Medical Policy

Transplantation of Pancreas or Pancreas-Kidney

Policy Number: OCA 3.25
Version Number: 15
Version Effective Date: 06/07/17

Product Applicability

<table>
<thead>
<tr>
<th>Well Sense Health Plan</th>
<th>Boston Medical Center HealthNet Plan</th>
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<tr>
<td>✗ New Hampshire Medicaid</td>
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</tbody>
</table>

Notes:
+ Disclaimer and audit information is located at the end of this document.
◊ The guidelines included in this Plan policy are applicable to members enrolled in Senior Care Options only if there are no criteria established for the specified service in a Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) on the date of the prior authorization request. Review the member’s product-specific benefit documents at [www.SeniorsGetMore.org](http://www.SeniorsGetMore.org) to determine coverage guidelines for Senior Care Options.

Policy Summary

The Plan considers pancreas or pancreas-kidney transplantation to be medically necessary as an alternative to continued insulin therapy in diabetic patients when applicable Plan medical criteria are met. All transplant-related consultations, evaluations, procedures, and post-transplant follow-up services should be managed within the Plan’s provider network or at the most appropriate preferred transplant facility, depending upon the type of transplant. Prior authorization is required for all transplantation services.

It will be determined during the Plan’s prior authorization process if the specific transplant service is considered medically necessary for the stated indication within the Plan’s provider network, as

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appropriate. When there is no Plan medical policy for the requested type of transplantation, the Plan uses applicable InterQual® criteria to determine medical necessity for the transplantation services. The Plan reviews requests for transplantation services using the Plan’s *Medically Necessary* medical policy when medical policy criteria or InterQual® criteria are not established for the requested type of transplantation. See the Plan policy, *Medically Necessary* (policy number OCA 3.14), for the product-specific definitions of medically necessary treatment. See the Plan’s policy, *Experimental and Investigational Treatment* (policy number OCA 3.12), for the product-specific definitions of experimental or investigational treatment.

The Plan member must meet the eligibility criteria from the transplanting institution. The eligibility criteria of the transplanting institution must follow the applicable United Network for Organ Sharing (UNOS) guidelines. The hospital in which the organ transplants are performed must be a member of the Organ Procurement and Transplantation Network (OPTN) in accordance with the Public Health Service Act, comply with applicable OPTN organ allocation and procurement guidelines, and follow the Centers for Medicare & Medicaid Services (CMS) applicable conditions of participation for the specified organ to be transplanted (including but not limited to the following Code of Federal Regulations: 42 CFR Parts 405, 482, 488, and 498). The transplant program (including affiliated transplant facility, transplant surgeons, transplant physicians, and staff) must follow the designated UNOS/OPTN transplant program criteria for the applicable transplant service and comply with all applicable UNOS/OPTN professional standards. Senior Care Options members will have access to transplant services according all applicable CMS guidelines, including but not limited to the provisions specified in the Medicare Managed Care Manual, Chapter 4 – Benefits and Beneficiary Protections, 10.11 Transplant Services.

**Description of Item or Service**

**Pancreas Transplantation:** A pancreas transplant alone (PTA), simultaneous pancreas kidney (SPK), pancreas after kidney (PAK), and simultaneous deceased donor pancreas and living donor kidney (SPLK) procedures involve surgically implanting healthy organs into the recipient from a deceased or living donor (i.e., transplant of the whole pancreas, pancreas segment, or both the pancreas and kidney). Typically, the recipient’s pancreas is not removed. The Plan considers a partial pancreas (segmental) transplant from a living donor an acceptable alternative to a deceased donor transplant for members who meet Plan medical criteria for pancreas transplant, as specified in the Medical Policy Statement section of this policy.

1. **Pancreas After Kidney (PAK):** Surgical implantation of a deceased or living donor pancreas following a successful prior kidney transplant in the same recipient.

2. **Pancreas Transplant Alone (PTA):** The surgical implantation of pancreas alone from a deceased or living donor.

3. **Simultaneous Pancreas Kidney (SPK):** The concurrent surgical implantation of a pancreas and kidney into a single recipient from a single deceased donor.

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4. **Simultaneous Pancreas Living Donor Kidney (SPLK):** The concurrent implantation of a pancreas from a deceased donor and a kidney from a living donor in one surgical procedure.

**Medical Policy Statement**

Pancreatic transplantation, with or without concurrent kidney transplantation, is considered medically necessary when the medical record documentation supports that ALL of the following applicable criteria have been met, as specified below in item A (Initial Transplantation and Retransplantation Criteria) and item B (Procedure-Specific Criteria):

**A. Initial Transplantation and Retransplantation Criteria:**

See applicable criteria below, EITHER item 1 for criteria for an initial transplantation or item 2 for criteria for retransplantation.

1. **Initial Transplantation Criteria:**

For initial transplantation, ALL of the following criteria are met for transplant clearance of the member as assessed by the transplant surgeon (or a designee of the multidisciplinary transplant team), as specified below in items a through e:

   a. Absence of identifiable potential complications in BOTH the member and the donor (after appropriate evaluation) that could diminish the success of transplantation; AND
   
   b. Member has acceptable nutritional status; AND
   
   c. Member has good rehabilitation potential; AND
   
   d. Member is compliant with medical management; AND
   
   e. Member has exhibited a satisfactory psychosocial profile and satisfactory emotional support system; OR

2. **Retransplantation Criteria:**

Retransplantation is covered when BOTH of the following criteria are met, as specified below in item a and item b:

   a. Criteria are met for the initial transplant (as specified in item 1 above, Initial Transplantation Criteria); AND
b. The member has ONE (1) of the following indications, as specified below in item (1), item (2), or item (3):

(1) Graft failure of an initial pancreas or pancreas-kidney transplant due to ONE (1) of the following, as specified below in item (a) or item (b):

(a) Technical reason, excluding serious reportable event and/or provider-preventable condition;† OR

† Note: See Plan policy, Reimbursement Guidelines – Health Care Acquired Conditions, Provider Preventable Conditions and Serious Reportable Events, policy number 4.610 for BMC HealthNet Plan products and policy number WS 4.29 for Well Sense Health Plan products, for definitions of serious reportable events and provider-preventable conditions

(b) Hyperacute rejection (see Definitions section); OR

(2) Chronic rejection (see Definitions section); OR

(3) Recurrent disease; AND

B. Procedure-Specific Criteria:

ALL applicable criteria are met for an initial transplantation or retransplantation (as specified above in EITHER item A1 or item A2) and ALL applicable disease-specific criteria are met for each procedure (as listed below in item B1, item B2, OR item B3):

1. Simultaneous Pancreas Kidney (SPK) Transplantation and/or Simultaneous Pancreas Living Donor Kidney Transplantation (SPLK)

For SPK transplantation and/or SPLK transplantation, ALL of the following criteria must be met, as specified below in items a, b, and c:

a. Member has a history of diabetes and ONE (1) of the following criteria is met, as specified below in item (1) or item (2):

(1) Member has severe, uncontrolled type 1 diabetes (defined as > 2 severe hypoglycemic episodes within last 24 months) and ALL of the following criteria are met, as specified below as items (a), (b), and (c):

(a) History of frequent, acute and severe metabolic complications (e.g., hypoglycemia, hyperglycemia, ketoacidosis) requiring medical attention; AND
(b) Incapacitating clinical and emotional problems with exogenous insulin therapy; AND

(c) Failure of insulin-based management to consistently prevent complications; OR

(2) Member has type 2 diabetes with history of secondary complications of diabetes; AND

b. Member has end-stage renal disease, as documented by creatinine clearance of 20 mL/min or less; AND

c. The member’s risks of transplantation and chronic immunosuppression are less than the risk of continued diabetic complications; OR

2. Pancreas After Kidney (PAK) Transplantation

For PAK transplantation, ALL of the following criteria must be met, as specified below in items a, b, and c:

a. Member has a history of diabetes and ONE (1) of the following criteria is met, as specified below in item (1) or item (2):

   (1) Member has severe, uncontrolled type 1 diabetes (defined as > 2 severe hypoglycemic episodes within last 24 months) and ALL of the following criteria are met, as specified below as items (a), (b), and (c):

      (a) History of frequent, acute and severe metabolic complications (e.g., hypoglycemia, hyperglycemia, ketoacidosis) requiring medical attention; AND

      (b) Incapacitating clinical and emotional problems with exogenous insulin therapy; AND

      (c) Failure of insulin-based management to consistently prevent complications; OR

   (2) Member has type 2 diabetes with history of secondary complications of diabetes; AND

b. Member has had a successful kidney transplant, as documented by creatinine clearance above 60 mL/min; AND

c. The dual transplant procedure does not pose an excessive surgical risk to the member; OR
3. Pancreas Transplantation Alone (PTA)

For PTA, BOTH of the following criteria must be met, as specified below in item a and item b:

a. Member has a history of diabetes and ONE (1) of the following criteria is met, as specified below in item (1) or item (2):

   (1) Member has severe, uncontrolled type 1 diabetes (defined as > 2 severe hypoglycemic episodes within last 24 months) and ALL of the following criteria are met, as specified below as items (a), (b), and (c):

   (a) History of frequent, acute and severe metabolic complications (e.g., hypoglycemia, hyperglycemia, ketoacidosis) requiring medical attention; AND

   (b) Incapacitating clinical and emotional problems with exogenous insulin therapy; AND

   (c) Failure of insulin-based management to consistently prevent complications; OR

   (2) Member has type 2 diabetes with history of secondary complications of diabetes; AND

b. Member does not have end-stage renal disease (which is documented by creatinine clearance above 40 mL/min)

Limitations

1. Pancreas or pancreas-kidney xenotransplantation (e.g., porcine xenografts) is considered experimental and investigational for any indication.

2. Many factors can affect the outcome of transplantation. Fairly rigid selection criteria are required to obtain optimal results for each patient. Contraindications to pancreas and pancreas-kidney transplantation include but are not limited to any ONE (1) of the following:

a. Absolute contraindications, where there is no reasonable circumstance for undertaking transplant surgery, are listed below and including any ONE (1) of the following, as specified below in items (1) through (12):

   (1) Active, untreated peptic ulcer disease; OR

   (2) Acute or chronic infection that is not adequately treated; OR

   (3) Advanced peripheral vascular disease not amenable to surgical therapy; OR

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(4) AIDS (diagnosis based on CDC definition of CD4 count, 200 cells/mm³) unless ALL of the following are noted, as specified below in items (a) through (d):

(a) CD4 count >200 cells/mm³ for > 6 months; AND

(b) HIV-1 RNA undetectable; AND

(c) No other complications from AIDS (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioides mycosis, resistant fungal infections, Kaposi’s sarcoma or other neoplasm); AND

(d) On stable anti-retroviral therapy > 3 months; OR

(5) Diabetes adequately controlled with insulin; OR

(6) Hepatitis B virus (HBV) surface Ag positive; OR

(7) Inability to adhere to the therapeutic regimen necessary to preserve the transplant, including but not limited to compliance with the prescribed medication regimen, monitoring for signs and symptoms of complications, avoidance of risk factors that may result in adverse clinical outcomes, and/or attendance at regular clinical checkups; OR

(8) Irreversible hepatic or pulmonary disease; OR

(9) Refractory congestive heart failure; OR

(10) Acute or chronic infection that is not adequately treated; OR

(11) Uncorrectable coronary artery disease; OR

(12) Tissue incompatibility between donor and recipient as determined by a positive preoperative cross match, meaning that the donor and recipient are not compatible; OR

b. Relative contraindications are listed below that put the member at higher risk of complications; this risk may be outweighed by other medical considerations and therefore transplant surgery may be considered with any ONE (1) of the following relative contraindications, as specified below in items (1) through (8), with Medical Director review and applicable Plan criteria must be met (as specified in the Medical Policy Statement section of this policy):
(1) Advanced autonomic neuropathy; OR

(2) Active substance abuse within the last 6 months including tobacco, alcohol and narcotics or other addictive pain medications; OR

(3) Age < 18 years or > 65 years on the date of service; OR

(4) Cerebrovascular accident (CVA) that is not amenable to rehabilitation; OR

(5) History of malignancy treated within the last 3 years (excluding non-melanoma skin cancer); OR

(6) Morbid obesity (BMI > 35); ‡ OR

‡ Note: Pancreas transplantation requires intra-abdominal surgery, and post-transplantation wound healing is affected by an elevated BMI. Furthermore, an elevated BMI is associated with insulin resistance and may be associated with post-transplant diabetes

(7) Recent retinal hemorrhage; OR

(8) Uncontrolled hypertension

Definitions

End-Stage Renal Disease (ESRD): Chronic irreversible renal failure resulting in the kidneys inability to excrete wastes, concentrate urine and regulate electrolytes. Complications are multiple and severe, and without dialysis or kidney transplantation, death will likely occur.

Kidney: A bean-shaped organ that removes waste products of metabolism from the blood and excretes them in urine; one of a pair of organs located on each side of the abdominal cavity.

Pancreas: A tongue shaped glandular organ that is located below and behind the stomach that secretes insulin and glucagon for the regulation of blood sugar and digestive enzymes.

Segmental Pancreas: A portion or segment of the pancreas.

Transplant Rejection: A process in which a transplant recipient’s immune system attacks the transplanted organ or tissue. There are three (3) clinicopathologic stages of rejection:

1. Hyperacute Rejection: A recipient’s immune reaction that occurs within a few minutes after the transplant when the antigens are completely unmatched, resulting in organ failure within
the first hours after transplantation. The tissue must be removed right away so the recipient does not die.

2. Acute Rejection: A recipient’s immune reaction that occurs any time from the first week after the transplant (during which the immune response increases in intensity) and generally up to 60 to 90 days after organ transplantation. It may be Grade I (mild), Grade II (moderate) or Grade III (severe). All recipients have some amount of acute rejection.

3. Chronic Rejection: A recipient’s immune reaction that occurs more than 60 days after transplantation and can take place over many years. This is the body's constant immune response against the new organ that slowly damages the transplanted tissues or organ.

**Type 1 Diabetes Mellitus:** Also known as insulin dependent diabetes mellitus (IDDM) or juvenile diabetes, this type of diabetes is characterized by a severe deficiency of insulin secretion that usually develops during childhood or adolescence resulting in atrophy of the islets of Langerhans in the pancreas and causes hyperglycemia and a tendency towards ketoacidosis.

**Type 2 Diabetes Mellitus:** Also known as non-insulin dependent diabetes mellitus (NIDDM) or maturity onset diabetes, this type of diabetes is characterized by an abnormal pattern of glucose metabolism, including increased tissue insulin resistance resulting in decreased glucose uptake, decreased insulin secretion, increased hepatic glucose production, and increased carbohydrate intake.

**Uremia:** The accumulation of constituents in the blood that are normally eliminated in the urine, producing a severe toxic condition that usually occurs in end stage renal disease.

**Xenotransplantation:** According to the U.S. Public Health Service, xenotransplantation is defined as any procedure that involves the transplantation, implantation, or infusion into a human recipient of either of the following, as specified below in item 1 or item 2:

1. Live cells, tissues, or organs from a non-human animal source; or

2. Human body fluids, cells, tissues or organs that have had ex vivo contact with live non-human animal cells, tissues, or organs. (See this policy’s Limitations section.)

**Applicable Coding**

The Plan uses and adopts up-to-date Current Procedural Terminology (CPT) codes from the American Medical Association (AMA), International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) diagnosis codes developed by the World Health Organization and adapted in the United States by the National Center for Health Statistics (NCHS) of the Centers for Disease Control under the U.S. Department of Health and Human Services, and the Health Care Common Procedure Coding System (HCPCS) established and maintained by the Centers for Medicare &
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Medicaid Services (CMS). Because the AMA, NCHS, and CMS may update codes more frequently or at different intervals than Plan policy updates, the list of applicable codes included in this Plan policy is for informational purposes only, may not be all inclusive, and is subject to change without prior notification. Whether a code is listed in the Applicable Coding section of this Plan policy does not constitute or imply member coverage or provider reimbursement. Providers are responsible for reporting all services using the most up-to-date industry-standard procedure and diagnosis codes as published by the AMA, NCHS, and CMS at the time of the service.

Providers are responsible for obtaining prior authorization for the services specified in the Medical Policy Statement section and Limitation section of this Plan policy, even if an applicable code appropriately describing the service that is the subject of this Plan policy is not included in the Applicable Coding section of this Plan policy. Coverage for services is subject to benefit eligibility under the member’s benefit plan. Please refer to the member’s benefits document in effect at the time of the service to determine coverage or non-coverage as it applies to an individual member. See Plan reimbursement policies for Plan billing guidelines.

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<thead>
<tr>
<th>CPT Codes</th>
<th>Description: Codes Covered When Medically Necessary</th>
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<tbody>
<tr>
<td>48554</td>
<td>Transplantation of pancreatic allograft</td>
</tr>
<tr>
<td>48556</td>
<td>Removal of transplanted pancreatic allograft</td>
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<tr>
<th>HCPCS Codes</th>
<th>Description: Code Covered When Medically Necessary</th>
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<tbody>
<tr>
<td>S2065</td>
<td>Simultaneous pancreas kidney transplantation</td>
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Plan note: Code is not payable for the Senior Care Options product.

Clinical Background Information

Pancreas transplantation is intended to restore normal insulin secretion in patients with diabetes mellitus and is the most proven therapy that restores continuous euglycemic control, slows the progression of end-organ complications, and improves quality of life in type I diabetics. The American Diabetes Association (2003) has concluded that pancreas-kidney transplantation is indicated in patients with insulin-dependent diabetes and end stage renal disease: “Pancreas transplantation should be considered an acceptable therapeutic alternative to continued insulin therapy in diabetic patients with imminent or established end-stage renal disease who have had or plan to have a kidney transplant, because the successful addition of a pancreas does not jeopardize patient survival, may improve kidney survival, and will restore normal glycemia.”

There are three types of kidney/pancreas transplants: simultaneous pancreas kidney (SPK) transplant, pancreas transplant alone (PTA), and pancreas after kidney (PAK) transplant. SPK transplant is typically offered to patients who have insulin-dependent diabetes mellitus and in whom diabetic nephropathy and renal insufficiency have developed. Many of these patients have other complications of diabetes, including retinopathy, neuropathy, and/or gastropathy. In most SPK transplants, both organs are from the same deceased donor, but it is possible to use a living donor for a segmental pancreas transplant and a deceased donor kidney. Additionally, it is possible to do a living donor kidney transplant.
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Patients undergoing simultaneous pancreas-kidney (SPK) transplantation may include cases where a deceased donor pancreas and a living donor kidney are transplanted at the same time. Patients undergoing pancreas transplantation without a kidney (PTA) are generally selected for patients with severe, uncontrolled diabetes (defined as > 2 severe hypoglycemic episodes within last 24 months) without renal failure, who have failed insulin-based management and may have incapacitating clinical or emotional problems with insulin therapy. Pancreas transplant is generally the option for patients who have a living donor for the kidney. The timing of the transplantation is different for each. With a SPK transplant, both organs are transplanted at the same time, whereas with a PAK transplant, the pancreas is transplanted as a planned separate procedure that is usually done several months following a successful kidney transplant. For PTA, life-long immunosuppression is required to prevent rejection of the graft and potential recurrence of the autoimmune process that might destroy pancreatic islet cells again. Pancreas transplants are typically not performed in children under the age of 18 but may be done as part of a multivisceral transplant involving other organs such as liver, pancreas, stomach, and/or kidney.

Candidates for pancreas transplantation must undergo a thorough pre-transplant evaluation by a multidisciplinary team comprised of surgeons, transplant coordinators, social workers, nutritionist, pharmacist, and other specialists, as clinically indicated. Typically, the pre-transplant work-up includes the following, as specified below in items 1 through 4:

1. Blood work: CBC with differential count, sedimentation rate, electrolytes, pancreatic enzymes (i.e., lipase and amylase), lipid profile, liver function tests, coagulation profile and serological tests.
2. Cardiovascular: 12 lead ECG, chest x-ray, echocardiogram, carotid artery ultrasound, exercise treadmill test, and vascular Doppler studies
3. Endocrine: Cortisol level, thyroid studies, and bone density testing
4. Renal: Urinalysis, 24 hour creatinine clearance, glomerular filtration rate, urine microalbumin, and total protein

Postoperative care of the transplant recipient includes monitoring and management that focuses on the prevention of infection, thrombosis, and graft rejection. Patients are given antibiotics, anti-coagulation, and immunosuppression therapy following the surgery. Surgical complications can include graft thrombosis, infection, anastomotic leak, pancreatitis, and/or bleeding. Rejection of the transplant can occur at any time following the transplant.

The U.S. Department of Health and Human Services (DHHS) has oversight responsibility for the organ allocation system in the United States. Congress established the Organ Procurement and Transplantation Network (OPTN) when it enacted the National Organ Transplant Act (NOTA) of 1984. The Act called for a unified transplant network to be operated by a private, nonprofit organization under federal contract. United Network for Organ Sharing (UNOS) was awarded the initial OPTN contract in 1986 and continues to administer the OPTN.
At the time of the Plan’s most recent policy review, the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) #260.3 for pancreas transplants states that whole organ pancreas transplantation is covered by Medicare when performed simultaneous with or after a kidney transplant. Pancreas transplantation is generally limited to patients with severe secondary complications of diabetes (e.g., kidney failure); it is performed to induce an insulin-independent, euglycemic state in patients with diabetes. Pancreas transplantation is sometimes performed on patients with labile diabetes and hypoglycemic unawareness. If the pancreas transplant occurs after the kidney transplant, immunosuppressive therapy begins with the date of discharge from the inpatient stay for the pancreas transplant. CMS requires that services be provided at a Medicare-approved kidney transplant centers that perform pancreas transplants, alone or subsequent to a kidney transplant, and that also perform kidney-pancreas transplants (as specified in 42 CFR Parts 405, 482, 488, and 498 Medicare Program, Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers to Perform Organ Transplants, Final Rule, March 30, 2007). CMS evaluates detailed criteria for facility participation that include but are not limited to the following: Clinical experience, patient selection of suitable candidates, patient management, maintenance of data, organ procurement, laboratory services, and billing guidelines. Senior Care Options members will have access to transplant services according all applicable CMS guidelines, including but not limited to the provisions specified in the Medicare Managed Care Manual, Chapter 4 – Benefits and Beneficiary Protections, 10.11 Transplant Services. Determine what applicable CMS criteria are in effect for pancreas or pancreas-kidney transplant services in an NCD or LCD on the date of the prior authorization request for a Senior Care Options member.

References


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Gruessner AC et al. Pancreas transplant outcomes for United States (US) cases as reported to the United Network for Organ Sharing (UNOS) and the International Pancreas Transplant Registry (IPTR). Clin Transpl. 2008:45-56.


Palmer SC. Interventions for Preventing Bone Disease in Kidney Transplant Recipients. Cochrane Database 2005.


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<th>Summary of Revisions</th>
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<tr>
<td>07/11/07</td>
<td>Updated template, added coding, and added references.</td>
<td>Version 2</td>
<td>07/11/07: MPCTAC 07/24/07: Utilization Management Committee (UMC) 08/13/07: QIC</td>
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<td>09/09/08</td>
<td>No changes.</td>
<td>Version 3</td>
<td>09/09/08: MPCTAC 09/30/08: UMC 10/22/08: QIC</td>
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<tr>
<td>08/25/09</td>
<td>Review for effective date 12/01/09. Updated references and coding. Added AIDS criteria to the contraindications section.</td>
<td>12/01/09 Version 4</td>
<td>08/25/09: MPCTAC 08/25/09: UMC 09/23/09: QIC</td>
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<tr>
<td>09/01/10</td>
<td>Updated references and coding.</td>
<td>Version 5</td>
<td>09/15/10: MPCTAC 10/27/10: QIC</td>
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<td>09/01/11</td>
<td>Updated clinical criteria for type 2 diabetics and updated references.</td>
<td>Version 6</td>
<td>09/21/11: MPCTAC 10/26/11: QIC</td>
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<tr>
<td>08/01/12</td>
<td>Off cycle review for Well Sense Health Plan, revised Summary statement, reformatted Medical Policy Statement, revised Applicable Coding introduction, updated code list.</td>
<td>Version 7</td>
<td>08/13/12: MPCTAC 09/06/12: QIC</td>
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<tr>
<td>09/01/12</td>
<td>Specified prior authorization requirement and referenced the Plan’s <em>Experimental and Investigational Treatment</em> policy in Summary section. Reformatted medical criteria in Medical Policy Statement section. Updated and categorized applicable code list. Revised language in the Applicable Coding section and Limitations section. Contraindications moved from Clinical Background Information to Limitations section. Updated references.</td>
<td>Version 8</td>
<td>09/19/12: MPCTAC 10/24/12: QIC</td>
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<tr>
<td>03/01/13</td>
<td>Review for effective date 07/01/13. Revised title, updated Description of Item or Service section, revised clinical criteria in the Medical Policy Statement section (formerly named the Clinical Guideline Statement section), revised</td>
<td>07/01/13 Version 9</td>
<td>03/20/13: MPCTAC 04/18/13: QIC</td>
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<tr>
<td>Limitations and Definitions sections, changed relative contraindication of BMI &gt; 35 to BMI &gt; 40, revised applicable code list, updated and added references, and changed name of policy category from “Clinical Coverage Guidelines” to “Medical Policy.” Referenced <em>Medically Necessary</em> policy and <em>Reimbursement Guidelines: Serious Reportable Event/Provider Preventable Condition</em> policy.</td>
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Policy Revisions History

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<tbody>
<tr>
<td>03/01/17</td>
<td>Updated Summary, Definitions, Clinical Background Information, and References</td>
<td>Version 15</td>
<td>03/15/17: MPCTAC</td>
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<tr>
<td></td>
<td>in the Limitations section. Revised criteria in the Medical Policy Statement</td>
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<tr>
<td></td>
<td>Plan note added to the Applicable Coding section.</td>
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<tr>
<td>06/07/17</td>
<td>Review for effective date 06/07/17. Updated Summary, Definitions, Clinical</td>
<td>06/07/17</td>
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<td></td>
<td>Background Information, and References sections. Revised criteria in the</td>
<td>Version</td>
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<td>Medical Policy Statement section.</td>
<td>15</td>
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<td></td>
<td>Plan note added to the Applicable Coding section.</td>
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Last Review Date

03/01/17

Next Review Date

03/01/18

Authorizing Entity

MPCTAC

Other Applicable Policies

Administrative Policy – Clinical Criteria, policy number OCA 3.201
Administrative Policy – Transplantation Administration, policy number OCA 3.10
Medical Policy – Experimental and Investigational Treatment, policy number OCA 3.12
Medical Policy – Medically Necessary, policy number OCA 3.14
Medical Policy – Transplantation of Lung or Lobar Lung, policy number OCA 3.24
Medical Policy – Transplantation of Small Bowel, Small Bowel-Liver, or Multivisceral Organs, policy number OCA 3.26
Reimbursement Policy – Anesthesia, policy number 4.103
Reimbursement Policy – General Billing and Coding Guidelines, policy number 4.31
Reimbursement Policy – General Clinical Editing and Payment Accuracy Review Guidelines, policy number 4.108

Transplantation of Pancreas or Pancreas-Kidney

*Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.
Reimbursement Policy – *Inpatient Hospital*, policy number 4.110
Reimbursement Policy – *Outpatient Hospital*, policy number 4.17
Reimbursement Policy – *Physician and Non Physician Practitioner Services*, policy number 4.608

**Reference to Applicable Laws and Regulations**


New Hampshire Medicaid. Hospitals, Hospital-Based Rural Health Clinics (RHC-HB), and Swing Bed

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Disclaimers Information: *

Medical Policies are the Plan’s guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member’s benefit document, and when appropriate, coordinates with the Member’s health care Providers to consider the individual Member’s health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan’s service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member’s benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

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