LOUISIANA BLUE

Islet Transplantation for Chronic Pancreatitis and Donislecel-jujn for Type 1 Diabetes

Policy # 00007
Original Effective Date: 08/26/2002
Current Effective Date: 12/09/2024

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 (CIIIT) 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 ~~i~~individuals with chronic pancreatitis to be **eligible for coverage.****

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers allogeneic islet transplantation using an FDA-approved cellular therapy product (donislecel-jujn [ie, Lantidra™‡]) for the treatment of type 1 diabetes to be **not medically necessary.****

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 and use of an FDA-approved cellular therapy product (donislecel-jujn [ie, Lantidra™‡]) for all non-FDA approved indications to be **investigational.***

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

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Policy Guidelines

Only adult subjects were enrolled in donislecel-jujn (Lantidra™‡) clinical studies, although clinical studies did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently than younger patients. Risks of donislecel-jujn infusion in pregnancy have not been assessed.

There are risks associated with the infusion procedure and long-term immunosuppression. There is no evidence of donislecel-jujn benefit for individuals whose diabetes is well-controlled with insulin therapy or for those with hypoglycemic unawareness who are able to prevent current repeated severe hypoglycemic events (neuroglycopenia requiring active intervention from a third party) using intensive diabetes management (including insulin, devices, and education).

Repeated intraportal islet infusions are not recommended in patients who have experienced prior portal thrombosis, unless the thrombosis was limited to second- or third-order portal vein branches. There is no evidence to support donislecel-jujn for individuals with liver disease, renal failure, or who have received a renal transplant.

Islet transplantation does not supplant future whole pancreatic transplantation (see medical policy 00092 Allogeneic Pancreas Transplant).

A specific target of HbA1c cannot be provided for all patients, as the target can be different based on age, duration of diabetes, and diabetic complications.

"Current repeated episodes" indicates risk within 1 year of the intended transplantation and is not related to events more than 1 year prior to the intended transplantation.

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 patients with type 1 diabetes. 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. 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.

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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 (FDA) 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. Donislecel-jujn (Lantidra™‡), a first-in-class deceased donor-derived allogeneic pancreatic islet cellular therapy product, was approved by the FDA in June 2023 for the treatment of type 1 diabetes in adults who are unable to approach target hemoglobin A1c due to repeated episodes of severe hypoglycemia despite intensive diabetes management and education.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Description

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

Summary of Evidence

For individuals with chronic pancreatitis undergoing total or near-total pancreatectomy who receive autologous pancreas islet transplantation, the evidence includes nonrandomized studies and systematic reviews. Relevant outcomes are overall survival (OS), 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 an improvement in the net health outcome.

For individuals with type 1 diabetes who receive allogeneic pancreas islet transplantation with donislecel-jujn, the evidence includes single-arm prospective trials conducted at a single study site

without strict protocols demonstrating insulin independence for over 1 year in a majority of participants, with mean insulin independence of approximately 5 years, resulting in Food and Drug Administration approval of donislecel for adults who are unable to approach target HbA1c because of current repeated episodes of severe hypoglycemia despite intensive diabetes management and education and for use in conjunction with concomitant immunosuppression. Additional well-designed studies are required to determine the effects of allogeneic islet transplantation in patients with type 1 diabetes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in ‘Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

National Institute for Health and Care Excellence

In 2008, NICE published guidance indicating 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... complications result mainly from the major surgery involved in pancreatectomy (rather than from the islet cell transplantation)."

American Diabetes Association

In 2024, the American Diabetes Association (ADA) standards of medical care recommended autologous islet cell transplantation be considered in patients undergoing total pancreatectomy for chronic pancreatitis to prevent postsurgical diabetes. The standards of care note that islet cell transplantation may have a role in type 1 diabetes. Because of the need for immunosuppressive agents posttransplantation, the guidelines note that transplantation in type 1 diabetes should be reserved for patients also undergoing renal transplantation or experiencing recurrent ketoacidosis with severe hypoglycemia despite intensive management. The ADA also states that 'In much of the world, allogenic islet transplantation is regulated as an organ transplant. However, in the U.S., allogenic islet transplantation is regulated as a cell therapy, and the first such allogeneic islet cell therapy, donislecel-jujn, was approved in 2023. Donislecel is indicated for the treatment of adults with type 1 diabetes who are unable to approach their A1C goal because of current repeated episodes of severe hypoglycemia despite intensive diabetes management and education.' However, no recommendation was provided for the use of allogenic islet transplantation.

International Consensus Guidelines for Chronic Pancreatitis
In 2020, the International Consensus Guidelines for Chronic Pancreatitis panel released a statement on the role of total pancreatectomy and islet transplant in patients with chronic pancreatitis. The panel stated that islet transplant should be considered for patients undergoing total pancreatectomy due to the potential for insulin independence and better long-term glycemic outcomes compared to pancreatectomy alone (weak recommendation based on low quality evidence). However, there is not enough information to definitively conclude when transplant should be performed relative to other interventions. Major indications for pancreatectomy with islet transplant include debilitating pain or recurrent pancreatitis episodes that diminish quality of life (strong recommendation based on low quality evidence). Contraindications to pancreatectomy with islet transplant include active alcoholism, pancreatic cancer, end-stage systemic illness, or psychiatric illness or socioeconomic status that would hinder either the procedure itself or posttransplant care (strong recommendation based on low quality evidence). Pancreatectomy with islet transplant improves quality of life, opioid use, and pancreatic pain in this population, but evidence about the effect on healthcare utilization is limited.

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 covered.

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
Ongoing			
NCT05287737	Clinical Outcome After Total Pancreatectomy With Islet Autotransplantation	100	Mar 2047
NCT04711226	An Open-Label Study to Evaluate the Safety, Tolerability and Efficacy of Immunomodulation With AT-1501 in Adults With Type 1 Diabetes Undergoing Islet Cell Transplant	6	June 2026

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	17	Nov 2024
NCT00306098	Islet Cell Transplantation Alone in Patients With Type 1 Diabetes Mellitus: Steroid-Free Immunosuppression	40	May 2026
NCT01897688	A Phase 3 Single Center Study of Islet Transplantation in Non-uremic Diabetic Patients	40	Mar 2027
NCT00679042[a]	Islet Transplantation in Type 1 Diabetic Patients Using the University of Illinois at Chicago (UIC) Protocol, Phase 3	21	Jun 2026
NCT05662267	Targeted Trial Emulation of Kidney Alone Versus Islet-After-Kidney in Type 1 Diabetic Transplant Recipients: a French Nationwide Cohort Study	500	Mar 2023
NCT01630850	Islet Transplantation in Patients With "Brittle" Type I Diabetes	20	Jun 2030
Unpublished			
NCT03698396	A Phase I/II, Open-Arm Study Evaluating the Safety of Islet Transplant in Patients With Type I Diabetes	10	Dec 2023 (unknown status)

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

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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
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

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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.
04/01/2021	Medical Policy Committee review
04/14/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/07/2022	Medical Policy Committee review
04/13/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/06/2023	Medical Policy Committee review
04/12/2023	Medical Policy Implementation Committee approval. Replaced "patients" with "individuals" in the coverage section. Coverage eligibility unchanged.
11/02/2023	Medical Policy Committee review
11/08/2023	Medical Policy Implementation Committee approval. Title changed from "Islet Transplantation" to "Islet Transplantation for Chronic Pancreatitis and Donislecel-jujn for Type 1 Diabetes". Added a Not Medically Necessary statement for the use of an FDA-approved cellular therapy product ([donislecel-jujn [ie, Lantidra™‡]) for allogeneic islet transplantation for the treatment of diabetes type I. Added an Investigational statement for allogeneic islet transplantation for the treatment of type 1 diabetes and use of an FDA-approved cellular therapy product (donislecel-jujn [ie, Lantidra™‡]) for all non-FDA approved indications. Revised the Investigational statement to only include autologous islet cell transplantation for all other indications.
11/07/2024	Medical Policy Committee review
11/13/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 11/2025

Coding

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2023 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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CPT is a registered trademark of the American Medical Association.

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

Code Type	Code
CPT	0584T, 0585T, 0586T, 48160, 48999
HCPCS	C9399, G0341, G0342, G0343, J3590, S2102
ICD-10 Diagnosis	All related diagnoses

*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 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 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.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.