

02-40000-21

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## Subject: Islet Transplantation

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

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### DESCRIPTION:

The islets of Langerhans in the glandular tissue of the pancreas contain alpha, beta, and delta cells. Beta cells secrete insulin and are used in islet cell transplantation. Transplantation of autologous (individual's own pancreas) beta cells is performed for individuals undergoing total or near total pancreatectomy for severe, chronic pancreatitis that is refractory to medical therapy. Transplantation of allogeneic (deceased donor pancreas) beta cells has been proposed for those with type I diabetes with frequent and severe metabolic complications, who have consistently failed to achieve control with insulin based management.

In autologous islet transplantation during the pancreatectomy procedure, islet cells are isolated from the resected pancreas using enzymes, and a suspension of the cells is injected into the portal vein of the liver. Once implanted, the beta cells in these islets begin to make and release insulin.

In allogeneic islet cell transplantation, cells are harvested from a deceased donor's pancreas, processed, and injected into the recipient's portal vein. Up to three donor pancreas transplants may be required to achieve insulin independence.

### POSITION STATEMENT:

#### Certificate of Medical Necessity

Submit a completed Certificate of Medical Necessity (CMN) along with your request to expedite the medical review process.

1. Click the link Solid Organ Transplant under Certificates of Medical Necessity in the side navigation of this page to access the form.

2. Complete all fields on the form thoroughly.
3. Print and submit a copy of the form with your request.

Note: Florida Blue regularly updates CMNs. Ensure you are using the most current copy of a CMN before submitting to Florida Blue.

Autologous pancreas islet cell transplantation **meets the definition of medical necessity** as an adjunct to a total or near total pancreatectomy in individuals with chronic pancreatitis.

Islet cell transplantation is considered **experimental or investigational** for all other conditions. Data in published medical literature are inadequate to permit scientific conclusions on long-term and net health outcomes.

## BILLING/CODING INFORMATION:

### CPT Coding:

48160	Pancreatectomy, total or subtotal, with autologous transplantation of pancreas or pancreatic islets
0584T	Islet cell transplant, includes portal vein catheterization and infusion, including all imaging, including guidance, and radiological supervision and interpretation, when performed; percutaneous
0585T	Islet cell transplant, includes portal vein catheterization and infusion, including all imaging, including guidance, and radiological supervision and interpretation, when performed; laparoscopic
0586T	Islet cell transplant, includes portal vein catheterization and infusion, including all imaging, including guidance, and radiological supervision and interpretation, when performed; open

### HCPCS Coding:

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

## REIMBURSEMENT INFORMATION:

None applicable.

## PROGRAM EXCEPTIONS:

**Federal Employee Program (FEP):** Follow FEP guidelines.

**State Account Organization (SAO):** Follow SAO guidelines.

**Medicare Advantage products:** The following National Coverage Determinations (NCDs) were reviewed on the last guideline reviewed date: Pancreas Transplants (260.3) and Islet Cell Transplantation in the Context of a Clinical Trial (260.3.1), located at cms.gov.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at [Coverage Protocol Exemption Request](#).

## DEFINITIONS:

**Islets of Langerhans (islet cells):** groups of specialized cells in the pancreas that secrete insulin and glucagon.

## RELATED GUIDELINES:

[Allogeneic Pancreas Transplant, 02-40000-17](#)

[Donislecel \(Lantidra\) allogeneic islet cell transplant, 09-J4000-58](#)

## OTHER:

**Florida Statute 765.523 Discrimination in access to anatomical gifts and organ transplants prohibited. (excerpt)**

(3)(d) "Organ transplant" means the transplantation or transfusion of a part of a human body into the body of another individual for the purpose of treating or curing a medical condition.

**Florida Statute 627.64197 Coverage for organ transplants.**—A health insurance policy issued, delivered, or renewed on or after July 1, 2020, in this state by an insurer which provides coverage for organ transplants on an expense-incurred basis may not deny coverage for an organ transplant solely on the basis of an insured's disability. This section may not be construed to require such insurer to provide coverage for an organ transplant that is not medically necessary. For purposes of this section, the term "organ transplant" has the same meaning as in s. 765.523.

**Florida Statute 627.65736 Coverage for organ transplants.**—A group health insurance policy delivered, issued, or renewed on or after July 1, 2020, in this state by an insurer or nonprofit health care services plan which provides coverage for organ transplants on an expense-incurred basis may not deny coverage for an organ transplant solely on the basis of an insured's disability. This section may not be construed to require such insurer or nonprofit health care service plan to provide coverage for an organ transplant that is not medically necessary. For purposes of this section, the term "organ transplant" has the same meaning as in s. 765.523.

**Florida Statute 641.31075 Coverage for organ transplants.**—A health maintenance contract issued or renewed on or after July 1, 2020, in this state by a health maintenance organization which provides coverage for organ transplants may not deny coverage for an organ transplant solely on the basis of a subscriber's disability. This section may not be construed to require such health maintenance

organization to provide coverage for an organ transplant that is not medically necessary. For purposes of this section, the term "organ transplant" has the same meaning as in s. 765.523.

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## COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 04/24/25.

## GUIDELINE UPDATE INFORMATION:

06/15/03	Medical Coverage Guideline Developed.
06/15/04	Scheduled review, no revisions.
10/01/04	4th Quarter HCPCS coding update; added procedure codes G0341, G0342, and G0343.
03/15/05	Scheduled review with revisions consisting of adding investigational statement for allogeneic islet cell transplantation for the treatment of type 1 diabetes.
01/01/06	Annual HCPCS coding update: add 0141T, 0142T, and 0143T.
03/15/06	Scheduled review; no change in coverage statement.
03/15/07	Scheduled review; no change in coverage statement.
06/15/07	Reformatted guideline.
03/15/08	Scheduled review; no change in position statement. Update references.
03/15/09	Scheduled review; no change in position statement. Update references.
03/15/10	Scheduled review; no change in position statement. Update references.
10/15/10	Revision; related ICD-10 codes added.
01/01/12	Annual HCPCS coding update. Deleted 0141T, 0142T and 0143T.
03/15/12	Scheduled review. Position statement maintained; updated description section and references.
03/15/13	Scheduled review. Maintain position statement and update references.
05/11/14	Revision: Program Exceptions section updated.

10/15/14	Scheduled review. Position statement maintained. Revised description and program exceptions. Updated references.
12/05/19	Scheduled review. Revised MCG title and description. Maintained position statement and updated references.
01/01/20	Annual CPT/HCPCS coding update. Added 0584T, 0585T, 0586T.
07/01/20	Revision: added Florida statute language regarding discrimination in access to anatomical gifts and coverage of organ transplants. Updated references.
10/15/20	Revision. Added clarification for autologous versus allogeneic transplantation.
09/15/21	Scheduled review. Revised MCG title, maintained position statement and updated references.
05/25/23	Update to Program Exceptions section.
09/15/23	Scheduled review. Maintained position statement and updated references.
05/15/25	Scheduled review. Deleted coverage statement for allogeneic islet transplant and deleted code S2102. Added related MCG for Lantidra (09-J4000-58). Updated references.