I. **POLICY**

It is the policy of MedStar Health, Inc. to cover pancreas alone and pancreas/kidney transplantation when it is medically necessary (refer to CRM.015.MH Medical necessity policy) and covered under the member’s specific benefit plan.

MedStar Health, Inc. recognizes pancreas transplantation as appropriate and consistent with good medical practice. Coverage for members requesting pancreas or pancreas/kidney transplant services will be considered on an individual basis for the specific indications detailed in this policy.

All denials are based on medical necessity and appropriateness as determined by a MedStar Health, Inc. Medical Director (Medical Director).

II. **DEFINITIONS**

**HAART – Highly Active Antiretroviral Therapy** (also known as “Triple Drug Cocktail”) - The combination of at least three anti-retroviral (ARV) drugs (a protease inhibitor, and two other drugs called reverse transcriptase inhibitors) that attack different parts of HIV or stop the virus from entering blood cells. Even among people who respond well to HAART, the treatment does not get rid of HIV. The virus continues to reproduce, but at a slower pace.
HIV – (Human Immunodeficiency Virus) - The virus that causes AIDS (Acquired Immunodeficiency Syndrome)

Pancreas Transplant (alone) – Surgical implantation of a normal, immunologically compatible donor pancreas into a person with type 1 diabetes that is poorly controlled despite demonstrated adherence to optimal medical therapy.

Pancreas/Kidney Transplant (simultaneous) – An immunologically compatible donor pancreas transplant performed in conjunction with a cadaver or living donor kidney transplant as a treatment for insulin dependent diabetes associated with end-stage renal failure.

Pancreas After Kidney (PAK) Transplant – Surgical implantation of an immunologically compatible donor pancreas into a person with poorly controlled type 1 diabetes who has had a previous successful kidney transplant.

III. PURPOSE

The purpose of this policy is to define the criteria for Pancreas and Pancreas/Kidney transplantation.

IV. SCOPE

This policy applies to various MedStar Health, Inc. departments as indicated by the Benefit and Reimbursement Committee. These include but are not limited to Medical Management, Benefit Configuration and Claims departments.

V. PROCEDURE

A. Medical Description

Pancreas transplantation is a procedure in which a member who has no endogenous insulin synthesis is implanted with a healthy deceased donor pancreas. Members with diabetes are divided into three main categories for pancreas transplantation:

1. Members with end-stage renal failure and undergoing simultaneous kidney transplantation (SPK)
2. Members who have already had a successful kidney transplant in the past (Pancreas after kidney: PAK)
Islet cell transplantation is the biological replacement of insulin producing cells of the pancreas (Islet of Langerhans). These are also for members with diabetes. Islet cells are separated and purified from deceased donor pancreas and administered to the member by various routes such as intra-portal injection of purified islets, which will lodge in the liver and become vascularized.

B. Specific Indications

Members requesting Pancreas Transplants must meet the criteria for recipient characteristics and the general/specific criteria for the transplant.

Recipient Characteristics
The member has no medical, cognitive, or other psychiatric condition that is likely to interfere with their ability to manage the sequelae of the transplant, including complex medication regimens.

General Criteria
1. The member meets the institution’s selection criteria for pancreas or pancreas/kidney transplantation.

Specific Criteria for Pancreas Transplant Alone (PTA)
PTA is considered medically necessary for carefully selected members who meet all of the following criteria:
1. Members must have a diagnosis of Type I Diabetes.
2. Member must be positive for autoantibodies directed against pancreatic Beta cells, which include anti-islet cell, anti-insulin, and/or anti-glutamic acid decarboxylase autoantibodies.
3. Member must be insulin dependent, adherent to treatment and refractory to intensive insulin therapy, with documented severe and/or life-threatening metabolic complications requiring urgent medical care and/or hospitalizations, including:
   • Hypoglycemia unawareness
   or
   • Recurring severe hypoglycemic attacks
   or
   • Recurring severe ketoacidosis
   or
   • Recurring, severe and/or persistent hyperglycemia requiring medical attention
4. Members must have been managed by an endocrinologist for at least twelve (12) months before evaluation for the transplant.
Specific Criteria for Simultaneous Pancreas/Kidney Transplant (SPK)

SPK is considered medically necessary for carefully selected members with end-stage renal disease from diabetic nephropathy who meets all of the following criteria:

1. End-stage renal disease requiring chronic dialysis or glomerular filtration rate less than 20 ml/min/1.73m² or less than 30 ml/min/1.73m² with uremia and all other indications in policy MP.041 - Transplant: Renal
2. Type 1 diabetes refractory to intensive insulin therapy as described above under the Specific Criteria for Pancreas Transplant Alone (PTA) or type 1 diabetes with one or more progressive complications of diabetes, including:
   - Diabetic retinopathy
   - Diabetic neuropathy
   - Diabetic gastroparesis
   - Arteriosclerotic vascular disease,

For other indications related to kidney transplantation, refer to MP.041 - Transplant: Renal.

Specific Criteria for Pancreas Transplant after Kidney Transplantation (PAK)

PAK is considered medically necessary for members with insulin dependent diabetes who meet all of the following criteria:

1. Member has undergone successful kidney transplant
2. There is absence of significant chronic rejection of the transplanted kidney
3. The transplanted kidney is stable and functioning well with a minimum creatinine clearance of 30 ml/min and the absence of significant proteinuria, and
4. All of the criteria are met for pancreas transplant alone or for simultaneous pancreas/kidney transplant

Specific Criteria for Pancreas Retransplantation

Pancreas retransplantation is considered medically necessary for selected members case by case based on treating physician’s recommendations after a failed primary pancreas transplant.

Partial Pancreatic Tissue or Islet Cell Transplantation
(Refer to MP.095.MH Pancreatectomy with Autologous Islet Cell Transplantation)

Specific Criteria for Pancreas/Pancreas-Kidney Transplant in HIV+ Members

Pancreas/pancreas-kidney transplantation in HIV+ members are considered medically necessary when all of the following conditions are met:

1. The member has a life expectancy of at least 5 years
2. CD4 count ≥200 cells/mL for at least 6 months
3. Undetectable HIV viremia for 6 months
4. Adherence to HAART regimen for ≥ 6 months
5. Treatable with HAART post transplant

C. Limitations

1. Non-transplant treatment of the member’s medical condition must first be attempted and shown to be unsuccessful before consideration of transplant
2. Members must first undergo stringent physical and psychological evaluation to determine eligibility for transplant

General Contraindications include any of the following:
1. Blood type A, B or O (ABO) incompatibility between recipient and donor
2. Donor-recipient Human Leukocyte Antigen (HLA) and/or lymphocytotoxic crossmatch incompatibility according to the United Network for Organ Sharing (UNOS) guidelines for renal transplantation
3. Ongoing alcohol or drug abuse
   (Persons with history of drug or alcohol abuse must be abstinent for at least six (6) months prior to consideration for coverage of transplant.)
4. Active smoking
   (Persons with a past smoking history or recent cessation should currently be enrolled in a smoking cessation program.)
   **EXCEPTION: Dialysis dependence**
5. Active infection (recipients developing infections while on a waiting list may become temporarily inactive and may return to active status if the infection resolves)
6. Active malignancy (other than non-melanoma skin cancers) unless there has been definitive surgical and/or medical therapy with a small likelihood of recurrence. The follow-up period prior to eligibility is variable, and is a function of the specific type of cancer.
7. Active systemic vasculitis
8. Contraindication to immunosuppressive drugs
9. Morbid obesity evidenced by a body mass index (BMI) > 40
10. Absence of appropriate social support group
11. History or probability of non-compliance with medical regimen
12. Not up to date with all applicable preventive services recommended by the U.S. Preventive Services Task Force guidelines (i.e. immunizations and screenings)
13. Female recipients of childbearing potential with either positive pregnancy test or inability/unwillingness to use contraception
Pancreas-Renal Specific Contraindications includes any of the following:
1. Severe and irreversible non-intestinal organ dysfunction determined to be prohibitive to transplantation, including:
   - Significant untreatable coronary artery disease or left ventricular dysfunction
   - Severe limiting chronic pulmonary disease
   - Advanced dementia
   - Severe chronic liver disease
2. Active alcoholic hepatitis

HIV+ Specific Contraindications in HIV positive members include
1. Documented history of progressive multifocal leukoencephalopathy (PML)
2. Epstein-Barr virus (EBV) and Human Herpesvirus 8 (HHV8) related lymphoproliferative disorders (lymphomas and multi-centric Castleman’s disease)
3. Persistent viremia despite HAART therapy
4. Kaposi’s Sarcoma or lymphomas
5. Demonstrated non-compliance with HAART therapy
6. Unwillingness to comply with anti-fungal and antiviral prophylaxis as required
7. If co-infected with Hepatitis B Virus (HBV) or Hepatitis C Virus (HCV), evidence of cirrhosis on liver biopsy

D. Information Required for Review

In order to assess medical necessity for transplantation, adequate information must be furnished by the treating physician. Necessary documentation includes but is not limited to the following:
1. Member’s age, clinical history, physical and functional status
2. Documentation of diagnosis, staging, and treatment history
3. Documentation of any history of substance use disorder
4. Documentation of no active smoking and currently enrolled in a smoking cessation program
5. Documentation of any history of emotional instability or non-compliance with medical management
6. Social work and nutritional assessment consultations
7. Results of pre-transplant testing including:
   - Electrocardiogram (EKG), chest x-ray (CXR), echocardiogram,
   - Ultrasound of native kidneys and right upper quadrant (gallbladder)
   - Skin testing (purified protein derivative standard (PPD) tuberculosis test, mumps, trichophyton)
   - Diabetic members over age 50:
     - Adenosine or persantine thallium stress test
• Voiding cystourethrogram and flat plate of abdomen (males = 50 years old or anuric > 6 months, or urologic history involving bladder)
• Members over 50 years old or if qualifying family history::
  o Colonoscopy

8. Results of laboratory studies and serologic testing, including:
• Blood typing
• Complete blood count (CBC) and chemistry profile (including blood urea nitrogen (BUN), creatinine, electrolytes, glucose, calcium (Ca), phosphorus, uric acid, magnesium (Mg), total protein, albumin, amylase)
• 24-hour creatinine clearance
• Prothrombin Time /Partial Thromboplastin Time (PT/PTT)
• Glycosylated hemoglobin
• Liver function tests (LFT) and lipid panel
• Histocompatibility Antigens (HLA) typing
• Serology testing for cytomegalovirus, varicella virus, herpes simplex virus, Epstein Barr virus, Rapid Plasma Reagin (RPR), and hepatitis virus A, B and C
• Hepatitis panel
• Human immunodeficiency virus (HIV) antibody
• Urine culture
• Diabetes auto-antibodies.
• Serum alpha-fetoprotein (AFP)
• For females – pregnancy test

Documentation for HIV + Members
In addition to the above documentation, the following information should be furnished:
1. The member’s life expectancy
2. CD4 count for the last 6 months
3. Documentation of absence of HIV viremia for 6 months
4. Indication that the member is treatable with HAART post-transplant
5. Demonstrated compliance with anti-fungal and HAART regimen for ≥ 6 months
6. Willingness to use contraception
7. Documentation to support the absence of Kaposi’s Sarcoma or lymphomas
8. If co-infected with HBV or HCV, documented absence of cirrhosis on liver biopsy

For members approved for transplantation and continuing to meet the transplanting institution’s criteria, updated review provided by the requesting facility is required upon expiration of existing authorization.
E. Review Process

1. The Medical Management Ancillary Service staff reviews the request. If the case does not meet the established criteria, it is referred to a MedStar Health, Inc. Medical Director (Medical Director).
2. If referred, the Medical Director determines if the requested service is medically necessary and appropriate.
3. The Medical Management Ancillary Service staff completes the review process and communicates the review decision according to the Timeliness of UM Decisions policy for the member’s benefit plan.

F. Variations

N/A

G. Records Retention

Records Retention for documents, regardless of medium are provided within the MedStar Health, Inc. Policy and Procedure CORP.028.MH Records Retention.

H. Codes

The following codes for treatments and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Applicable Coding:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>48160</td>
<td>Pancreatectomy, total or subtotal, with transplantation of pancreas or pancreatic islet cells</td>
</tr>
<tr>
<td>48551</td>
<td>Backbench preparation of cadaver donor pancreas</td>
</tr>
<tr>
<td>48552</td>
<td>Backbench reconstruction of cadaver donor pancreas; venous anastomosis</td>
</tr>
<tr>
<td>48554</td>
<td>Transplantation of pancreatic allograft</td>
</tr>
</tbody>
</table>
I. References

Medical Literature/Clinical Information:

1. ECRI Institute. Hotline Response: Islet Cell Transplantation for Treating Type 1 Diabetes. Published: 05/06/2014.  
   https://members2.ecri.org/Components/Hotline/Documents/IssueFiles/11902.pdf


**Regulatory/Government Source:**


Disclaimer:

MedStar Health Inc. medical payment and prior authorization policies do not constitute medical advice and are not intended to govern or otherwise influence the practice of medicine. The policies constitute only the reimbursement and coverage guidelines of MedStar Health Inc. and its affiliated managed care entities. Coverage for services varies for individual members in accordance with the terms and conditions of applicable Certificates of Coverage, Summary Plan Descriptions, or contracts with governing regulatory agencies.

MedStar Health Inc. reserves the right to review and update the medical payment and prior authorization guidelines in its sole discretion. Notice of such changes, if necessary, shall be provided in accordance with the terms and conditions of provider agreements and any applicable laws or regulations.

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