



Louisiana

Islet Transplantation

Policy # 00007

Original Effective Date: 08/26/2002

Current Effective Date: 05/11/2020

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Chronic Intermittent Intravenous Insulin Therapy (CIIT) is addressed separately in medical policy 00015.

Note: Allogeneic Pancreas Transplant is addressed separately in medical policy 00092.

When Services Are Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider autologous pancreas islet transplantation as an adjunct to a total or near total pancreatectomy in patients with chronic pancreatitis to be **eligible for coverage.****

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers allogeneic islet transplantation for the treatment of type 1 diabetes to be **investigational.***

Based on review of available data, the Company considers autologous or allogeneic islet transplantation for all other indications to be **investigational.***

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Background/Overview

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 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."

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

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.

Rationale/Source

Performed in conjunction with pancreatectomy, autologous islet transplantation is proposed to reduce the likelihood of insulin-dependent diabetes. Allogeneic islet cell transplantation is also being investigated as a treatment or cure for patients with type 1 diabetes.

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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. The 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. The 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 on whether allogeneic islet 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.

Supplemental Information

Practice Guidelines and Position Statements

National Institute for Health and Care Excellence

Guidance from the National Institute for Health and Care Excellence (2008) indicated the evidence on allogeneic pancreatic islet cell transplantation for type 1 diabetes has shown that serious procedure-related complications may occur, and the long-term immunosuppression required is associated with risk of adverse events. A related 2008 guidance addressed autologous islet cell transplantation for improved glycemic control after pancreatectomy and stated that studies have shown "some short-term efficacy, although most patients require insulin therapy in the long term..."

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complications result mainly from the major surgery involved in pancreatectomy (rather than from the islet cell transplantation)."

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

Medicare covers pancreatic islet transplantation in patients with type 1 diabetes participating in a clinical trial sponsored by the National Institutes of Health. Partial pancreatic tissue transplantation or islet transplantation performed outside a clinical trial are not.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT02505893	Minimal Islet Transplant at Diabetes Onset (MITO)	6	May 2018 (last updated February 2018)
NCT00160732	Allogenic Islet Cell Transplantation	50	Oct 2025

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NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT00706420	Islet Transplantation Alone (ITA) in Patients With Difficult to Control Type I Diabetes Mellitus Using a Glucocorticoid-free Immunosuppressive Regimen	20	Dec 2019
NCT00306098	Islet Cell Transplantation Alone in Patients With Type 1 Diabetes Mellitus: Steroid-Free Immunosuppression	40	May 2021
NCT01909245	Islet Cell Transplant for Type 1 Diabetes (TCD)	30	Jul 2021
NCT01974674	Allogeneic Islet Transplantation for the Treatment of Type 1 Diabetes (GRIIF)	19	Jan 2022
NCT01897688	A Phase 3 Single Center Study of Islet Transplantation in Non-uremic Diabetic Patients	40	Mar 2027
NCT00679042	Islet Transplantation in Type 1 Diabetic Patients Using the	36	Jul 2027

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NCT No.	Trial Name	Planned Enrollment	Completion Date
	University of Illinois at Chicago (UIC) Protocol		

NCT: national clinical trial.

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<https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=286&ncdver=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&Keyword=islet+cell&KeywordLookUp=Title&KeywordSearchType=And&bc=gAAAABAAAAA&>

Policy History

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- 08/15/2002 Medical Policy Committee review
- 08/26/2002 Managed Care Advisory Council approval
- 08/31/2004 Medical Director review
- 09/21/2004 Medical Policy Committee review. Format revision. No substance change to policy.
- 09/27/2004 Managed Care Advisory Council approval
- 09/07/2005 Medical Director review
- 09/20/2005 Medical Policy Committee review. Coverage eligibility changes. Investigational statement for allogeneic islet cell transplantation for treatment of type 1 diabetes added. Format revision. FDA approval information added.
- 09/22/2005 Quality Care Advisory Council approval
- 09/06/2006 Medical Director review
- 09/20/2006 Medical Policy Committee approval. No changes to policy guidelines.
- 09/05/2007 Medical Director review
- 09/19/2007 Medical Policy Committee approval. No change to coverage eligibility.
- 09/03/2009 Medical Policy Committee approval
- 09/16/2009 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 09/09/2010 Medical Policy Committee review
- 09/15/2010 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 09/01/2011 Medical Policy Committee review
- 09/14/2011 Medical Policy Implementation Committee approval. No change to coverage statement.
- 09/06/2012 Medical Policy Committee review

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- 09/19/2012 Medical Policy Implementation Committee approval. Title changed to “Islet Transplantation”. The words pancreatic and cell were dropped from the coverage statements.
- 09/05/2013 Medical Policy Committee review
- 09/18/2013 Medical Policy Implementation Committee approval. No change to coverage.
- 09/04/2014 Medical Policy Committee review
- 09/17/2014 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 08/03/2015 Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
- 09/03/2015 Medical Policy Committee approval
- 09/23/2015 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 10/01/2016 Coding update
- 11/03/2016 Medical Policy Committee approval
- 11/16/2016 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes
- 11/02/2017 Medical Policy Committee approval
- 11/15/2017 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 11/08/2018 Medical Policy Committee review
- 11/21/2018 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 11/07/2019 Medical Policy Committee review
- 11/13/2019 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 04/02/2020 Medical Policy Committee review
- 04/08/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 04/2021

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Coding

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	48160, 48999 Codes added eff 1/1/2020: 0584T, 0585T, 0586T
HCPCS	G0341, G0342, G0343, S2102
ICD-10 Diagnosis	E08.3211-E08.3299, E08.3311-E08.3399, E08.3411-E08.3499, E08.3511-E08.3599, E08.37X1-E08.37X9, E09.3211-E09.3299, E09.3311-E09.3399, E09.3411-E09.3499, E09.3511-E09.3599, E09.37X1-E09.37X9, E10.10-E10.11, E10.21-E10.29, E10.311-E10.359, E10.3211-E10.3299, E10.3311-E10.3399, E10.3511-E10.3599, E10.36,

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	E10.37X1-E10.37X9, E10.39-E10.49, E10.51-E10.59, E10.610, E10.618, E10.620-E10.628, E10.630-E10.638, E10.641-E10.649, E10.65, E10.69, E10.8-E10.9, E11.3211-E11.3299, E11.3311-E11.3399, E11.3411-E11.3499, E11.3511-E11.3599, E11.37X1-E11.37X9, K86.0-K86.1
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*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 - 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
 - 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 - 3. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services

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at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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