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1.0 Description of the Procedure, Product, or Service

Recipients with chronic pancreatitis may experience intractable pain that can only be relieved with a total or near total pancreatectomy. The pain relief must be balanced against the certainty that the recipient will become an insulin dependent diabetic if a pancreatectomy is performed.

Autologous islet cell transplantation has been investigated as a technique to prevent this from occurring. During the pancreatectomy procedure, a suspension of isolated islet cells is created from the resected pancreas specimen and then injected into the portal vein of the liver. The cells function as a free graft continuing to make insulin. While the procedure does not prevent insulin dependent diabetes in every case, use of the most recent techniques in islet cell isolation demonstrate about a 55% success rate.

Allogeneic islet transplantation has been researched for use in type 1 diabetes to restore normal glycemia which could reduce long-term complications (i.e., retinopathy, neuropathy, nephropathy, and cardiovascular disease). This procedure is an alternative to pancreas transplantation. It typically requires two (2) or more donor organs to obtain enough cells for islet transplantation. These cells are usually obtained from a pancreas that has been rejected as a whole organ for transplant. Islet transplantation is only recommended for those with frequent and severe metabolic complications who have failed to achieve control with insulin.

Islet cells are regulated by the U.S. Food and Drug Administration (FDA). Allogeneic islet cells are classified as somatic cell therapy which requires premarket approval. Islet cells also fall under the definition of a drug which requires that clinical studies be done to determine the safety and effectiveness of islet transplantation to comply with the investigational new drug (IND) regulation.

2.0 Eligible Recipients

2.1 General Provisions

To be eligible, NC Health Choice (NCHC) recipients must be enrolled on the date of service.

3.0 When the Procedure, Product, or Service Is Covered

3.1 General Criteria

NCHC covers procedures, products, and services related to this policy when they are medically necessary and

- a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the recipient's needs;

- b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available; **AND**
- c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.

3.2 Specific Criteria

NCHC covers autologous islet cell transplantation when medically necessary and performed together with a total or near total pancreatectomy in NCHC recipients with chronic pancreatitis.

4.0 When the Procedure, Product, or Service Is Not Covered

4.1 General Criteria

Procedures, products, and services related to this policy are not covered when

- a. the recipient does not meet the eligibility requirements listed in **Section 2.0**;
- b. the recipient does not meet the medical necessity criteria listed in **Section 3.0**;
- c. the procedure, product, or service unnecessarily duplicates another provider's procedure, product, or service; or
- d. the procedure, product, or service is experimental or investigational.

4.2 Specific Criteria

NCHC does not cover islet cell transplantation for any of the following:

- a. allogeneic islet transplantation, as it is considered investigational for the treatment of type I diabetes;
- b. islet cell transplantation for all other indications as it is considered investigational; or
- c. islet cell transplantation when the NCHC recipient does not meet the criteria in **Subsection 3.2**.

4.3 Psychosocial History

Islet cell transplantation is not covered when the recipient's psychosocial history limits the recipient's ability to comply with pre- and post-transplant medical care.

4.4 Medical Compliance

Current recipient or caretaker non-compliance that would make compliance with a disciplined medical regime improbable

4.5 Substance Abuse

Islet cell transplantation is not covered when the recipient has an active substance abuse or, for recipients with a recent history of substance abuse, there is no documentation of the completion of a substance abuse or therapy program plus six months of negative sequential random drug screens.

5.0 Requirements for and Limitations on Coverage

5.1 Prior Approval

Prior approval is required for islet cell transplantation.

All applicable NCHC policies and procedures must be followed in addition to the ones listed in this procedure.

Only those NCHC recipients accepted for transplantation by a transplantation center and eligible for transplant listing shall be considered for prior review. Guidelines must be followed for transplant network or consortiums, if available.

5.2 Prior Approval Requirements

The provider(s) shall submit to DMA's designee the health care records and any other records that support the recipient has met the specific criteria in **Subsection 3.2**.

6.0 Providers Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for procedures, products, and services related to this policy, providers shall

- a. meet NCHC qualifications for participation;
- b. be currently enrolled with NCHC; **AND**
- c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

7.0 Additional Requirements

7.1 Compliance

Providers shall comply with all applicable federal, state, and local laws and regulations, including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements.

FDA approved procedures, products, and devices for implantation must be utilized for islet cell transplantation.

Implants, products, and devices must be used in accordance with all FDA requirements current at the time of surgery-

A statement signed by the surgeon certifying all FDA requirements for the implants, products, and devices must be retained in the recipient's medical record and made available for review upon request.

8.0 Policy Implementation/Revision Information

Original Effective Date: July 1, 2010

Revision Information:

Date	Section Revised	Change
7/1/2011		Policy Conversion: Implementation of Session Law 2009-451, Section 10.32 “NC HEALTH CHOICE/PROCEDURES FOR CHANGING MEDICAL POLICY.”
12/1/2011	Subsection 2.1	Spelled out NC Health Choice
12/1/2011	Subsection 3.2	Updated criteria
12/1/2011	Subsection 4.2	Updated criteria
12/1/2011	Subsection 4.4	Added Medical Compliance
12/1/2011	Subsection 4.5	Added Substance Abuse
12/1/2011	Subsection 5.2	Added Prior Approval requirements
12/1/2011	Section 7.0	Updated compliance
12/1/2011	Attachment A	Updated codes and changed “must” to “shall”

Attachment A: Claims-Related Information

Reimbursement requires compliance with all NCHC guidelines.

A. Claim Type

Professional (CMS-1500/837P transaction)

B. Diagnosis Codes

Providers shall must bill the ICD-9-CM diagnosis codes(s) to the highest level of specificity that supports medical necessity.

C. Procedure Code(s)

CPT Code	Description
48160	Pancreatectomy, total or subtotal, with autologous transplantation of pancreas or pancreatic islet cells

HCPCS Code	Description
G0341	Percutaneous islet cell transplant
G0342	Laparoscopy for islet cell transplant
G0343	Laparotomy for islet cell transplant

D. Modifiers

Providers are required to follow applicable modifier guidelines.

E. Billing Units

The appropriate procedure code(s) used determines the billing unit(s).

F. Place of Service

Acute Inpatient Hospital

G. Co-payments

Co-payment(s) may apply to covered prescription drugs and services.

H. Reimbursement

Providers shall bill their usual and customary charges.

I. Billing for Donor Expenses

Donor expenses (procuring, harvesting, and associated surgical and laboratory costs) for the autologous donation are covered for an islet cell transplant if the recipient has received prior approval for the procedure.