

POLICY TITLE	ISLET TRANSPLANTATION
POLICY NUMBER	MP-9.012

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I. POLICY

Autologous pancreas islet transplantation may be considered **medically necessary** as an adjunct to a total or near total pancreatectomy in patients with chronic pancreatitis.

Allogeneic islet transplantation is considered **investigational** for the treatment of type 1 diabetes, as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Islet transplantation is considered **investigational** in all other situations, as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Cross-References:

MP-2.010 Clinical Trials and Expanded Access Services

MP-9.005 Kidney Transplants, Pancreas Transplants, and Simultaneous Kidney/Pancreas Transplants.

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital BlueCross please see additional information below, and subject to benefit variations as discussed in Section VI below.

FEP PPO - Refer to FEP Medical Policy Manual MP-7.03.12 Autologous Islet Transplantation. The FEP Medical Policy manual can be found at: <https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies>

III. DESCRIPTION/BACKGROUND

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Islet Transplantation

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

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vein of the patient's liver. Once implanted, the beta cells in these islets begin to make and release insulin.

Allogeneic islet transplantation potentially offers an alternative to whole-organ pancreas transplantation. In the case of 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. However, a limitation of islet transplantation is that two or more donor organs are usually required for successful transplantation, although experimentation with single-donor transplantation is occurring. A pancreas that is rejected for whole-organ transplant is typically used for islet transplantation. Therefore, islet transplantation has generally been reserved for patients with frequent and severe metabolic complications who have consistently failed to achieve control with insulin-based management. Allogeneic transplantation may be performed in the radiology department.

In 2000, a modified immunosuppression regimen increased the success of allogeneic islet transplantation. This regimen is known as the "Edmonton protocol."

Regulatory Status

The U.S. Food and Drug Administration regulates human cells and tissues intended for implantation, transplantation, or infusion through the Center for Biologics Evaluation and Research, under Code of Federal Regulation Title 21, parts 1270 and 1271. Allogeneic islet cells are included in these regulations.

IV. RATIONALE

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Summary of Evidence

For individuals with chronic pancreatitis undergoing total or near total pancreatectomy who receive autologous pancreas islet transplantation, the evidence includes case series and systematic reviews. Relevant outcomes are overall survival, change in disease status, medication use, resource utilization, and treatment-related morbidity. Autologous islet transplants are performed in the context of total or near total pancreatectomies to treat intractable pain from chronic pancreatitis. The procedure appears to decrease significantly the incidence of diabetes after total or near total pancreatectomy in patients with chronic pancreatitis. Also, this islet procedure is not associated with serious complications and is performed in patients who are already undergoing a pancreatectomy procedure. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals with type 1 diabetes who receive allogeneic pancreas islet transplantation, the evidence includes a randomized controlled trial, case series, and systematic reviews. Relevant outcomes are overall survival, change in disease status, medication use, resource utilization, and treatment-related morbidity. Results of a 2018 randomized trial have suggested some reduction in the number of severe hypoglycemic incidence annually, but limited follow-up and other trial limitations reduce the certainty in conclusions drawn. A wide range of insulin independence has been reported in case series. There is conflicting evidence whether allogeneic islet

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transplantation reduces long-term diabetic complications. Long-term comparative studies are required to determine the effects of allogeneic islet transplantation in type 1 diabetics. The evidence is insufficient to determine the effects of the technology on health outcomes.

V. DEFINITIONS

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ALLOTRANSPLANTATION refers to grafting or transplantation of tissue from one individual into another of the same species.

AUTOTRANSPLANTATION refers to surgical transfer of tissue from one part of the body to another.

AUTOLOGOUS refers to originating within an individual; i.e., self-donation.

CADAVER refers to a dead body or corpse.

IMMUNOSUPPRESSIVE refers to any treatment used to block abnormal or excessive immune responses.

INSULIN is a hormone secreted by the beta cells of the pancreas that controls the metabolism and cellular uptake of sugars, proteins and fat.

PANCREATITIS refers to inflammation of the pancreas often caused by alcohol abuse or obstruction of the pancreatic ducts by gallstones.

PANCREATECTOMY is an operation to remove all or part of the pancreas.

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital BlueCross. Members and providers should consult the member's health benefit plan for information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

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Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital BlueCross' Provider Services or Member Services. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

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VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational: therefore, not covered for allogeneic islet transplantation:

CPT Codes®							
48999							

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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
S2102	Islet cell tissue transplant from pancreas; allogeneic

Covered when medically necessary:

CPT Codes®							
0584T	0585T	0586T	48160				

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ICD-10-CM Diagnosis Codes	Description
K86.0	Alcohol-induced chronic pancreatitis
K86.1	Other chronic pancreatitis

IX. REFERENCES

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	CAC 11/30/04
	CAC 11/29/05
	CAC 11/28/06
	CAC 1/29/08
	CAC 1/27/09
	CAC 1/26/10 Consensus review
	CAC 7/26/11 Adopt BCBSA. No change to policy statements.
	CAC 10/30/12 Consensus review. No change to policy statement. References updated. Added FEP variation to reference the manual MP-7.03.12 Autologous Islet Transplantation. Code reviewed. 10/23/12
	CAC 11/26/13 Consensus review. No changes to the policy statements. References updated. Rationale added.
	CAC 11/25/14 Consensus review. Statement added that islet transplantation is considered investigational in all other situations. Remains consensus – coding not impacted. Rationale and reference sections updated.
	11/06/2014 Admin update. Coding reviewed
	CAC 11/24/15 Consensus review. No changes to the policy statements. Reference and rationale update. Coding updated.

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	CAC 09/27/16 Consensus review. No change to the policy statements. References updated. Variations reformatted. Coding reviewed.
	CAC 11/28/17 Consensus review. No change to policy statements. References and rationale updated. Coding reviewed.
	3/9/18 Admin update. Coding reviewed and updated.
	8/9/18 Consensus review. No changes to the policy statements. Added a clarification statement that islet transplantation is considered investigational in all other situations. Background and rationale revised. References updated.
	05/21/19 Consensus review. No changes to the policy statements. References updated.
	01/01/20 Admin update Coding update. New 2020 codes added to policy; 0584T, 0585T, & 0586T.
	5/14/2020- Consensus review. Policy statement unchanged. Background and References updated. Coding reviewed.
	4/28/2021 Consensus review. Policy statement unchanged. References updated.

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