PANCREAS TRANSPLANTS (NCD 260.3)

Guideline Number: MPG232.04
Approval Date: June 13, 2018

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POLICY SUMMARY

Overview
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. Pancreas transplantation is sometimes performed on patients with hypoglycemic unawareness and labile diabetes.

Guidelines
Nationally Covered Indications
Whole organ pancreas transplantation is nationally covered by Medicare when performed simultaneous with or after a kidney transplant. If the pancreas transplant occurs after the kidney transplant, immunosuppressive therapy begins with the date of discharge from the inpatient stay for the pancreas transplant.

Pancreas transplants alone (PA) are reasonable and necessary for Medicare beneficiaries in the following limited circumstances:

- PA will be limited to those facilities that are Medicare-approved for kidney transplantation. Approved centers can be found at Approved Transplant Programs
- Patients must have a diagnosis of type I diabetes:
  - Patient with diabetes must be beta cell autoantibody positive; or
  - Patient must demonstrate insulinopenia defined as a fasting C-peptide level that is less than or equal to 110% of the lower limit of normal of the laboratory's measurement method. Fasting C-peptide levels will only be considered valid with a concurrently obtained fasting glucose ≤ 225 mg/dL;
- Patients must have been optimally and intensively managed by an endocrinologist for at least 12 months with the most medically-recognized advanced insulin formulations and delivery systems;
- Patients must have a history of medically-uncontrollable labile (brittle) insulin-dependent diabetes mellitus with documented recurrent, severe, acutely life-threatening metabolic complications that require hospitalization. Aforementioned complications include frequent hypoglycemia unawareness or recurring severe ketoacidosis, or recurring severe hypoglycemic attacks;
- Patients must have the emotional and mental capacity to understand the significant risks associated with surgery and to effectively manage the lifelong need for immunosuppression; and,
- Patients must otherwise be a suitable candidate for transplantation.

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 status code to indicate a previous kidney transplant. If the status code is not on the claim for the pancreas transplant, UnitedHealthcare will search the beneficiary's claim history for a status code indicating a prior kidney transplant.

Nationally Non-Covered Indications
The following procedure is not considered reasonable and necessary within the meaning of section 1862(a)(1)(A) of the Social Security Act:
- Transplantation of partial pancreatic tissue or islet cells (except in the context of a clinical trial, see section 260.3.1 of the National Coverage Determinations Manual).

**APPLICABLE CODES**

The following list(s) of codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

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<th>CPT Code</th>
<th>Description</th>
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<tr>
<td>48160</td>
<td>Pancreatectomy, total or subtotal, with autologous transplantation of pancreas or pancreatic islet cells (Not covered by Medicare)</td>
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<tr>
<td>48554</td>
<td>Transplantation of pancreatic allograft (CMS sourced)</td>
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**PURPOSE**

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers’ submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:
- Medicare coding or billing requirements, and/or
- Medical necessity coverage guidelines; including documentation requirements.

UnitedHealthcare follows Medicare guidelines such as LCDs, NCDs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the References section below to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

**REFERENCES**

**CMS National Coverage Determinations (NCDs)**
- NCD 260.3 Pancreas Transplants

**CMS Claims Processing Manual**
- Chapter 3, § 90.5 Pancreas Transplants with Kidney Transplants, § 90.5.1 Pancreas Transplants Alone (PA)

**CMS Transmittals**
- Transmittal 56, Change Request 5093, Dated 05/19/2006 (Pancreas Transplants Alone (PA))
- Transmittal 957, Change Request 5093, Dated 05/16/2006 (Pancreas Transplants Alone (PA))
- Transmittal 471, Dated 04/01/2016 (Chapter 31, Organ Acquisition Payment Policy)

**MLN Matters**
- Article MM5093, Pancreas Transplants Alone (PA)
- Article SE1608, Updates to Medicare's Organ Acquisition and Donation Payment Policy

**UnitedHealthcare Commercial Policies**
- Omnibus Codes

**Others**
- CMS Transplant - Laws and Regulations, CMS Website
GUIDELINE HISTORY/REVISION INFORMATION

Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

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<tr>
<th>Date</th>
<th>Action/Description</th>
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<tbody>
<tr>
<td>04/01/2019</td>
<td>Reorganized policy template; relocated Terms and Conditions and Purpose section</td>
</tr>
<tr>
<td>06/13/2018</td>
<td>Annual review</td>
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<tr>
<td></td>
<td>Updated CPT codes; removed codes 48550, 48551 and 48552</td>
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TERMS AND CONDITIONS

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document* and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication, and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

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*For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the Administrative Guide.