Medical Policy

Transplantation of Pancreas or Pancreas-Kidney

Policy Number: OCA 3.25  
Version Number: 18  
Version Effective Date: 04/01/20

Product Applicability

- All Plan® Products

Well Sense Health Plan
- Well Sense Health Plan

Boston Medical Center HealthNet Plan
- MassHealth ACO
- MassHealth MCO
- Qualified Health Plans/ConnectorCare/Employer Choice Direct
- Senior Care Options ◊

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 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 and clinical appropriateness) and according to the administrative guidelines specified in the Plan’s Transplant Administration policy, policy number OCA 3.10. Prior authorization is required for ALL transplantation services provided to a Plan member (even when a separate Plan authorization has already been obtained for an inpatient admission but

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.
the authorization does NOT include transplantation services), with final approval required by a Plan Medical Director. It will be determined during the Plan’s prior authorization process if the specific transplant service is considered medically necessary for the requested indication within the Plan’s provider network, as appropriate.

Prior authorization requests for transplantation services for Plan members are evaluated utilizing medical necessity criteria in the applicable Plan medical policy. If there is no Plan medical policy for the requested type of transplantation (e.g., simultaneous pancreas and lung transplantation), the Plan uses InterQual® criteria to determine the medical necessity of the requested transplantation services. The Plan conducts an individual evaluation of the member’s medical condition based on the guidelines outlined in the Plan’s Clinical Review Criteria administrative policy, policy number OCA 3.201, when there is no applicable Plan medical policy and InterQual® criteria are not established for the requested type of transplantation. When a member is deemed to be an appropriate candidate for transplantation services based on the Plan’s applicable medical necessity criteria and the evaluation conducted by the treating provider, final approval is required by a Plan Medical Director for the member’s transplantation. In addition, Plan Medical Director review is required when the Plan’s applicable medical necessity criteria are not met for requested transplantation services.

The Plan’s Clinical Technology Evaluation administrative policy, policy number OCA 3.13, outlines the Plan’s process for evaluating new technology and the new application of existing technology. The Plan’s Medically Necessary medical policy, policy number OCA 3.14, specifies the product-specific definitions of medically necessary treatment, and the Plan’s Experimental and Investigational Treatment medical policy, policy number OCA 3.12, indicates the product-specific definitions of experimental or investigational treatment.

Plan prior authorization is required for genetic testing according to the guidelines specified in the Plan’s Genetic/Genomic Testing and Pharmacogenetics medical policy, policy number OCA 3.727, rather than criteria included in this Plan policy and are based on the type of genetic test requested, indication(s) for testing, and if the test is ordered, administered, and processed by participating providers and participating laboratories (or non-participating providers and non-participating laboratories); this includes all genetic testing associated with pre-and/or post-transplantation services (e.g., genetic testing of transplant recipients to identify the probability of active rejection using tests such as AlloMap® by CareDx, AlloSure® by CareDx, or myTAIHEART by TAI Diagnostics). Genetic/genomic testing is considered medically necessary when the Plan’s applicable medical policy criteria are met or Plan-adopted InterQual® criteria are met for the requested genetic test when criteria are not included in a Plan medical policy. Plan Medical Director review is required for individual consideration when clinical review criteria are not established for the requested genetic test and/or specified indication(s) for testing.

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

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.
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.

Section 14.20 Transplantation of Pancreas or Pancreas-Kidney 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.

Review the member’s applicable benefit documents available at www.bmchp.org for benefit coverage and associated transplant guidelines for a BMC HealthNet Plan member, at www.SeniorsGetMore.org for a Senior Care Options member, and at www.wellsense.org for a Well Sense Health Plan member. If a transplant is requested for a Well Sense Health Plan member and authorized by the Plan as medically necessary, a Plan-approved transplant center will review the case to determine the member’s status as a candidate for a transplant at that facility (based on the clinical guidelines utilized by the transplant program).

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.

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.

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.
Medical Policy Statement

When a member is deemed an appropriate candidate for transplantation services based on the Plan’s applicable medical necessity criteria and the evaluation conducted by the treating provider, **final approval is required by a Plan Medical Director** for the member’s transplantation. In addition, Plan Medical Director review is required when the Plan’s applicable medical necessity criteria are not met for requested transplantation services. An evaluation for transplantation services conducted by the treating provider is defined as a consultation and diagnostic testing or other testing required to assess a member’s appropriateness and readiness for transplantation; an evaluation does not include care required as part of the course of treatment for the underlying medical condition. See the Policy Statement section of the Plan’s *Transplant Administration* policy, administrative policy number OCA 3.10, for guidelines on how the Plan processes requests for evaluations by participating providers and non-participating providers.

The Plan member must meet eligibility criteria from the transplanting institution for the requested transplantation services. The eligibility criteria of the transplanting institution must follow applicable United Network for Organ Sharing (UNOS) guidelines. The hospital in which the organ transplant is performed must be a member of the Organ Procurement and Transplantation Network (OPTN) and comply with applicable OPTN organ allocation and procurement guidelines. Pancreatic transplantation, with or without concurrent kidney transplantation, is considered medically necessary when the medical record documentation supports that ALL of 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

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.*
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 the Plan’s *Provider Preventable Conditions and Serious Reportable Events* reimbursement policy (policy number 4.610 for BMC HealthNet Plan members, policy number SCO 4.610 for Senior Care Options members, and policy number WS 4.29 for Well Sense Health Plan members) 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)**

ALL of the following criteria must be met for SPK transplantation and/or SPLK transplantation, as specified below in items a through d:

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 greater than 2 severe hypoglycemic episodes within last 24 months with documentation of severe hypoglycemia unawareness and/or potentially life-threatening labile diabetes and failure of insulin-based management to consistently prevent complications (as evidenced by medical record documentation, emergency department visits, or hospitalization); OR

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

b. Member is on insulin and has a C-peptide value specified below in EITHER item (1) or item (2):

   (1) C-peptide value less than or equal to 2 ng/mL; OR

   (2) C-peptide value greater than 2 ng/mL and has a body mass index (BMI) less than or equal to the maximum allowable BMI (according to applicable eligibility criteria from the transplanting institution and the procedure-specific clinical guidelines established by the Organ Procurement and Transplantation Network/OPTN in effect on the date of service); AND

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

   d. 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**

ALL of the following criteria must be met for PAK transplantation, as specified below in items a through d:

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) C-peptide value less than or equal to 2 ng/mL; OR

   (2) C-peptide value greater than 2 ng/mL and has a body mass index (BMI) less than or equal to the maximum allowable BMI (according to applicable eligibility criteria from the transplanting institution and the procedure-specific clinical guidelines established by the Organ Procurement and Transplantation Network/OPTN in effect on the date of service); AND

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

   d. The member’s risks of transplantation and chronic immunosuppression are less than the risk of continued diabetic complications; OR
(1) Member has severe, uncontrolled type 1 diabetes defined as greater than 2 severe hypoglycemic episodes within last 24 months with documentation of severe hypoglycemia unawareness and/or potentially life-threatening labile diabetes and failure of insulin-based management to consistently prevent complication (as evidenced by medical record documentation, emergency department visits, or hospitalization); OR

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

b. Member is on insulin and has a C-peptide value specified below in EITHER item (1) or item (2):

(1) C-peptide value less than or equal to 2 ng/mL; OR

(2) C-peptide value greater than 2 ng/mL and has a body mass index (BMI) less than or equal to the maximum allowable BMI (according to applicable eligibility criteria from the transplanting institution and the procedure-specific clinical guidelines established by the Organ Procurement and Transplantation Network/OPTN in effect on the date of service); AND

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

d. The dual transplant procedure does not pose an excessive surgical risk to the member; OR

3. Pancreas Transplantation Alone (PTA)

BOTH of the following criteria must be met for PTA, 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 greater than 2 severe hypoglycemic episodes within last 24 months with documentation of severe hypoglycemia unawareness and/or potentially life-threatening labile diabetes and failure of insulin-based management to consistently prevent complication (as evidenced by medical record documentation, emergency department visits, or hospitalization); 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

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) and according to the administrative guidelines specified in the Plan’s Transplant Administration policy, administrative policy number OCA 3.10. Prior authorization is required for ALL transplantation services. **Prior authorization is required for ALL transplantation services provided to a Plan member (even when a separate Plan authorization has already been obtained for an inpatient admission but the authorization does NOT include transplantation services), with final approval required by a Plan Medical Director.** The Plan member must meet the eligibility criteria from the transplanting institution. The eligibility criteria of the transplanting institution and must comply with all applicable United Network for Organ Sharing (UNOS) guidelines and recipient selection criteria.

Prior authorization requests for transplantation services for Plan members are evaluated utilizing medical necessity criteria in the applicable Plan medical policy. If there is no Plan medical policy for the requested type of transplantation (e.g., simultaneous pancreas and lung transplantation), the Plan uses InterQual® criteria to determine the medical necessity of the requested transplantation services. The Plan conducts an individual evaluation of the member’s medical condition based on the guidelines outlined in the Plan’s Clinical Review Criteria administrative policy, policy number OCA 3.201, when there is no applicable Plan medical policy and InterQual® criteria are not established for the requested type of transplantation. When a member is deemed to be an appropriate candidate for transplantation services based on the Plan’s applicable medical necessity criteria and the evaluation conducted by the treating provider, final approval is required by a Plan Medical Director for the member’s transplantation.

1. **Individual Consideration by Plan Medical Director for Pancreas or Pancreas-Kidney Transplantation:**

   Any request for a pancreas or pancreas-kidney transplantation that does NOT meet applicable medical necessity criteria specified in the Medical Policy Statement section of this policy requires individual consideration by a Plan Medical Director. The Plan Medical Director will evaluate the individual member’s clinical needs and circumstances based on the guidelines included in the Plan’s Clinical Review Criteria administrative policy, policy number OCA 3.201.

2. **Genetic Testing:**

   Plan prior authorization is required for genetic testing according to the guidelines specified in the Plan’s Genetic/Genomic Testing and Pharmacogenetics medical policy, policy number OCA 3.727, rather than criteria included in this Plan policy and are based on the type of genetic test requested, indication(s) for testing, and if the test is ordered, administered, and processed by participating providers and participating laboratories (or non-participating providers and non-

---

* 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.
participating laboratories); this includes all genetic testing associated with pre-and/or post-transplantation services (e.g., genetic testing of transplant recipients to identify the probability of active rejection using tests such as AlloMap® by CareDx, AlloSure® by CareDx, or myTAIHEART by TAI Diagnostics). Genetic/genomic testing is considered medically necessary when the Plan’s applicable medical policy criteria are met or Plan-adopted InterQual® criteria are met for the requested genetic test when criteria are not included in a Plan medical policy. Plan Medical Director review is required for individual consideration when clinical review criteria are not established for the requested genetic test and/or specified indication(s) for testing.

3. **Experimental and Investigational Services:**

Pancreas or pancreas-kidney xenotransplantation (e.g., porcine xenografts) is considered experimental and investigational for any indication. See the Plan’s *Experimental and Investigational Treatment* medical policy, policy number OCA 3.12, for the product-specific definitions of experimental or investigational treatment.

4. **Contraindications:**

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, as specified below in item a or b:

a. **Absolute contraindications**, where there is generally 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 (9):

   (1) Acute or chronic infection that is not adequately treated; OR
   (2) Advanced peripheral vascular disease not amenable to surgical therapy; OR
   (3) Immunosuppressed or potentially exacerbated by immunosuppression with at least ONE (1) of the following conditions, as specified below in items (a) through (d):

      (a) Known active malignancy, including metastatic cancer, other than non-melanomatous skin cancer; OR
      (b) Recently treated malignancy within two (2) years of curative treatment without evidence of recurrence (or within five [5] years for breast cancer, colorectal cancer, or melanoma); this absolute contraindication does NOT include an early stage cancer in which the cancerous growth or tumor is still confined to the site from which it started, and has not spread to surrounding tissue or other organs.

---

*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.*

9 of 29
in the body (i.e., carcinoma in situ, cancer in situ, preinvasive carcinoma, in situ lesions);** OR

(c) Malignancy with a moderate or high risk of recurrence;** OR

** Note: The assessment of risk recurrence must be determined by the transplant team; the transplant team must then submit a written statement to the Plan explaining why the member with a recently treated malignancy or a member with a moderate or high risk of recurrence is an appropriate candidate for transplant surgery.

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

i. CD4 count >200cells/mm3 for > 6 months; AND

ii. HIV-1 RNA undetectable; AND

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

iv. On stable anti-retroviral therapy > 3 months; OR

(4) 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

(5) Irreversible hepatic or pulmonary disease; OR

(6) Refractory congestive heart failure; OR

(7) Uncorrectable coronary artery disease; OR

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

(9) Severe systemic disease that could be exacerbated by immunosuppression.
b. **Relative contraindications** are listed below in items 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) Active, untreated peptic ulcer disease; OR

(2) Advanced autonomic neuropathy; OR

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

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

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

(6) Morbid obesity (BMI > 35) UNLESS the member’s BMI meets the applicable eligibility criteria from the transplanting institution and the procedure-specific clinical guidelines established by the Organ Procurement and Transplantation Network (OPTN) in effect on the date of service; ‡ 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, 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).

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 form of diabetes is caused by autoimmunity in which the islets of Langerhans are destroyed by the patient’s immune system, and the result is severe insulin deficiency. This type of diabetes usually develops during childhood or adolescence.

**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 & Medicaid Services (CMS). Since 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.

<table>
<thead>
<tr>
<th>CPT Codes</th>
<th>Description: Codes Covered When Medically Necessary</th>
</tr>
</thead>
<tbody>
<tr>
<td>48554</td>
<td>Transplantation of pancreatic allograft</td>
</tr>
<tr>
<td>48556</td>
<td>Removal of transplanted pancreatic allograft</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description: Code Covered When Medically Necessary</th>
</tr>
</thead>
<tbody>
<tr>
<td>S2065</td>
<td>Simultaneous pancreas kidney transplantation</td>
</tr>
</tbody>
</table>

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.”

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.
There are three types of kidney/pancreas transplants: simultaneous pancreas kidney (SPK) transplant, pancreas transplantation 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 simultaneously with a deceased donor pancreas (SPLK). A pancreas transplantation alone (PTA) is generally done for a patient who has a severe, uncontrolled diabetes (defined as > 2 severe hypoglycemic episodes within last 24 months) without renal failure, who has failed insulin-based management and may have incapacitating clinical or emotional problems with insulin therapy. PAK 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 and 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 transplantations alone 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, cardiac stress 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, anticoagulation, 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 NCD 190.1 states histocompatibility testing is safe and effective when it is performed on patients in preparation for a kidney 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


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.


* 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.


* 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.


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.


Policy History

<table>
<thead>
<tr>
<th>Original Approval Date</th>
<th>Original Effective Date* and Version Number</th>
<th>Policy Owner</th>
<th>Original Policy Approved by</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulatory Approval: N/A</td>
<td>10/01/06 Version 1</td>
<td>Medical Policy Manager as Chair of Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC)</td>
<td>Quality and Clinical Management Committee (Q&amp;CMC)</td>
</tr>
<tr>
<td>Internal Approval: 08/01/06</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Effective Date for the BMC HealthNet Plan Commercial Product(s): 01/01/12
*Effective Date for the Well Sense Heath Plan New Hampshire Medicaid Product(s): 01/01/13
*Effective Date for Senior Care Options Product(s): 01/01/16

Policy Revisions History

<table>
<thead>
<tr>
<th>Review Date</th>
<th>Summary of Revisions</th>
<th>Revision Effective Date and Version Number</th>
<th>Approved by</th>
</tr>
</thead>
<tbody>
<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>
</tr>
<tr>
<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>
</tr>
<tr>
<td>08/25/09</td>
<td>Review for effective date 12/01/09. Updated references and coding. Added</td>
<td>12/01/09 Version 4</td>
<td>08/25/09: MPCTAC 08/25/09: UMC</td>
</tr>
</tbody>
</table>

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.
<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
<th>Version</th>
<th>Date</th>
<th>Author</th>
</tr>
</thead>
<tbody>
<tr>
<td>09/01/10</td>
<td>Updated references and coding.</td>
<td>Version 5</td>
<td>09/15/10</td>
<td>MPCTAC 10/27/10: QIC</td>
</tr>
<tr>
<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</td>
<td>MPCTAC 10/26/11: QIC</td>
</tr>
<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</td>
<td>MPCTAC 09/06/12: QIC</td>
</tr>
<tr>
<td>09/01/12</td>
<td>Specified prior authorization requirement and referenced the Plan’s Experimental and Investigational Treatment 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</td>
<td>MPCTAC 10/24/12: QIC</td>
</tr>
<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 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 Medically Necessary policy and Reimbursement Guidelines: Serious Reportable Event/Provider Preventable Condition policy.</td>
<td>07/01/13 Version 9</td>
<td>03/20/13</td>
<td>MPCTAC 04/18/13: QIC</td>
</tr>
<tr>
<td>08/14/13 and 08/15/13</td>
<td>Off cycle review for Well Sense Health Plan and merged policy format. Incorporate policy revisions dated</td>
<td>Version 10</td>
<td>08/14/13</td>
<td>MPCTAC (electronic vote) 08/15/13: QIC</td>
</tr>
<tr>
<td>Date</td>
<td>Description</td>
<td>Version</td>
<td>Action</td>
<td></td>
</tr>
<tr>
<td>------------</td>
<td>-----------------------------------------------------------------------------</td>
<td>---------</td>
<td>------------------</td>
<td></td>
</tr>
<tr>
<td>03/01/13</td>
<td>03/01/13 (as specified above) for the Well Sense Health Plan product; these policy revisions were approved by MPCTAC on 03/20/13 and QIC on 04/18/13 for applicable Plan products.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>03/01/14</td>
<td>Review for effective date 07/01/14. Updated Description of Item or Service, Clinical Background Information, and References sections. Revised policy title. Revised criteria in the Medical Policy Statement section and Limitations section.</td>
<td>07/01/14 Version 11</td>
<td>03/19/14: MPCTAC 04/16/14: QIC</td>
<td></td>
</tr>
<tr>
<td>03/01/15</td>
<td>Review for effective date 07/01/15. Updated Summary and References sections. Revised criteria in the Medical Policy Statement section and Limitations section. Removed Commonwealth Care, Commonwealth Choice, and Employer Choice from the list of applicable products because the products are no longer available. Removed pancreatic islet cell transplantation from this medical policy. Updated applicable code list.</td>
<td>07/01/15 Version 12</td>
<td>03/18/15: MPCTAC 04/08/15: QIC</td>
<td></td>
</tr>
<tr>
<td>11/25/15</td>
<td>Review for effective date 01/01/16. Updated template with list of applicable products and notes. Revised language in the Applicable Coding section.</td>
<td>01/01/16 Version 13</td>
<td>11/18/15: MPCTAC 11/25/15: MPCTAC (electronic vote) 12/09/15: QIC</td>
<td></td>
</tr>
<tr>
<td>03/01/16</td>
<td>Review for effective date 07/01/16. Updated Summary, Description of Item or Service, Clinical Background Information, References, and Reference to Applicable Laws and Regulations sections. Administrative changes made to the Medical Policy Statement section. Revised criteria in the Limitations section. Removed CPT code 48550 from the applicable code list.</td>
<td>07/01/16 Version 14</td>
<td>03/16/16: MPCTAC 04/13/16: QIC</td>
<td></td>
</tr>
<tr>
<td>03/01/17</td>
<td>Review for effective date 06/07/17. Updated Summary, Definitions, Clinical Background Information, and References sections. Revised criteria in the Medical Policy Statement section.</td>
<td>06/07/17 Version 15</td>
<td>03/15/17: MPCTAC</td>
<td></td>
</tr>
</tbody>
</table>
Policy Revisions History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Effective Date</th>
<th>Version</th>
<th>Authorizing Entity</th>
</tr>
</thead>
<tbody>
<tr>
<td>03/01/18</td>
<td>Plan note added to the Applicable Coding section.</td>
<td>04/01/18 Version 16</td>
<td>03/21/18: MPCTAC</td>
<td></td>
</tr>
<tr>
<td>03/01/19</td>
<td>Review for effective date 04/01/18. Administrative changes made to the Medical Policy Statement and Limitations sections. Updated the Policy Summary, References, and Other Applicable Policies sections.</td>
<td>03/20/19 Version 17</td>
<td>03/20/19: MPCTAC</td>
<td></td>
</tr>
<tr>
<td>03/01/20</td>
<td>Review for effective date 04/01/20. Administrative changes made to the Policy Summary, Limitations, Clinical Background Information, References, Other Applicable Policies, and Reference to Applicable Laws and Regulations sections.</td>
<td>04/01/20 Version 18</td>
<td>03/12/20: MPCTAC (electronic vote)</td>
<td></td>
</tr>
</tbody>
</table>

Last Review Date
03/01/20

Next Review Date
03/01/21

Authorizing Entity
MPCTAC

Other Applicable Policies

Administrative Policy - Clinical Review Criteria, policy number OCA 3.201
Administrative Policy - Clinical Technology Evaluation, policy number OCA 3.13
Administrative Policy - Transplantation Administration, policy number OCA 3.10
Medical Policy - Continuous Glucose Monitoring Systems and Insulin Delivery Devices, policy number OCA 3.966

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.
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 - *Provider Preventable Conditions and Serious Reportable Events*, policy number WS 4.29

**Reference to Applicable Laws and Regulations**


130 CMR 450.000. Code of Massachusetts Regulations. Division of Medical Assistance. Administrative and Billing Regulations.


---

* 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.

Disclaimer 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.