FEP Medical Policy Manual

FEP 7.03.12 Autologous Islet Transplantation

**Effective Policy Date:** January 1, 2020

**Original Policy Date:** September 2012

**Related Policies:**
- 7.03.02 - Allogeneic Pancreas Transplant

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**Islet Transplantation**

**Description**

Performed in conjunction with pancreatectomy, autologous islet transplantation is proposed to reduce the likelihood of insulin-dependent diabetes.

**OBJECTIVE**

The objective of this evidence review is to determine whether autologous pancreas islet transplantation improves the net health outcome in individuals with chronic pancreatitis.

**POLICY STATEMENT**

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

Autologous Islet transplantation is considered **investigational** in all other situations.

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The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.
BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

See brochure regarding allogeneic islet cell transplantation.

FDA REGULATORY STATUS

Autologous islet cells are not regulated by the U.S. Food and Drug Administration.

RATIONALE

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. The 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 a meaningful improvement in the net health outcome.

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) 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)."

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.

REFERENCES


**POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:**

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<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>September 2012</td>
<td>New policy</td>
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<tr>
<td>March 2013</td>
<td>Replace policy</td>
<td>Policy updated with literature review; policy statement unchanged.</td>
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<tr>
<td>September 2013</td>
<td>Replace policy</td>
<td>Policy updated with literature review; references added; policy statements unchanged.</td>
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<tr>
<td>September 2014</td>
<td>Replace policy</td>
<td>Policy updated with literature review. Reference 4 added. No change in policy statement.</td>
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<tr>
<td>September 2015</td>
<td>Replace policy</td>
<td>Policy updated with literature review; references 1, 3, 6, and 11 added. Policy statements unchanged.</td>
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<tr>
<td>December 2017</td>
<td>Replace policy</td>
<td>Policy updated with literature review through June 22, 2017; Policy statements unchanged.</td>
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<tr>
<td>December 2018</td>
<td>Replace policy</td>
<td>Policy updated with literature review through June 21, 2018; references 1 and 10 added. Policy statements unchanged.</td>
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<tr>
<td>December 2019</td>
<td>Replace policy</td>
<td>Policy updated with literature review through June 10, 2019; no references added, some references removed. Policy statements unchanged.</td>
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