



POLICY AND PROCEDURE MANUAL

Policy Title: Pancreas Transplant	Policy Number: F.23
Primary Department: Medical Management	NCQA Standard: N/A
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Applicable Lines of Business: <input type="checkbox"/> MeridianCare <input checked="" type="checkbox"/> MeridianHealth <input type="checkbox"/> MeridianComplete <input checked="" type="checkbox"/> MeridianChoice	
Applicable States: <input type="checkbox"/> All <input checked="" type="checkbox"/> MI <input checked="" type="checkbox"/> IL <input type="checkbox"/> OH <input type="checkbox"/> _____ <input type="checkbox"/> _____	
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If the request is for a Medicare or MMP member please see either NCD 260.3 (Pancreas Transplants) or NCD 260.3.1 (Islet Cell Transplantation in the Context of a Clinical Trial)

Policy: Pancreas transplantation is considered a treatment for members with Diabetes Mellitus Type I to induce an insulin-independent, euglycemic state in these diabetic patients. Pancreas transplantation can restore glucose control with resultant reversal of secondary complications of Diabetes type I, decreased morbidity, and improved quality of life. The procedure is generally limited to those patients with severe secondary complications of diabetes, including kidney failure. However, pancreas transplantation is sometimes performed on patients with labile diabetes and hypoglycemic unawareness.

Procedure:

I. Pancreas Transplantation

There are three major variations of pancreatic transplantation, two of which also involve a kidney transplant:

1. The pancreas and kidney can be transplanted at the same time, during a single procedure, referred to as Simultaneous Pancreas Kidney transplantation (SPK).
2. The pancreas can be transplanted sometime after the kidney transplant, in a separate procedure, referred to as the Pancreas After Kidney transplantation (PAK)
3. The pancreas can be transplanted alone, called the Pancreas Transplant Alone (PTA).

Specific Diagnoses:

Pancreas transplantation is covered for members when the following criteria are met:

Pancreas Kidney Transplant (SPK): A Type I diabetic member with renal failure who may receive a simultaneous Pancreas Kidney Transplant (SPK)

- a. Type I Diabetes Mellitus: C-peptide assay less than normal with additional criteria as outlined in PTA indications #3 below; *And*
- b. Estimated glomerular filtration rate is less than 20 ml/min and fitting criteria for renal transplant as outlined in Policy F.21 Kidney Transplantation *Or*

Pancreas After Kidney (PAK): A Type I diabetic member who may receive a deceased donor or living-related pancreas after a kidney transplantation

- a. Eligible for pancreas transplant and 3 months following kidney transplant; *And*
- b. Fulfills PTA indications as outlined in #3 below *Or*

Pancreas Transplant Alone (PTA): A nonuremic Type I diabetic member with severely disabling and potentially life-threatening diabetic problems who may receive a Pancreas Transplant Alone (PTA)

- a. 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.
- b. Aforementioned complications include frequent hypoglycemia unawareness or recurring severe ketoacidosis, or recurring severe hypoglycemic attacks;
- c. Patients must have been optimally and intensively managed by an endocrinologist for at least 12 months
- d. Patient with diabetes must be beta cell autoantibody positive; or
- e. 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 ≤ 225 mg/dL;

Network:

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)

Required Documentation

1. Transplant team evaluation recommending listing for transplant, documenting indications and contraindications, if any.
2. Psychosocial evaluation completed by qualified mental health professional
3. CBC, LFT's, Renal profile, coagulation profile
4. Documentation of blood or urine screening for alcohol, tobacco, and illicit drug use.
5. Cardiac evaluation with assessment of cardiac risk factors in all patients over 40 years of age and for those younger than 40 with multiple risk factors for coronary artery disease. This must include EKG and echocardiogram as an initial screening test and stress test and/ or cardiac catheterization where clinically indicated.
6. Pulmonary function tests if indicated for pulmonary disease
7. Documentation of age-appropriate screening for extrahepatic malignancies (e.g., colonoscopy, mammogram, pap smear, skin cancer screening by dermatologist) and abdominal ct or mri to screen for hepatocellular carcinoma.
8. Liver function tests with transaminases $< 3X$ upper limit of normal and total bilirubin < 2.5 mg/dl
9. For PTA: serum creatinine < 2.5 mg/dl (< 1.5 mg/dl in children) or GFR > 35 ml/min. If abnormal may be eligible for a combined kidney/pancreas transplant.
10. Carotid Doppler ultrasound (if patient has known coronary artery disease of $>$ age 50)-Abnormal findings evaluated further. Intervention and/or clearance required for abnormal findings.
11. Dental exam, x-rays and treatment completed to eliminate sources of infection in the oral cavity
 - a. Examples include, but are not limited to gum disease, tooth decay, tooth abscesses and poor oral hygiene.

12. Documentation of completion of dietary counseling if BMI > 30.

For additional selection criteria see the special instructions section below

Absolute Contraindications:

1. Persistent noncompliance, see criteria in Member Assessment of Compliance
2. Inadequate support system as documented by a formal social worker evaluation
3. BMI > 40 – relative contraindication
4. Malignancy present with exception of non-melanotic skin cancer
5. Systemic illness or comorbidities that would be expected to substantially and negatively impact the successful completion and/or outcome of transplant surgery, such as, but not limited to:
 - a. Severe cardiac disease (ejection fraction less than 40%)
 - b. Severe pulmonary disease (diffusion capacity (DLCO) < 65% of predicted or dyspnea at rest requiring O2 or FEV1 < 1 L or FVC < 50%,)
 - c. Severe end stage organ damage including: irreversible severe hepatic disease, irreversible severe renal disease except with pancreatic – kidney transplant
 - d. Advanced neurological disorders (e.g., neuroaxonal dystrophy, Tay-Sachs disease, Niemann-Pick disease and its variants, neuronal ceroid lipofuscinosis, and Huntington disease)
6. Significant infection that could be exacerbated by immunosuppressive therapy (such as chronic active viral hepatitis, hepatitis B, hepatitis C and AIDS-SEE APPENDIX A). **NOTE:** HIV infection must be controlled as evidenced by the following:
 - a. CD4 counts > 200 for more than 6 months
 - b. HIV-1 RNA undetectable
 - c. The member is stable on anti-retroviral therapy more than 3 months
 - d. The member has no other complications from acquired human immunodeficiency (AIDS) (e.g. opportunistic infection including aspergillus, tuberculosis, coccidioides mycosis, resistant fungal infections, Kaposi's sarcoma, or other neoplasm).
7. Irreversible severe brain damage
8. Social and Psychiatric Issues-refer for psychosocial evaluation and/or psychiatry consultation for guidance.
 - a. Emotional instability, significant depression or other psychiatric illness that cannot be controlled that would impact ability to comply with a complex evaluation process, surgical procedure and post-transplant plan of care and/or ability to give informed consent (and does not have a representative/guardian/conservator).
 - b. Limited cognitive ability (memory loss, dementia, etc.) that would impact ability to comply with a complex evaluation process, surgical procedure and post-transplant plan of care and/or ability to give informed consent (and does not have a representative/guardian/conservator).
 - c. Lack of psychosocial support as indicated by either no identified caregiver or an uncommitted caregiver. This would include the lack of ability to adhere to the requirements of transplant related treatment plan. A care contract may be needed.
 - d. History of non-adherence that has not been successfully remediated.
 - e. Inability to give informed consent. If the patient has an authorized representative/guardian/conservator or patient in the case of a minor, that individual must understand and support the ongoing health care needs of the patient.
9. Post-transplant lymphoproliferative disease (PTLD) unless no active disease demonstrated by negative positive emission tomography (PET) scan and resolved adenopathy on computed tomography (CT) and/or magnetic resonance emission tomography (CT) and/or magnetic resonance imaging.
10. Limited irreversible rehabilitative potential

Member Assessment of Compliance with Plan of Care (applicable for ages 10 and above):

Transplant will not be approved if any one of the following indicators of non-compliance are observed or documented:

1. Alcohol screen- abstinence for the past 6 months prior to actual transplant approval, if member history includes use of alcohol. If no history exists then 1 negative alcohol screen must be submitted for members with no history of past alcohol use
2. Drug screen-abstinence for the past 6 months prior to actual transplant approval if history exists of drug use. If no history exists then 1 negative drug screen must be submitted for members with no history of positive drug screen.
3. Nicotine screening- abstinence for the past 6 months prior to actual transplant approval if history of smoking. If no history exists then 1 negative cotinine level must be submitted

Refusal or failure to undergo monthly testing for those members with a history of alcohol, tobacco, and/or drug use will be interpreted as a positive test result.

Six month abstinence period may be shortened in cases where patient's condition is sufficiently advanced that mortality is reasonably expected before the full abstinence period can be completed. Patients granted a waiver of the six month abstinence period require documentation of participation in a formal outpatient treatment program, when practical, as well as serial blood or urine testing no less frequently than monthly. A positive test result at any time prior to the procurement phase will result in denial.

II. Islet Cell Transplantation

Specific Diagnoses:

Total pancreatectomy with islet cell transplantation (TPICT) may be covered for adult and pediatric members when the following criteria are met:

- a. Underlying reason for transplant request is Chronic Pancreatitis
- b. Failure of prior medical and surgical interventions for above diagnosis
- c. Member is experiencing frequent bouts of refractory pain requiring ongoing narcotic use
- d. Request is for Autologous islet cell transplantation
- e. Member has been evaluated by a National Pancreas Foundation Center and the NPF Center is recommending TPICT

Required Documentation

1. Transplant team evaluation recommending listing for transplant, documenting indications and contraindications, if any.
2. Psychosocial evaluation completed by qualified mental health professional.
3. CBC, LFT's, Renal profile, coagulation profile
4. Documentation of blood or urine screening for alcohol, tobacco, and illicit drug use.
5. Cardiac evaluation with assessment of cardiac risk factors in all patients over 40 years of age and for those younger than 40 with multiple risk factors for coronary artery disease. This must include EKG and echocardiogram as an initial screening test and stress test and/ or cardiac catheterization where clinically indicated.
6. Pulmonary function tests if indicated for pulmonary disease
7. Documentation of age-appropriate screening for extrahepatic malignancies (e.g., colonoscopy, mammogram, pap smear, skin cancer screening by dermatologist) and abdominal CT or MRI to screen for hepatocellular carcinoma).
8. Liver function tests with transaminases < 3X upper limit of normal and total bilirubin < 2.5mg/dl
9. For PTA: serum creatinine <2.5 mg/dl (<1.5 mg/dl in children) or GFR > 35 ml/min. If abnormal may be eligible for a combined kidney/pancreas transplant.
10. Carotid Doppler ultrasound (if patient has known coronary artery disease of > age 50). Any abnormal findings evaluated further. Intervention and/or clearance required for abnormal findings.
11. For additional selection criteria see the special instructions section below

Absolute Contraindications:

Islet Cell Transplantation is considered investigational/experimental and not covered in the following circumstances:

- a. When the specified criteria above in specific diagnosis has not been met
- b. Request is for allogeneic or xenogeneic islet cell transplantation
- c. Request is for a diagnosis other than Chronic Pancreatitis
- d. C-peptide-negative diabetes
- e. Type 1 diabetes,
- f. Portal vein thrombosis or portal hypertension
- g. Severe cardiac disease (ejection fraction less than 40%)
- h. Severe pulmonary disease (diffusion capacity (DLCO) < 65% of predicted or dyspnea at rest requiring O2 or FEV1<1 L or FVC <50%,)
- i. Pancreatic cancer

Member Assessment of Compliance with Plan of Care (applicable for ages 10 and above):

Transplant will not be approved if any one of the following indicators of non-compliance are observed or documented:

1. Alcohol screen- abstinence for the past 6 months prior to actual transplant approval, if member history includes use of alcohol. If no history exists then 1 negative alcohol screen must be submitted for members with no history of past alcohol use
2. Drug screen-abstinence for the past 6 months prior to actual transplant approval if history exists of drug use. If no history exists then 1 negative drug screen must be submitted for members with no history of positive drug screen.
3. Nicotine screening- abstinence for the past 6 months prior to actual transplant approval if history of smoking. If no history exists then 1 negative cotinine level must be submitted

Refusal or failure to undergo monthly testing for those members with a history of alcohol, tobacco, and/or drug use will be interpreted as a positive test result.

Six month abstinence period may be shortened in cases where patient's condition is sufficiently advanced that mortality is reasonably expected before the full abstinence period can be completed. Patients granted a waiver of the six month abstinence period require documentation of participation in a formal outpatient treatment program, when practical, as well as serial blood or urine testing no less frequently than monthly. A positive test result at any time prior to the procurement phase will result in denial.

Developmental or Acquired Cognitive Impairment and Dementia: Psychosocial and guardianship support as well as reversibility of impairment must be assessed and documented prior to non-compliance determinations.

State specific special instructions:

None:

ALL: The Chief Medical Officer and/or Senior Medical Director must receive notification for all possible approved requests by the UM team

MI:

Medicaid

Non-covered indications: MHP does not cover either of the following because each is considered experimental, investigational or unproven (this list may not be all inclusive):

1. Transplantation of partial pancreatic tissue
2. Bio artificial pancreas device

Medicare:

Please refer to NCD 260.3 Medicare coverage of Pancreas Transplantation: <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=107&ncdver=3&bc=AgAAQAAAAAAAAAA%3d%3d&>

Please refer to NCD 260.3.1 for Medicare coverage of Islet Cell Transplantation: <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=286&ncdver=1&bc=AgAAQAAAAAAAAAA%3d%3d&>

IL:

Medicaid

Non-covered indications: MHP does not cover either of the following because each is considered experimental, investigational or unproven (this list may not be all inclusive):

1. Transplantation of partial pancreatic tissue
2. Bio artificial pancreas device

Medicare:

Please refer to NCD 260.3 Medicare coverage of Pancreas Transplantation: <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=107&ncdver=3&bc=AgAAQAAAAAAAAAA%3d%3d&>

Please refer to NCD 260.3.1 for Medicare coverage of Islet Cell Transplantation: <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=286&ncdver=1&bc=AgAAQAAAAAAAAAA%3d%3d&>

OH:

Line of Business Applicability:

This policy applies to Michigan Medicaid, Illinois Medicaid, and Individual Plans.

For **Medicaid/Medicaid Expansion Plan** members, this policy will apply. Coverage is based on medical necessity criteria being met and the codes being submitted and considered for review being included on either the Michigan Medicaid Fee Schedule (located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html), the Illinois Medicaid Fee Schedule (located at: <http://www.illinois.gov/hfs/MedicalProviders/MedicaidReimbursement/Pages/default.aspx>). If there is a discrepancy between this policy and either the Michigan Medicaid Provider Manual (located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html), or the Illinois Medicaid Provider Manual (located at: <http://www.illinois.gov/hfs/MedicalProviders/Handbooks/Pages/default.aspx>) the applicable Medicaid Provider Manual will govern.

For **Individual** members, consult the individual insurance policy. If there is a discrepancy between this policy and the individual insurance policy document, the guidelines in the individual insurance policy will govern.

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State Letters/Bulletins					
CMS National/Local Coverage Determination (NCD/LCD)	NCD 260.3 Pancreas Transplants (v.3 04/2006) NCD 260.3.1 Islet Cell Transplantation (v.1 10/04)				
Medicare Managed Care Manual:					
Medicaid CFR:	1862(a)(1)(A) of the Social Security Act				
State Administrative Codes:					
Contract Requirements:					
Related Policies:	I.07 Member Compliance Medical Policy	F.21 Kidney Transplant			

Appendix A AIDS-Defining Conditions

Certain serious and life-threatening diseases that occur in HIV-positive people are called “AIDS-defining” conditions. When a person gets one of these illnesses, he or she is diagnosed with the advanced stage of HIV infection known as AIDS.

The Centers for Disease Control and Prevention (CDC) has developed a list of these conditions (see below). No single patient is likely to have all of these problems. Some of the conditions are rare.

1. Bacterial infections, multiple or recurrent (a)
2. Candidiasis of bronchi, trachea, or lungs
3. Candidiasis of esophagus (b)
4. Cervical cancer, invasive (c)
5. Coccidioidomycosis, disseminated or extrapulmonary
6. Cryptococcosis, extrapulmonary
7. Cryptosporidiosis, chronic intestinal (>1 month's duration)
8. Cytomegalovirus disease (other than liver, spleen, or nodes), onset at age >1 month
9. Cytomegalovirus retinitis (with loss of vision) (b)
10. Encephalopathy, HIV related
11. Herpes simplex: chronic ulcers (>1 month's duration) or bronchitis, pneumonitis, or esophagitis (onset at age >1 month)
12. Histoplasmosis, disseminated or extrapulmonary
13. Isosporiasis, chronic intestinal (>1 month's duration)
14. Kaposi sarcoma (b)
15. Lymphoid interstitial pneumonia or pulmonary lymphoid hyperplasia complex (ab)
16. Lymphoma, Burkitt (or equivalent term)
17. Lymphoma, immunoblastic (or equivalent term)
18. Lymphoma, primary, of brain
19. *Mycobacterium avium* complex or *Mycobacterium kansasii*, disseminated, or extrapulmonary (b)
20. *Mycobacterium tuberculosis* of any site, pulmonary (bc), disseminated (b), or extrapulmonary (b)
21. *Mycobacterium*, other species or unidentified species, disseminated (b), or extrapulmonary (b)
22. *Pneumocystis jiroveci* pneumonia (b)
23. Pneumonia, recurrent (bc)
24. Progressive multifocal leukoencephalopathy
25. *Salmonella* septicemia, recurrent
26. Toxoplasmosis of brain, onset at age >1 month (b)
27. Wasting syndrome attributed to HIV

Legend:

(a) Only among children aged <13 years. (CDC. Revised classification system for human immunodeficiency virus infection in children less than 13 years of age. MMWR 1994; 43 [No. RR-12].)

(b) Condition that might be diagnosed presumptively.

(c) Only among adults and adolescents aged \geq 13 years. (CDC. 1193 Revised classification system for HIV infection and expanded surveillance case definition for AIDS among adolescents and adults. MMWR 1992; 41 [No. RR-17])