not pay separately for this service."
- Use the following Remittance Advice Message:
 - Claim adjustment reason code B15, "Claim/service denied/reduced because this procedure or service is not paid separately."

- If a claim is denied because no evidence of a prior kidney transplant is presented, use the following MSN message:

- MSN 15.4, "The information provided does not support the need for this service or item."

The contractor uses the following Remittance Advice Message:

- Claim adjustment reason code 50, "These are non-covered services because this is not deemed a 'medical necessity' by the payer."

To further clarify the situation, the contractor should also use new claim level remark code MA 126, "Pancreas transplant not covered unless kidney transplant performed."

90.5.1 – Pancreas Transplants Alone (PA)

(Rev.)

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 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. Billing and Claims Processing

Contractors shall pay for Pancreas Transplantation Alone (PA) effective for services on or after April 26, 2006 when performed in those facilities that are Medicare-approved for kidney transplantation. Approved facilities are located at the following address:

http://www.cms.hhs.gov/CertificationandCompliance/20_Transplant.asp#TopOfPage

Contractors who receive claims for PA services that were performed in an unapproved facility, should reject such claims. **Contractors** should use the following messages upon the reject or denial:

Medicare Summary Notice MSN Message - MSN code 16.2 (This service cannot be paid when provided in this location/facility)

Remittance Advice Message - Claim Adjustment Reason Code 58 (Payment adjusted because treatment was deemed by the payer to have been rendered in an inappropriate or invalid place of service)

Payment will be made for a PA service performed in an approved facility, and which meets the coverage guidelines mentioned above for beneficiaries with type I diabetes.

All-Inclusive List of Covered ICD-9 CM Diagnosis Codes for PA

(NOTE: “X” = 1 and 3 only)

250.0X	Diabetes mellitus without mention of complication, type I (insulin dependent) (IDDM) (juvenile), not stated as uncontrolled.
250.1X	Diabetes with ketoacidosis
250.2X	Diabetes with hyperosmolarity
250.3X	Diabetes with coma
250.4X	Diabetes with renal manifestations
250.5X	Diabetes with ophthalmic manifestations
250.6X	Diabetes with neurological manifestations
250.7X	Diabetes with peripheral circulatory disorders
250.8X	Diabetes with other specified manifestations
250.9X	Diabetes with unspecified complication

Procedure Codes

ICD-9 CM

52.80 - Transplant of pancreas

52.82 - Homotransplant of pancreas

Contractors who receive claims for PA that are not billed using the covered diagnosis/procedure codes listed above *shall reject* such claims. *The MCE edits to ensure that the transplant is covered based on the diagnosis. The MCE also considers 52.80 and 52.82 as limited coverage dependent upon whether the facility is approved to perform the transplant and is certified for the age of the patient.* **Contractors** should use the following messages upon the reject or denial:

Medicare Summary Notice MSN Message - MSN code 15.4 (The information provided does not support the need for this service or item)

Remittance Advice Message - Claim Adjustment Reason Code 50 (These are non-covered services because this is not deemed a 'medical necessity' by the payer).

Contractors shall hold the provider liable for denied/rejected claims unless the hospital issues a Hospital Issued Notice of Non-coverage (HINN) or a physician issues an Advanced Beneficiary Notice (ABN) for Part-B for physician services.

90.6 - Intestinal and Multi-Visceral Transplants

(Rev.)

A. Background

Effective for services on or after April 1, 2001, Medicare covers intestinal and multi-visceral transplantation for the purpose of restoring intestinal function in patients with irreversible intestinal failure. Intestinal failure is defined as the loss of absorptive capacity of the small bowel secondary to severe primary gastrointestinal disease or surgically induced short bowel syndrome. Intestinal failure prevents oral nutrition and may be associated with both mortality and profound morbidity. Multi-Visceral transplantation includes organs in the digestive system (stomach, duodenum, liver, and intestine). See §260.5 of the National Coverage Determinations Manual for further information.

B. Approved Transplant Facilities

Medicare will cover intestinal transplantation if performed in an approved facility. The approved facilities are located at:

http://www.cms.hhs.gov/CertificationandCompliance/20_Transplant.asp#TopOfPage

C. Billing

ICD-9-CM procedure code 46.97 is effective for discharges on or after April 1, 2001. The Medicare Code Editor (MCE) lists this code *as a limited coverage* procedure. The *contractor shall* override the MCE when this procedure code is listed and the coverage criteria are met in an approved transplant facility, *and also determine if the facility is certified for adults and/or pediatric transplants dependent upon the patient's age.*

For this procedure where the provider is approved as transplant facility and *certified for the adult and/or pediatric population*, and the service is performed on or after the transplant approval date, the *contractor* must suspend the claim for clerical review of the operative report to determine whether the beneficiary has at least one of the covered conditions listed when the diagnosis code is for a covered condition.

This review is not part of the *contractor's* medical review workload. Instead, the *contractor* should complete this review as part of its claims processing workload.

Charges for ICD-9-CM procedure code 46.97 should be billed under revenue code 0360, Operating Room Services.

For discharge dates on or after October 1, 2001, acquisition charges are billed under revenue code 081X, Organ Acquisition. For discharge dates between April 1, 2001, and September 30, 2001, hospitals were to report the acquisition charges on the claim, but there was no interim pass-through payment made for these costs.

Bill the procedure used to obtain the donor's organ on the same claim, using appropriate ICD-9-CM procedure codes.

The 11X bill type should be used when billing for intestinal transplants.

Immunosuppressive therapy for intestinal transplantation is covered and should be billed consistent with other organ transplants under the current rules.

There is no specific ICD-9-CM diagnosis code for intestinal failure. Diagnosis codes exist to capture the causes of intestinal failure. Some examples of intestinal failure include, but are not limited to:

- Volvulus 560.2,
- Volvulus gastroschisis 756.79, other [congenital] anomalies of abdominal wall,
- Volvulus gastroschisis 569.89, other specified disorders of intestine,
 - o Necrotizing enterocolitis 777.5, necrotizing enterocolitis in fetus or newborn,
 - o Necrotizing enterocolitis 014.8, other tuberculosis of intestines, peritoneum, and mesenteric,
 - o Necrotizing enterocolitis and splanchnic vascular thrombosis 557.0, acute vascular insufficiency of intestine,
 - o Inflammatory bowel disease 569.9, unspecified disorder of intestine,
 - o Radiation enteritis 777.5, necrotizing enterocolitis in fetus or newborn, and
 - o Radiation enteritis 558.1.

D. Acquisition Costs

A separate organ acquisition cost center was established for acquisition costs incurred on or after October 1, 2001. The Medicare Cost Report will include a separate line to account for these transplantation costs. For intestinal and multi-visceral transplants performed between April 1, 2001, and October 1, 2001, the DRG payment was payment in full for all hospital services related to this procedure.

E. Medicare Summary Notices (MSN), Remittance Advice Messages, and Notice of Utilization Notices (NOU)

If an intestinal transplant is billed by an unapproved facility after April 1, 2001, the *contractor shall* deny the claim and use MSN message 21.6, "This item or service is not covered when performed, referred, or ordered by this provider;" 21.18, "This item or service is not covered when performed or ordered by this provider;" or, 16.2, "This service cannot be paid when provided in this location/facility;" and Remittance Advice Message, Claim Adjustment Reason Code 52, "The referring/prescribing/rendering provider is not eligible to refer/prescribe/order/perform the service billed."

120 - Renal Transplantation and Related Services

(Rev.)

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Renal transplantation is a principal form of treatment available to patients with end-stage renal disease. See Medicare Provider Reimbursement Manual, Part I, §§2771, for a description of related payment policies. *For a list of approved facilities, refer to the following Web site:*

http://www.cms.hhs.gov/CertificationandCompliance/20_Transplant.asp#TopOfPage