TITLE: PANCREAS TRANSPLANTATION (PANCREAS ALONE)

EFFECTIVE DATE: April 22, 2019

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 plans. Please refer to the member's plan document for 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 and Minnesota Health Care Programs, this policy will apply unless those 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 about this Medica utilization management policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica utilization management 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 reviewers in utilization management decision-making by providing the criteria that generally determine the medical necessity of pancreas transplantation. The Benefit Considerations box below outlines the process for addressing the needs of individuals who do not meet these criteria.

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).
A. There are three types of pancreas transplantation:
1. Simultaneous pancreas/kidney (SPK)
2. Pancreas after kidney (PAK)
B. 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 same (autologous) or different (allogeneic) individual. (Refer to the Coverage Issues section for additional information.)
C. Substance use disorder, as defined by the fifth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) is a problematic pattern of use of an intoxicating substance leading to clinically significant impairment or distress. The symptoms associated with a substance use disorder fall into four major groupings: impaired control, social impairment, risky use, and pharmacological criteria (i.e., tolerance and withdrawal).
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. Medica 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.
   6. Islet cell transplants except for autologous islet cell transplants associated with pancreatectomy are investigative and therefore, not covered.
   7. If the Medical Necessity and Coverage Criteria are met, Medica will authorize benefits within the limits in the member’s plan document.
   8. If it appears that the Medical Necessity and Coverage Criteria 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 Medica Provider Administrative Manual.
   9. See also related Medica UM Policy, Pancreas-Kidney (SPK, PAK) Transplantation (No. 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 Medica UM policy.]
      Documentation in the medical records indicates that the individual has labile insulin-dependent diabetes mellitus (IDDM).
   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 has labile insulin-dependent diabetes mellitus (IDDM).
      C. Despite optimal medical management and adherence to treatment recommendations the individual meets one of the following criteria:
         1. A history of frequent, acute and severe metabolic and potentially life-threatening complications (e.g., hyperglycemia, hypoglycemia, severe hypoglycemic unawareness, diabetic ketoacidosis [DKA]), requiring medical attention as documented by chart notes, frequent emergency room visits or hospitalizations
         2. Inability to tolerate exogenous insulin
         3. Consistent failure of exogenous insulin-based management to prevent acute complications.
         D. Individual or guardian is able to give informed consent. Individual/guardian and family/social support system
are able to comply with the treatment regimen and the necessary follow-up. Inadequate funding to pay for immunosuppressive medications post-transplant is addressed and resolved.

E. For individuals with a recent (24 months) history of substance use disorder, successful completion of a chemical dependency program and 6 months of documented ongoing abstinence.

F. None of the following contraindications are present:
   1. Uncorrectable medical condition that would itself significantly shorten life expectancy or make transplant success unlikely
   2. Active systemic or localized infection
   3. Active untreated or untreatable malignancy (NOTE: Individuals with underlying malignancy may require oncology consult to assess prognosis and risk of recurrence)
   4. Irreversible multisystem organ failure
   5. HIV infection with detectable viral load and CD4 counts less than 200/mm³, acquired immunodeficiency syndrome (AIDS) or AIDS-defining condition (See Appendix 1)
   6. Active substance use disorder
   7. Irreversible severe brain damage
   8. Significant non-correctable coronary artery disease
   9. Post-transplant lymphoproliferative disease (PTLD) unless no active disease demonstrated by negative PET scan and resolved adenopathy on CT/MRI
   10. Limited irreversible rehabilitative potential
   11. Ongoing pattern of noncompliance, psychiatric illness, psychological condition, or limited cognitive ability that would make compliance with a disciplined medical regimen impossible
   12. Lack of psychosocial support as indicated by either no identified caregiver or an uncommitted caregiver.
   13. Inability to obtain informed consent from individual or guardian.

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: http://www.cms.hhs.gov/mcd/search.asp?

DOCUMENT HISTORY

<table>
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<tr>
<th>Original Effective Date</th>
<th>September 15, 1998</th>
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<tbody>
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<td>Administrative Update(s)</td>
<td>05/01/2017</td>
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References:

Pre-06/2016 MPC


06/2016 MPC:

02/2017 MPC:

02/2018 MPC:

02/2019 MPC:
APPENDIX 1 – AIDS-Defining Conditions

- Bacterial infections, multiple or recurrent*
- Candidiasis of bronchi, trachea, or lungs
- Candidiasis of esophagus
- Cervical cancer, invasive†
- Coccidioidomycosis, disseminated or extrapulmonary
- Cryptococcosis, extrapulmonary
- Cryptosporidiosis, chronic intestinal (greater than 1 month’s duration)
- Cytomegalovirus disease (other than liver, spleen, or nodes), onset at age greater than 1 month
- Cytomegalovirus retinitis (with loss of vision)
- Encephalopathy attributed to HIV§
- Herpes simplex: chronic ulcers (greater than 1 month’s duration) or bronchitis, pneumonitis, or esophagitis (onset at age greater than 1 month)
- Histoplasmosis, disseminated or extrapulmonary
- Isosporiasis, chronic intestinal (greater than 1 month’s duration)
- Kaposi sarcoma
- Lymphoma, Burkitt (or equivalent term)
- Lymphoma, immunoblastic (or equivalent term)
- Lymphoma, primary, of brain
- Mycobacterium avium complex or Mycobacterium kansasii, disseminated or extrapulmonary
- Mycobacterium tuberculosis of any site, pulmonary†, disseminated, or extrapulmonary
- Mycobacterium, other species or unidentified species, disseminated or extrapulmonary
- Pneumocystis jirovecii (previously known as “Pneumocystis carinii”) pneumonia
- Pneumonia, recurrent†
- Progressive multifocal leukoencephalopathy
- Salmonella septicemia, recurrent
- Toxoplasmosis of brain, onset at age greater than 1 month
- Wasting syndrome attributed to HIV§

* Only among children aged less than 6 years.
† Only among adults, adolescents, and children aged greater than or equal to 6 years.
§ Suggested diagnostic criteria for these illnesses, which might be particularly important for HIV encephalopathy and HIV wasting syndrome, are described in the following references:
  - CDC. 1994 Revised classification system for human immunodeficiency virus infection in children less than 13 years of age. MMWR 1994;43(No. RR-12).
  - CDC. 1993 Revised classification system for HIV infection and expanded surveillance case definition for AIDS among adolescents and adults. MMWR 1992;41(No. RR-17).