

Medical Necessity Guidelines

Indications and Limitations of Coverage

B. Nationally Covered Indications

Effective for services performed on or after July 1, 1999, whole organ pancreas transplantation is nationally covered by Medicare when performed simultaneous with or after a kidney transplant. If the pancreas transplant occurs after the kidney transplant, immunosuppressive therapy begins with the date of discharge from the inpatient stay for the pancreas transplant.

Effective for services performed on or after April 26, 2006, pancreas transplants alone (PA) are reasonable and necessary for Medicare beneficiaries in the following limited circumstances:

1. PA will be limited to those facilities that are Medicare-approved for kidney transplantation. (Approved centers can be found at http://www.cms.gov/ESRDGeneralInformation/02_Data.asp#TopOfPage)
2. Patients must have a diagnosis of type I diabetes:
 - Patient with diabetes must be beta cell autoantibody positive; or
 - Patient must demonstrate insulinopenia defined as a fasting C-peptide level that is less than or equal to 110% of the lower limit of normal of the laboratory's measurement method. Fasting C-peptide levels will only be considered valid with a concurrently obtained fasting glucose \leq 225 mg/dL;
3. Patients must have a history of medically-uncontrollable labile (brittle) insulin-dependent diabetes mellitus with documented recurrent, severe, acutely life-threatening metabolic complications that require hospitalization. Aforementioned complications include frequent hypoglycemia unawareness or recurring severe ketoacidosis, or recurring severe hypoglycemic attacks;
4. Patients must have been optimally and intensively managed by an endocrinologist for at least 12 months with the most medically-recognized advanced insulin formulations and delivery systems;
5. Patients must have the emotional and mental capacity to understand the significant risks associated with surgery and to effectively manage the lifelong need for immunosuppression; and,
6. Patients must otherwise be a suitable candidate for transplantation.

Limits or Restrictions

C. Nationally Non-Covered Indications

The following procedure is not considered reasonable and necessary within the meaning of section 1862(a)(1)(A) of the Social Security Act:

Transplantation of partial pancreatic tissue or islet cells (except in the context of a clinical trial (see section 260.3.1 of the National Coverage Determinations Manual).

D. Other

Not applicable.

(This NCD last reviewed April 2006.

Reference Information

CMS

Medicare Processing Manual Chapter 3 section 90.4, 90.4.1, 90.4.2 Pancreas with Kidney Transplants

Link: <https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c03.pdf>

CMS

NCD 260.3

Pancreas Transplant

Medicare Coverage Database (MCD)

Link: <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx>

Policy History

Date	Version	Comments
12/07/2023	Draft	New Medical Policy
12/15/2023	Final	Approved by Medical Policy Committee