



Medica Central Utilization Management Policy

Title: Pancreas Transplantation (Pancreas Alone) MP9616 (III-TRA.04)

Effective Date: July 01, 2025

This policy was developed with input from specialists in endocrinology, nephrology and transplant surgery, and endorsed by the Medical Policy Committee.

IMPORTANT INFORMATION – PLEASE READ BEFORE USING THIS POLICY

These services may or may not be covered by all Medica Central 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 Provider Service Center. Please use the Quick Reference Guide on the Provider Communications page for the appropriate phone number. <https://mo-central.medica.com/Providers/SSM-employee-health-plan-for-IL-MO-OK-providers>

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

PURPOSE

To promote consistency between utilization management reviewers by providing the criteria that determines the medical necessity.

BACKGROUND

I. Definitions

- A. **Labile diabetes** is a term that is sometimes used to describe hard-to-control diabetes (also called brittle diabetes). It is characterized by wide variations or "swings" in blood glucose (sugar) in which blood glucose levels can quickly move from too high (hyperglycemia) to too low (hypoglycemia).
- B. There are three types of **pancreas transplantation**:
 - 1. Simultaneous pancreas/kidney (SPK)
 - 2. Pancreas after kidney (PAK)
 - 3. Pancreas transplantation alone (PTA).
- C. **Pancreatic islet cell transplantation** is a procedure in which the insulin-producing islet cells alone (without the remainder of the pancreas) are transplanted from a donor to the

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same (autologous) or different (allogeneic) individual. (Refer to the Coverage Issues section for additional information.)

- D. **Transplant or graft** is a portion of the body or a complete organ removed from its natural site and transferred to a separate site in the same or different individual. Pancreas transplantation has been used to arrest or ameliorate secondary complications of diabetes by establishing insulin independence.
- E. Transplant **evaluation** is a physical and psychosocial exam to determine if an individual is an acceptable candidate for transplantation. The specific exams and tests depend on the individual's diagnosis and health history and vary from hospital to hospital. Tests may include the following: cardiac evaluation; lung function tests; lab tests, including blood typing, chemistry panels, and serology testing for hepatitis, HIV and other common viruses; appropriate cancer surveillance, as indicated (e.g., colonoscopy, pap smear, mammogram, prostate cancer screening); dental evaluation with treatment of existing problems; psychosocial evaluation. Additional testing or clearance may be required to address other significant coexisting medical conditions.

II. Comments

- A. Pancreas transplantation represents an alternative means of treating insulin dependence. Because organ transplantation requires commitment of the recipient to long term immunosuppression, the problems of diabetes must be of a magnitude to justify anti-rejection drugs. Thus, the main pancreas transplant applications have been in individuals who are extremely labile or experience hypoglycemia unawareness syndrome. The complications of uncontrolled labile diabetes with severe metabolic instability must be judged to be more serious than being immunosuppressed.
- B. Individuals with Type II Insulin Dependent Diabetes Mellitus (IDDM) may exhibit the secondary complications of diabetes, including nephropathy, retinopathy, and peripheral/autonomic neuropathy and vasculopathy. In these individuals, insulin resistance may be an important factor in the pathophysiology of diabetes and a pancreas transplant may not be helpful, if residual beta cell function exists. In order to differentiate between Type I and Type II IDDM, a C-peptide determination or antibody studies may be necessary. In individuals with Type I IDDM, there should be no detectable C-peptide and antibodies may be present. In individuals with Type II IDDM, C-peptide levels may be normal or even elevated and antibodies are absent.

BENEFIT CONSIDERATIONS

1. Prior authorization **is required** for:
 - Pancreas Transplant **Evaluation**
 - Pancreas **Transplantation**
 - Please see the prior authorization list for product specific prior authorization requirements.
2. Coverage may vary according to the terms of the member's plan document.
3. The Health Plan has entered into separate contracts with designated facilities to provide transplant-related health services, as described in the member's plan document.
4. Complex cases require medical director or external review and, as necessary, discussion with the individual's physician.
5. Underlying co-morbidity that significantly alters risk/benefit of transplant may preclude transplant eligibility.

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6. Autologous Islet cell transplants associated with pancreatectomy is not investigative. For allogeneic islet cell transplant refer to Prime Therapeutics (Magellan) UM policy, *Lantidra™* (donislecel-juju), for medical necessity criteria and prior authorization.
7. Allogeneic pancreatic islet cell transplants, also known as allotransplantation, or allogeneic pancreatic islet cellular therapy are not investigative when using an FDA-approved cellular product of allogeneic pancreatic islets (e.g., Lantidra™ - donislecel-jujn) and, when the medical necessity criteria listed in the pharmacy utilization management policy Lantidra™ are met.
Note: Allogeneic pancreatic islets products (e.g., Lantidra™) require prior authorization and are managed by Medica. See the related policy [Lantidra™ \(donislecel-juju\)](#) (Number IC-0717).
8. If the Medical Necessity Criteria and Benefit Considerations are met, The Health Plan will authorize benefits within the limits in the member's plan document.
9. If it appears that the Medical Necessity Criteria and Benefit Considerations are not met, the individual's case will be reviewed by the medical director or an external reviewer.
Practitioners are advised of the appeal process in their Provider Administrative Manual.
10. See also related Health Plan UM Policy, *Pancreas-Kidney (SPK, PAK) Transplantation* (III-TRA.05).

MEDICAL NECESSITY CRITERIA

I. Indications for Pancreas Transplantation **Evaluation**

(NOTE: For multiorgan transplant, the individual must meet criteria for each organ. Please refer to applicable UM policy.)

Documentation in the medical records indicates that the individual has labile insulin-dependent diabetes mellitus (IDDM) with documented life-threatening hypoglycemic unawareness and/or frequent hypoglycemic episodes (Clark Hypoglycemic Perception Awareness Scale Score ≥ 4) despite optimal medical management.

II. Indications for Pancreas **Transplantation**

Documentation in the medical records indicates that **all of the following** are met: (intervention and/or clearance required for abnormal findings)

- A. The individual meets the institution's suitability criteria for transplant
- B. The individual meets all of the above criteria in section I.

III. Indications for Pancreas **Retransplantation**

Documentation in the medical records indicates that **all of the following** criteria are met:

- A. Failed previous pancreas transplantation
- B. The above criteria in section II for initial transplantation must be met
- C. No history of behaviors since the previous transplant that would jeopardize a subsequent transplant.

CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS)

- For Medicare members, refer to the following, as applicable at:
<https://www.cms.gov/medicare-coverage-database/new-search/search.aspx>



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