

Islet Cell Transplantation in the Context of a Clinical Trial (NCD 260.3.1)

Guideline Number: MPG180.07

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[↪ Terms and Conditions](#)

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Related Medicare Advantage Coverage Summaries

- [Experimental Procedures and Items, Investigational Devices and Clinical Trials](#)
- [Transplants: Organ and Tissue Transplants](#)

Policy Summary

[↪ See Purpose](#)

Overview

The Secretary of the Department of Health and Human Services, acting through the National Institute of Diabetes and Digestive and Kidney Disorders, shall conduct a clinical investigation of pancreatic islet cell transplantation that includes Medicare beneficiaries (Section 733 of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (P.L. 108-173))

The transplant is performed on patients with Type I diabetes. One of the desired patient outcomes is insulin independence. A typical islet cell transplant requires over 500,000 islet cells, but varies depending on the recipient’s weight. Elimination of clinically significant hypoglycemia episodes and improved glucose control are other important patient outcomes.

One or more pancreata are obtained from donor(s). The islets must be removed within hours after the recovery of the donor pancreas to ensure viability. The islet cells are transplanted by injection into the portal vein of the recipient either using direct visualization, guided ultrasound or percutaneously. The islet cell transplant may be performed alone, in combination with a kidney transplant, or after a kidney transplant.

Islet recipients require immunosuppressant therapy to prevent rejection of the transplanted islet cells. Routine follow-up care is necessary for each trial participant.

Guidelines

Nationally Covered Indications

The term 'routine costs' means reasonable and necessary routine patient care costs, including immunosuppressive drugs and other follow-up care, as defined in section 310.1 of the NCD Manual. Medicare will pay for the routine costs, as well as transplantation and appropriate related items and services, for Medicare beneficiaries participating in a National Institutes of Health (NIH)-sponsored clinical trial(s).

Medicare will cover transplantation of pancreatic islet cells, the insulin producing cells of the pancreas. Coverage will include the costs of acquisition and delivery of the pancreatic islet cells, as well as clinically necessary inpatient and outpatient medical care and immunosuppressants.

Nationally Noncovered Indications

Partial pancreatic tissue transplantation or islet cell transplantation performed outside the context of a clinical trial continues to be noncovered.

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.

HCPCS Code	Description
G0341	Percutaneous islet cell transplant, includes portal vein catheterization and infusion
G0342	Laparoscopy for islet cell transplant, includes portal vein catheterization and infusion
G0343	Laparotomy for islet cell transplant, includes portal vein catheterization and infusion

Modifier	Description
Q0	Investigational clinical service provided in an approved clinical research study

ICD Procedure Code	Description
3E030U1	Introduction of nonautologous pancreatic islet cells into peripheral vein, open approach
3E033U1	Introduction of nonautologous pancreatic islet cells into peripheral vein, percutaneous approach
3E0J3U1	Introduction of nonautologous pancreatic islet cells into biliary and pancreatic tract, percutaneous approach
3E0J7U1	Introduction of nonautologous pancreatic islet cells into biliary and pancreatic tract, via natural or artificial opening
3E0J8U1	Introduction of nonautologous pancreatic islet cells into biliary and pancreatic tract, via natural or artificial opening endoscopic

References

CMS National Coverage Determinations (NCDs)

[NCD 260.3.1 Islet Cell Transplantation in the Context of a Clinical Trial](#)

Reference NCD: [NCD 310.1 Routine Costs in Clinical Trials](#)

CMS Claims Processing Manual

[Chapter 32: § 70 Billing Requirements for Islet Cell Transplantation for Beneficiaries in a National Institutes of Health \(NIH\) Clinical Trial](#)

CMS Transmittal(s)

[Transmittal 1798, Change Request 9982, Dated 02/17/2017 \(ICD-10 Coding Revisions to National Coverage Determinations \(NCDs\)\)](#)

[Transmittal 2955, Change Request 8401, Dated 05/14/2014 \(Mandatory Reporting of an 8-Digit Clinical Trial Number on Claims\)](#)

UnitedHealthcare Commercial Policies

[Clinical Trials](#)

[Omnibus Codes](#)

Other(s)

[ClinicalTrials.gov](https://clinicaltrials.gov), [U.S. National Library of Medicine](https://www.nlm.nih.gov)

[National Institutes of Health: National Diabetes Information Clearinghouse for Pancreatic Islet Transplantation](https://www.niddk.nih.gov), [NIDDK Website](https://www.niddk.nih.gov)

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.

Date	Summary of Changes
04/01/2021	Template Update <ul style="list-style-type: none">Reformatted policy; transferred content to new template
06/10/2020	Supporting Information <ul style="list-style-type: none">Updated <i>References</i> section to reflect the most current informationArchived previous policy version MPG180.06

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 NCDs, LCDs, LCAs, 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.

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.

Medicare Advantage Policy Guidelines are the property of UnitedHealthcare. Unauthorized copying, use, and distribution of this information are strictly prohibited.

*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](#).