

Policy Name:	Allogeneic Pancreatic Islet Cell Transplantation
Effective Date:	1/17/2022

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Coverage is subject to requirements in applicable federal or state laws. Please refer to the member’s plan document for other specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare, Medicaid, and other government programs, this policy will apply unless these programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

Coverage Policy

Allogeneic pancreatic islet cell transplantation is investigative and unproven, and therefore **NOT COVERED**. There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the effects on health care outcomes.

Note: See related Medica utilization management policies: *Pancreas Transplantation (Pancreas Alone) (III-TRA.04)* and *Pancreas-Kidney (SPK, PAK) Transplantation (III-TRA.05)*

Description

Pancreatic islets are small clusters of endocrine cells in the pancreas that include insulin-producing beta cells. In type 1 diabetes mellitus (DM), the islet cells are destroyed, rendering the patient dependent on exogenous sources of insulin. Allogeneic islet cell transplantation is under investigation for use in type 1 DM to restore normoglycemia, in an effort to reduce or eliminate long-term complications of diabetes.

In allogeneic islet cell transplantation, islets are taken from the pancreas of a deceased organ donor, purified, processed, and injected into the portal vein of the recipient’s liver. When successful, the beta cells in these islets begin to make and release insulin. While less invasive than whole pancreas transplantation, allogeneic islet cell transplantation requires lifelong immunosuppression to prevent rejection.

FDA Approval

Islet cells are regulated by the 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. While at least 35 IND applications have been submitted to the FDA, no center has submitted a biologics license application.

Prior Authorization

Prior authorization is not applicable. Claims for this service are subject to retrospective review and denial of coverage, as investigative services are not eligible for reimbursement.

Coding Considerations

Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

Codes:

- **S2102** - Islet cell tissue transplant from pancreas; allogeneic

Original Effective Date: 3/15/2015

Re-Review Date(s): 10/17/2018
2/10/2020 – administrative update; formatting
11/17/2021

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