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:  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).

Pancreas transplantation is covered for the following members:

1. 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
2. A Type I diabetic member who may receive a cadaveric or living-related pancreas after a kidney transplantation (Pancreas After Kidney, PAK)
   a. Eligible for pancreas transplant and 3 months following kidney transplant; And
   b. Fulfills PTA indications as outlined in #3 below Or
3. 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 with the most medically-recognized advanced insulin formulations and delivery systems)
   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;

Additional Selection criteria:
Members must comply with Meridian Health Policy I.07 Member Compliance Medical Policy in addition to the member completing and signing the member agreement form.

1. Age >18 and less than 70 years
2. Adequate support system as documented by a formal social worker evaluation
3. No active malignancy as documented with PAP smear, mammogram, colonoscopy, etc.as deemed appropriate for age and sex
4. BMI < 40
5. Left ventricular ejection fraction >or equal to 40% with no Left ventricular hypertrophy.
6. Liver function tests with transaminases <3X upper limit of normal and total bilirubin < 2.5mg/dl
7. 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.
8. 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.

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

1. For members with a history of tobacco use, if the member fails or refuses to submit to monthly cotinine testing for the preceding 6 months prior to the transplant and while listed, or refuses to actively and continuously participate in an accepted smoking cessation program.
2. For members with a history of alcohol abuse, member fails or refuses to submit to testing for alcohol use. Absence of documentation showing member has not engaged in alcohol use for at least six months prior to transplant and monthly while listed.
3. For members with a history of illicit drug use, member fails or refuses to submit to testing for illegal drug use. Absence of documentation showing member has not engaged in illegal drug use for at least six months prior to transplant and monthly testing while listed.
4. Tobacco, Alcohol and Drug Addiction: Refusal or failure to participate in available addiction interventions for actively using members must be documented in non-compliance determinations.
5. Documentation of non-impactable social issues that substantially increase the risks of an adverse outcome of the medical therapy or transplant at issue
6. Severely Mentally Ill Adults and Severely Emotionally Disturbed Minors: Non-adherence to psychotropic medications or medical regimen in SMI or SED members for whom core symptoms include lack of insight into illness, must be assessed for adequacy of and engagement with psychosocial resource supports in Care Coordination prior to non-compliance determinations.
7. 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.

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](http://www.cms.gov/ESRDGeneralInformation/02_Data.asp#TopOfPage))

1. 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
2. No significant cardiovascular or pulmonary co-morbidities
3. Absence of significant infection that could be exacerbated by immunosuppressive therapy (such as chronic active rival hepatitis B, hepatitis C and HIV). 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, coccidioses mycosis, resistant fungal infections, Kaposi’s sarcoma, or other neoplasm).
4. For additional selection criteria see the special instructions section below

**Special Instructions:**

**Medicaid/All:**

**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 or islet cells
2. Bio artificial pancreas device

**Medicare/All:**

**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:

1. 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)).

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1 (Ward, Slutsker, Buehler, Jaffe, Berkelman, & Curran, 1992)
Line of Business Applicability:

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), or the Iowa Medicaid Fee Schedule (located at: http://dhs.iowa.gov/ime/providers/csrp/fee-schedule). 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), the Illinois Medicaid Provider Manual (located at: http://www.illinois.gov/hfs/MedicalProviders/Handbooks/Pages/default.aspx), or the Iowa Medicaid Provider Manual (located at: http://dhs.iowa.gov/policy-manuals/medicaid-provider) the applicable Medicaid Provider Manual will govern.

For Medicare members, coverage is determined by the Centers for Medicare and Medicaid Services (CMS). If a coverage determination has not been adopted by CMS, this policy applies. Medicare Fee Schedules can be found on the CMS website (https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/FeeScheduleGenInfo/index.html).

For Exchange members, please refer to the Meridian Choice Certificate of Coverage located here: https://share13.mhplan.com/sites/communications/Bronson%20Healthcare/MCH%20Certificate%20of%20Coverage%202016.pdf. If there is a discrepancy between this policy and the Certificate of Coverage for Meridian Choice, the Certificate will govern.

References:

5. optn.transplant.hrsa.gov/CommitteeReports/board_main_Pancreas... · PDF file
8. Michigan Department of Community Health, Medicaid Provider Manual- Hospital, Sec. 3.22, p. 25-27 (Version Date: April 1, 2015)
9. Iowa Department of Human Services, Physician Services, Chapter III. Provider Specific Services. Pg. 52-55. Version Date: July 1, 2014.

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