STATE OF IOWA DEPARTMENT OF
Health AND Human
SERVICES

Pancreas Transplant
SRG-013

Iowa Medicaid Program:	Pre-Procedure	**Effective Date:**	9/11/2009
Revision Number:	13	**Last Rev Date:**	1/19/2024
Reviewed By:	Pancreas Transplant Consultant, MMD	**Next Rev Date:**	1/17/2025
Approved By:	Medicaid Clinical Advisory Committee	**Approved Date:**	9/12/2019

Criteria

Pre-procedure review is required.

Pancreas transplants are covered for members with insulin-requiring diabetes mellitus who meet **ALL** the following:

1. Must have clearance from psycho/social necessity consult. Evaluation should include an assessment of the member's ability to give informed consent and comply with instructions including drug therapy, an assessment of the support systems and resources in place at home or in the community, and an assessment of overall health literacy (Level of Evidence: C); **AND**
2. Dental exam and clearance must be provided; **AND**
3. Must be abstinent of all illicit drugs and not abuse any drugs or alcohol. Physician documentation must specifically address this issue. Need for laboratory testing to confirm compliance may be at the discretion of the attending physician. Social alcohol use and non-vaping/non-smoking marijuana use are acceptable; **AND**
4. Documentation of underlying co-morbidities must be provided; **AND**
5. Pertinent lab values must be provided; **AND**
6. Report of chest x-ray must be provided; **AND**
7. Report of abdominal ultrasound study or abdominal/pelvic CT scan must be provided; **AND**
8. Documentation of complications related to diabetes must be provided including HbA1c level, C-peptide level, and daily insulin requirements; **AND**
9. Echocardiogram and cardiac stress test results must be provided; **AND**
10. Documentation of renal function to determine qualification for appropriate pancreas transplant category must be provided; **AND**
11. Request may come in as "pancreas alone" or "simultaneous kidney/pancreas" request. Iowa Medicaid will review for the pancreas only; do not need approval for the kidney portion for a simultaneous pancreas/kidney or pancreas after kidney.

Contraindications

Transplantation cannot be approved in the presence of **ANY** of the following:

1. Active smoking is not necessarily considered an absolute contraindication; however, heavy smoking (more than 1 pack per day) or vaping are absolute contraindication. Complete cessation of smoking/vaping products cessation is strongly encouraged. For members who smoke/vape tobacco and have smoking-related morbidities (coronary artery disease, symptomatic or documented cerebrovascular or peripheral vascular disease, chronic obstructive lung disease, history of non-cutaneous malignancy), complete smoking or vaping products cessation is required and should be validated by urine nicotine test prior to transplant; **OR**
2. Malignancy in the last 2 years, with the exception of cutaneous squamous and basal cell tumors. Disseminated or incompletely treated cancer is an absolute contraindication. In cases of localized and treated cancer, the cancer-free interval required will vary depending on the stage and type of cancer. Consultation with a board-certified medical or surgical oncologist is required in most cases to determine if the member's mortality in the absence of transplantation is predicted to be higher than their risk of recurrence; **OR**
3. Incurable chronic, active, or unresolved infection including chronic active viral hepatitis B, uncontrolled hepatitis C, or uncontrolled human immunodeficiency virus (HIV).
    a. Adequately controlled HIV infection is defined by **ALL** the following:
        1) CD4 count greater than 200 cells/mm3; **AND**
        2) HIV-1 ribonucleic acid (RNA) undetectable; **AND**
        3) Stable combination anti-retroviral therapy for more than 3 months; **AND**
        4) Absence of serious complications associated with or secondary to HIV disease, such as progressive multifocal leukoencephalopathy, opportunistic infections within the past 12 months, including aspergillosis, tuberculosis or other mycobacterial infection, coccidiomycosis, resistant fungal infections, untreated or uncontrolled condylomata, chronic intestinal cryptosporidiosis more than 1 month, Kaposi's sarcoma or other neoplasm; **AND**
        5) In cases of chronic hepatitis C viral infection without cirrhosis, transplantation may precede treatment for HCV to take advantage of organs from HCV+ donors and provided the member has been accepted as a good candidate for anti-HCV treatment; **OR**
4. Documented non-adherence or inability to follow through with medical therapy or any aspect of follow-up care; **OR**
5. Untreatable psychiatric or psychological condition associated with the inability to cooperate or comply with medical therapy; **OR**
6. Absence of a consistent or reliable social support system; **OR**
7. Substance addiction (e.g., alcohol, tobacco, narcotics) that is either active or within the last 6 months and has not been evaluated for or entered into a structured rehabilitation or cessation program; **OR**
8. Poor overall functional and performance status with documented severe frailty, malnutrition, sarcopenia, deconditioning, or failure to thrive that is not expected to improve with transplantation or rehabilitation; **OR**

9. Fasting C-peptide >15 ng/ml or total daily insulin requirements >1.0 unit/kg. In selected circumstances, members with a type 2 diabetes phenotype will be considered for pancreas transplantation provided they are insulin-requiring for a minimum of 3 to 5 years and meet the above C-peptide and insulin requirement criteria. For those members who do not meet these criteria, a discussion of risks and benefits must specifically address this in the clinical documentation; **OR**
10. BMI >34 kg/m^2 is a relative contraindication. A discussion of risks and benefits must specifically address this in the clinical documentation; **OR**
11. Members 60 years of age and older is a relative contraindication. A discussion of risks and benefits must specifically address this in the clinical documentation; **OR**
12. Insufficient cardiovascular reserve with un-reconstructable coronary artery disease, refractory congestive heart failure, left ventricular ejection fraction <30 percent, or severe irreversible pulmonary hypertension (right ventricular systolic pressure/pulmonary artery systolic pressure ≥50 mm Hg confirmed by right heart catheterization); cardiac history of high probability of death with general anesthesia; **OR**
13. Chronic severe hypotension (may be marked by use of oral vasopressors such as midodrine) with evidence of significant and irreversible cardiac dysfunction; **OR**
14. Chronic lung disease requiring continuous oxygen therapy; **OR**
15. Moderate to advanced cirrhosis; **OR**
16. Life expectancy less than 2 years because of other irreversible systemic illness or multiple co-morbidities; **OR**
17. Not up-to-date with center-specific vaccination requirements.

Other Coverage Issues

1. Covered types of pancreas transplants are limited to the following:
   a. Simultaneous pancreas-kidney,
   b. Pancreas after kidney transplant,
   c. Pancreas transplants alone for members exhibiting **ANY** of the following:
      1) A history of frequent, acute, and severe metabolic complications, such as hypoglycemia, hyperglycemia, or ketoacidosis, which require medical attention; **OR**
      2) Clinical problems with exogenous insulin therapy that are so severe as to be incapacitating or causing a significant impairment in quality of life; **OR**
      3) Consistent failure of insulin-based management to prevent either acute or chronic complications (i.e., retinopathy, peripheral or autonomic neuropathy, accelerated atherosclerosis).
2. Pancreas transplants require pre-procedure review and approval.
3. Covered pancreas transplants are only payable when performed in a facility that meets the requirements under Iowa Administrative Code (IAC) 441-78.3(10).
4. Donor expenses incurred directly in connection with a covered transplant are payable.
5. Expenses incurred for complications that arise with respect to the donor are covered only if they are directly and immediately attributed to surgery.
6. Expenses of searching for a donor are not covered.

Services Not Covered

1. Transplantation of islet cells or partial pancreatic tissue.
2. Expenses associated with organ preparation (e.g., "backbench prep") are not separately payable and are considered paid as part of the transplant procedure.

Coding

The following list is provided for reference purposes only and may not be all inclusive. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment, nor does the exclusion of a code imply that its association to the CPT code is inappropriate.

CPT	Description
48554	Transplantation of pancreatic allograft.

Compliance

1. Should conflict exist between this policy and applicable statute, the applicable statute shall supersede.
2. Federal and State law, as well as contract language, including definitions and specific contract provisions or exclusions, take precedence over medical policy and must be considered first in determining eligibility for coverage.
3. Medical technology is constantly evolving, and Iowa Medicaid reserves the right to review and update medical policy on an annual and as-needed basis.

Medical necessity guidelines have been developed for determining coverage for member benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Criteria are revised and updated annually, or more frequently if new evidence becomes available that suggests needed revisions.

References

441 IAC 78.1(20)"a"(7).

Ohler, L. & Cupples, S., (2008). Core Curriculum for Transplant Nurses. Mosby Elsevier, Philadelphia, PA.

Listing Criteria for Heart Transplantation (Guidelines) (J Heart Lung Transplant 2006:25(9): 1024-1042).

International Guidelines for the Selection of Lung Transplant Candidates: 2006 Update - A Consensus Report from the ISHLT Pulmonary Scientific Council (Consensus Document) (J Heart Lung Transplant 2006:25(7) 745-755).

Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

Criteria Change History

Change Date	Changed By	Description of Change	Version
Signature			
Change Date	**Changed By**	**Description of Change**	**Version**
Signature			
Change Date	**Changed By**	**Description of Change**	**Version**
1/19/2024	CAC	Annual specialist review. Added new criterion #8. Tweaked language regarding smoking, vaping, and immunizations in the Criteria section.	13
Signature William (Bill) Jagiello, DO			
Change Date	**Changed By**	**Description of Change**	**Version**
1/20/2023	CAC	Annual specialist review.	12
Signature William (Bill) Jagiello, DO			
Change Date	**Changed By**	**Description of Change**	**Version**
1/21/2022	Pancreas Transplant Specialist	Addition to criteria #7. Under Contraindications: #3.a.4) revised to include untreated/uncontrolled condylomata; #8 changed from C-peptide >10 to >15 and insulin requirements changed from >1 to >1.0; #9 BMI changed from >5 to >32; #16 added to include COVID vaccine requirement. Added Compliance section. Formatting changes.	11
Signature William (Bill) Jagiello, DO			
Change Date	**Changed By**	**Description of Change**	**Version**
8/6/2019	Pancreas Transplant Specialist	Amended criteria #3 to read: "Incurable chronic active or unresolved infection including chronic active viral hepatitis B, uncontrolled hepatitis C, or uncontrolled human immunodeficiency virus (HIV)."	10
Signature Mark E. Randleman, DO			

Criteria Change History (continued)

Change Date	Changed By	Description of Change	Version
1/2/2018	Pancreas Transplant Specialist	Changes in Contraindication #1 and #2. Added Contraindication #3 5). Added Contraindications 11 through 15.	9
Signature			

Change Date	Changed By	Description of Change	Version
4/11/2017	Policy	Services Not Covered added second bullet regarding associated expenses.	8
Signature			

Change Date	Changed By	Description of Change	Version
12/18/2016	Pancreas Transplant Consultant	Added narrative to Contraindication #1. Contraindication #4 3) added "combination" Contraindication #4 4) added "progressive multifocal leukoencephalopathy" "within the past twelve months" "other mycobacterial infection" "chronic intestinal cryptosporidiosis greater than one month". Contraindication #9 added narrative. Added Contraindication #11. Other coverage issues #3b added "or causing a significant impairment in quality of life". Other coverage #3c added "retinopathy, peripheral or autonomic neuropathy, accelerated atherosclerosis". Sentence on expenses incurred for complications added "or requisite immunosuppression".	7
Signature			

Change Date	Changed By	Description of Change	Version
1/7/2016	Pancreas Transplant Consultant	Added narrative to criterion #3 and #8.	6
Signature			

Change Date	Changed By	Description of Change	Version
1/16/2015	Medical Director	Added last paragraph in References.	5
Signature			

Change Date	Changed By	Description of Change	Version
7/24/2014	Medical Director	Contraindication #4 - removed hepatitis C and added definitions 1)-5) of adequately controlled HIV infection.	4
Signature			

Criteria Change History (continued)

Change Date	Changed By	Description of Change	Version
11/21/2013	Pancreas Transplant Consultant	Under criteria, change coverage for members with type 1 diabetes to insulin-requiring diabetes. Criterion #8 change insulin resistance to complications. Add Criterion #9 on echocardiogram and cardiac stress test. Add Criterion #10 on renal function. Under Contraindications, remove #4 regarding incurable viral disease. Add #8 on fasting C-peptide. Add #9 on BMI.	3
Signature			

Change Date	Changed By	Description of Change	Version
3/22/2013	Policy	Additions to criteria to reflect details contained in 441 IAC 78.1(20)"a"(7).	2
Signature			

Change Date	Changed By	Description of Change	Version
1/18/2013	CAC	Re-ordering and new information added to Criteria #1-#10. Added Contraindications. Added information under References.	1
Signature			