BOSTON MEDICAL CENTER HEALTHNet PLAN

bmchp.org | 888-566-0008

WELL SENSE HEALTH PLAN

wellsense.org | 877-957-1300

Medical Policy

Transplantation of Pancreas or Pancreas-Kidney

Policy Number: OCA 3.25
Version Number: 20
Version Effective Date: 12/01/21

Product Applicability	☒ **All Plan+ Products**
WellSense Health Plan	**Boston Medical Center HealthNet Plan**
☒ NH Medicaid	☒ MassHealth ACO
☒ NH Medicare Advantage	☒ MassHealth MCO
	☒ Qualified Health Plans/ConnectorCare/Employer Choice Direct
	☒ Senior Care Options

+ Note: Disclaimer and audit information is located at the end of this document.

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 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 the authorization does NOT include transplantation services), with final approval required by a Plan Medical Director. Prior authorization requests for transplantation services are evaluated with medical necessity criteria in the applicable Plan medical policy. If there is no Plan medical policy for the requested type of transplantation, the Plan uses InterQual® criteria to determine the medical necessity. 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. 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.

Clinical Criteria

Pancreatic transplantation, with or without concurrent kidney transplantation, is considered medically necessary when the medical record documentation supports that ALL of following applicable criteria in item A and item B:

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 -** ALL of the following criteria are met 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 satisfactory psychosocial profile and emotional support system; OR

2. **Retransplantation Criteria -** BOTH of the following criteria must be met in items item a and b:

    a. Criteria are met for the initial transplant; AND

    b. The member has ONE (1) of the following indications listed in items (1) through (3):

        (1) Graft failure of an initial pancreas or pancreas-kidney transplant due to either a technical reason (excluding serious reportable event and/or provider-preventable condition) or hyperacute rejection; OR

        (2) Chronic rejection; OR

(3) Recurrent disease; AND

B. **Procedure-Specific Criteria:**

ALL applicable criteria are met for an initial transplantation or retransplantation and ALL applicable disease-specific criteria are met for each procedure, as listed below in items 1 through 3:

1. **Simultaneous Pancreas Kidney (SPK) Transplantation and/or Simultaneous Pancreas Living Donor Kidney Transplantation (SPLK) -** ALL criteria are met in items a through d:

   a. Member has type 1 or 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 (2):

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

      (2) C-peptide value > 2 ng/mL and has a BMI $\leq$ the maximum allowable BMI; AND

   c. Member has end-stage renal disease with creatinine clearance < 20 mL/min; 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 criteria are met in items a through d:

   a. Member has type 1 or 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 (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; AND

   c. Member has had successful kidney transplant, as documented by creatinine clearance > 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 criteria are met in items a and b:

    a. Member has a history of diabetes and criteria are met in EITHER 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 > 40 mL/min)

Limitations and Exclusions

1. **Genetic testing:** Plan prior authorization is required for genetic testing according to the guidelines in the Plan's *Genetic/Genomic Testing and Pharmacogenetics* medical policy, policy number OCA 3.727, including genetic testing to estimate the probability of active rejection with AlloMap, AlloSure, or myTAIHEART. Plan-adopted InterQual® criteria must be met.

2. **Pancreas or pancreas-kidney xenotransplantation** (e.g., porcine xenografts) is considered experimental and investigational or NOT medically necessary due to limited evidence demonstrating the clinical utility or clinical validity of treatment for any indication.

4. **Contraindications** include but are not limited to any of the following conditions in item a or b:

    a. **Absolute contraindications**, where there is generally no reasonable circumstance for undertaking transplant surgery, are 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 years of curative treatment with no evidence of recurrence (within five years for breast cancer, colorectal cancer, melanoma); this does NOT include early stage cancer when cancerous growth or tumor is confined to the original site and has not spread to surrounding tissue or other organs (i.e., carcinoma in situ, preinvasive carcinoma, in situ lesions); OR

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

(d) AIDS (diagnosis based on CDC definition of CD4 count, 200 cells/mm^3) **unless** ALL of the following are noted, as specified below in items i through iv:

i. CD4 count >200 cells/mm^3 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 (1) through (8):

(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 UNLESS the member's age 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

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

(6) Morbid obesity (BMI $\geq$ 35) UNLESS the member's BMI meets the applicable eligibility criteria from the transplanting institution and the procedure-specific clinical guidelines established by 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.

Variations

The Plan uses guidance from the Centers for Medicare & Medicaid Services (CMS) for medical necessity and coverage determinations for Senior Care Options (SCO) members and WellSense Medicare Advantage HMO members, including but not limited to national coverage determinations (NCDs), local coverage determinations (LCDs), local coverage articles (LCAs), and documentation included in Medicare manuals. At the time of the Plan's most recent policy review, CMS NCD 260.3 includes nationally covered indications for pancreas transplants. Verify CMS guidelines in effect on the date of the prior authorization request. When there is no guidance from CMS for the requested service, Plan-adopted clinical review criteria will be used to determine the medical necessity of the service.

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 Clinical Criteria section and Limitation and Exclusions 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 this Applicable Coding section. Review the Plan's reimbursement policies for Plan billing guidelines. Coverage for services is subject to benefit eligibility under the member's benefit plan in effect at the time of the service. Member benefit documents are available at the following websites: www.bmchp.org for BMC HealthNet Plan members, www.SeniorsGetMore.org for Senior Care Options members, www.wellsense.org for WellSense New Hampshire Medicaid members, and www.WellSense.org/Medicare for WellSense Medicare Advantage HMO members.

CPT Codes	**Description: Codes Covered When Medically Necessary**
48554	Transplantation of pancreatic allograft
48556	Removal of transplanted pancreatic allograft
HCPCS Codes	**Description: Code Covered When Medically Necessary**
S2065	Simultaneous pancreas kidney transplantation Plan note: Code is NOT payable for the Senior Care Options and WellSense Medicare Advantage HMO products.

References

Alhamad T, Kukla A, Stratta RJ. Pancreas-kidney transplantation in diabetes mellitus: Pancreas allograft rejection. UpToDate. 2020 Feb 27.

Alhamad T, Stratta RJ. Pancreas-kidney transplantation in diabetes mellitus: Patient selection and pretransplant evaluation. UpToDate. 2020 Oct 29

American Diabetes Association (ADA). Chiang J, Kirkman MS, Laffel L, Peters A. Type 1 Diabetes Through the Life Span: A Position Statement of the American Diabetes Association. Diabetes Care. 2014 Jul;37(7):2034-54. doi: 10.2337/dc14-1140. PMID: 24935775.

American Diabetes Association (ADA). Statistics. Examine the Facts.

American Diabetes Association (ADA). Robertson RP, Davis C, Larsen J, Stratta R, Sutherland DE; ADA. Pancreas and Islet Transplantation in Type 1 Diabetes. Position Statement. Diabetes Care. 2006 Apr;29(4):935. PMID: 16567844.

American Diabetes Association (ADA). Standards of Medical Care in Diabetes-2021. Diabetes Care. 2021 Jan 1;44(Suppl. 1): S152-62.

American Society of Transplantation (AST). Fischer SA, Lu K; AST Infectious Diseases Community of Practice. Screening of donor and recipient in solid organ transplantation. Am J Transplant. 2013 Mar; 13 Suppl 4:9-21. doi: 10.1111/ajt.12094. PMID: 23464994.

American Society of Transplantation (AST). Guidelines and Opinions. Infectious Diseases, Kidney, Liver/Intestines, Heart and Lung.

Baid-Agrawal S, Pascua M, Moradpour D, Somasundaram R, Muche M. Hepatitis C Virus Infection and Kidney Transplantation. Amer J Transplantation. 2014 Oct; 14(10):2206-20. doi: 10.1111/ajt.12835. Epub 2014 Aug 4. PMID: 25091274.

Barbas AS, Al-Adra DP, Goldaracena N, Dib MJ, Selzner M, Sapisochin G, Cattral MS, McGilvray ID. Pancreas Transplantation with Portal-Enteric Drainage for Patients with Endocrine and Exocrine Insufficiency from Extensive Pancreatic Resection. Transplant Direct. 2017 Aug 9; 3(9):e203. doi: 10.1097/TXD.0000000000000721. eCollection 2017 Sep. PMID: 28894791.

Barlow AD, Saeb-Parsy K, Watson CJE. An analysis of the survival outcomes of simultaneous pancreas and kidney transplantation compared to live donor kidney transplantation in patients with type 1 diabetes: a UK Transplant Registry study. Transpl Int. 2017 Sep;30(9):884-92. doi: 10.1111/tri.12957. Epub 2017 May 2.PMID: 28319322.

Bazerbachi F, Selzner M, Marquez MA, Norgate A, McGilvray ID, Schiff J, Cattral MS. Pancreas-after-kidney versus synchronous pancreas-kidney transplantation: comparison of intermediate-term results. Transplantation. 2013 Feb 15;95(3):489-94. doi: 10.1097/TP.0b013e318274ab1a.PMID: 23183776.

Bédat B, Niclauss N, Jannot AS, Andres A, Toso C., Morel P, Berney T. (2015). Impact of recipient body mass index on short-term and long-term survival of pancreatic grafts. Transplantation, 2015 Jan;99(1):94-9. doi: 10.1097/TP.0000000000000226. PMID: 24914570.

Belga S, Doucette KE. Hepatitis C in non-hepatic solid organ transplant candidates and recipients: A new horizon. World J Gastroenterol. 2016 Jan; 22(4):1650-63. doi: 10.3748/wjg.v22.i4.1650. PMID: 26819530.

Brennan DC, Rodeheffer RJ, Ambinder RF. Development of malignancy following solid organ transplantation. UpToDate. 2019 Aug 19.

Bunnapradist S, Danovitch GM. Evaluation of adult kidney transplant candidates. Am J Kidney Dis. 2007 Nov; 50(5):890-8. doi: 10.1053/j.ajkd.2007.08.010. PMID: 17954303.

Canadian Society of Transplantation (CST). Reference Documents.

Centers for Disease Control and Prevention (CDC). Transplant Safety. Current Guideline for Organ Transplants.

Centers for Medicare & Medicaid Services (CMS). Conditions for Coverage (CfCs) & Conditions of Participations (CoPs). Transplant Centers.

Centers for Medicare & Medicaid Services (CMS). Manuals. Publication # 100-02. Medicare Benefit Policy Manual.

Centers for Medicare & Medicaid Services (CMS). Manuals. Publication # 100-03. Medicare National Coverage Determinations (NCD) Manual.

Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database (MCD).

Centers for Medicare & Medicaid Services (CMS). Medicare Managed Care Manual. Chapter 4 – Benefits and Beneficiary Protections. 10.11 Transplant Services. Rev 121. Issued 2016 Apr 22.

Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Pancreas Transplants 260.3. Version 3. 2006 Apr 26.

Centers for Medicare & Medicaid Services (CMS). Quality, Safety & Oversight – Certification & Compliance. Transplant. 2021 Oct 8.

Centers of Medicare & Medicaid Services (CMS). State Operations Manual. Appendix A - Survey Protocol, Regulations and Interpretive Guidelines for Hospitals. Rev. 200. 2020 Feb 21.

Centers for Medicare & Medicaid Services (CMS). Transmittals.

Centers of Medicare & Medicaid Services (CMS). Transplant.

Chakkera HA, Kudva YC, Chang YH, Heilman RL, Singer AL, Mathur AK, Hewitt WR, Khamash HA, Huskey JL, Katariya NN, Moss AA, Behmen S, Reddy KS. Glucose Homeostasis after Simultaneous Pancreas and Kidney Transplantation: A Comparison of Subjects with C-Peptide-Positive-Non-Type I Diabetes Mellitus and Type I Diabetes Mellitus. Clin Transplant. 2016 Jan; 30(1):52-9. doi: 10.1111/ctr.12658. Epub 2015 Nov 26. PMID: 26485408.

Chapman JR, Webster AC, Wong G. Cancer in the Transplant Recipient. Cold Spring Harb Perspect Med. 2013 Jul;3(7):a015677. doi: 10.1101/cshperspect.a015677. PMID: 23818517.

Commonwealth of Massachusetts. Division of Insurance (DOI) Bulletins.

Commonwealth of Massachusetts. MassHealth Guidelines for Medical Necessity Determination. Organ Transplant Procedures. Executive Office of the Health and Human Services.

Commonwealth of Massachusetts. MassHealth Provider Bulletins.

Commonwealth of Massachusetts. MassHealth Provider Manuals

Commonwealth of Massachusetts. MassHealth Transmittal Letters.

Cooper DKC. The Case for Xenotransplantation. Clin Transplant. 2015 Apr; 29(4):288–93. doi: 10.1111/ctr.12522. Epub 2015 Feb 28. PMID: 25728841.

Endocrine Society. Guidelines and Clinical Practice.

Fridell JA, Wozniak TC, Powelson JA, Reynolds JM. Simultaneous bilateral lung and pancreas transplantation in recipient with cystic fibrosis. Transplant Proc. 2008 Mar; 40(2):494-7. doi: 10.1016/j.transproceed.2008.01.010. PMID: 18374112.

Gasteiger S, Cardini B, Göbel G, Oberhuber R, Messner F, Resch T, Bösmüller C, Margreiter C, Schneeberger S, Maglione M. Outcomes of pancreas retransplantation in patients with pancreas graft failure. Br J Surg. 2018 Dec; 105(13):1816-1824. doi: 10.1002/bjs.10929. Epub 2018 Jul 14.PMID: 30007018.

Gruessner AC. 2011 update on pancreas transplantation: comprehensive trend analysis of 25,000 cases followed up over the course of twenty-four years at the International Pancreas Registry (IPTR). Rev Diabet Stud 2011 spring; 8(1):6-16. doi: 10.1900/RDS.2011.8.6. Epub 2011 May 10. PMID: 21720668.

Gruessner AC, Sutherland DE, Gruessner RW. Long-term outcome after pancreas transplantation. Curr Opin Organ Transplant. 2012 Feb;17(1):100-5. doi: 10.1097/MOT.0b013e32834ee700. PMID: 22186094.

Gruessner AC, Sutherland DE, Gruessner RW. Pancreas transplantation in the United States: a review. Curr Opin Organ Transplant. 2010 Feb; 15(1):93-101. doi: 10.1097/MOT.0b013e32833552d2. PMID: 20009932.

Han DJ, Sutherland DE. Pancreas transplantation. Gut Liver. 2010 Dec;4(4):450-65. doi: 10.5009/gnl.2010.4.4.450. Epub 2010 Dec 17. PMID: 21253293.

Hatamizadeh P, Molnar MZ, Streja E, Lertdumrongluk P, Krishnan M, Kovesdy CP, Kalantar-Zadeh K. Recipient-Related Predictors of Kidney Transplantation Outcomes in the Elderly. Clin Transplant. 2013 May-Jun; 27(3):436-43. doi: 10.1111/ctr.12106. Epub 2013 Mar 21. PMID: 23516994.

Hryhorowicz M, Zeyland J, Słomski R, Lipiński D. Genetically Modified Pigs as Organ Donors for Xenotransplantation. Mol Biotechnol. 2017 Oct; 59(9-10):435-44. doi: 10.1007/s12033-017-0024-9. PMID: 28698981.

Jiang AT, Rowe N, Sener A, Luke P. Simultaneous pancreas-kidney transplantation: The role in the treatment of type 1 diabetes and end-stage renal disease. Can Urol Assoc J. 2014 Mar; 8(3-4):135-8. doi: 10.5489/cuaj.1597. PMID: 24839485.

Kalantar-Zadeh K, Molnar MZ, Kovesdy CP, Mucsi I, Bunnapradist S. Management of mineral and bone disorder after kidney transplantation. Curr Opin Nephrol Hypertens. 2012 Jul; 21(4):389-403. doi: 10.1097/MNH.0b013e3283546ee0. PMID: 22614626.

Kamgar M, Huang E, Kamgar M, Nata N, Leeaphorn N, Kalantar-Zadeh K, Bunnapradist S. Zero-mismatch deceased-donor kidney versus simultaneous pancreas-kidney transplantation. Transplantation. 2012 Oct 27; 94(8):822-9. doi: 10.1097/TP.0b013e31826334a6. PMID: 23032866.

Kaufman DB, Sutherland. Simultaneous Pancreas-Kidney Transplants Are Appropriate in Insulin-Treated Candidates with Uremia Regardless of Diabetes Type. CJASN. 2011 May;6(5):957-9. doi: 10.2215/CJN.03180411.

Kirchner VA, Finger EB, Bellin MD, Dunn TB, Gruessner RW, Hering BJ, Humar A, Kukla AK, Matas AJ, Pruett TL, Sutherland DE, Kandaswamy R. Long-term Outcomes for Living Pancreas Donors in the Modern Era. Transplantation. 2016 Jun; 100(6):1322-8. doi: 10.1097/TP.0000000000001250. PMID: 27203593.

Laurence JM, Marquez MA, Bazerbachi F, Seal JB, Selzner M, Norgate A, McGilvray ID, Schiff J, Cattral MS. Optimizing pancreas transplantation outcomes in obese recipients. Transplantation. 2015 Jun; 99(6):1282-7. doi: 10.1097/TP.0000000000000495. PMID: 25539462.

Mittal S, Gough SC. Pancreas transplantation: a treatment option for people with diabetes. Diabet Med. 2014 May; 31(5):512-21. doi: 10.1111/dme.12373. PMID: 24313883.

Molmenti EP, Alex A, Rosen L, Alexander M, Nicastro J, Yang J, Siskind E, Alex L, Sameyah E, Bhaskaran M, Ali N, Basu A, Sachdeva M, Agorastos S, Rajendran P, Krishnan P, Ramadas P, Amodu L, Cagliani J, Rehman S, Kressel A, Sethna CB, Sotiropoulos GC, Radtke A, Sgourakis G, Schwartz R, Fishbane S, Bellucci A, Coppa G, Rilo H, Molmenti Cl. Recipient Criteria Predictive of Graft Failure in Kidney Transplant. Int J Angiol. 2016 Mar; 25(1):29-38. doi: 10.1055/s-0035-1563605. Epub 2015 Sep 15. PMID: 26900309.

New Hampshire Department of Health and Human Services. Billing Manuals.

New Hampshire Department of Health and Human Services. Provider Notices.

Organ Procurement and Transplantation Network (OPTN). Allocation Calculators. Calculated Panel Reactive Antibody (CPRA) Calculator, Estimated Post Transplant Survival (EPTS) Calculator, Kidney Donor Profile Index (KDPI) Calculator, Lung Allocation Score (LAS) Calculator, Model for End-Stage Liver Disease (MELD) and Pediatric End-Stage Liver Disease (PELD) Calculators, Archived Allocation Calculator Resources.

Organ Procurement and Transplantation Network (OPTN). Bylaws

Organ Procurement and Transplantation Network (OPTN). Kidney-Pancreas Allocation System Frequently Asked Questions.

Organ Procurement and Transplantation Network (OPTN). Organ Procurement and Transplantation Network.

Organ Procurement and Transplantation Network (OPTN). Policies.

Organ Procurement and Transplantation Network (OPTN) and United Network for Organ Sharing (UNOS). OPTN/UNOS Ethics Committee. Ethical Principles in the Allocation of Human Organs. 2015 Jun 2.

Organ Procurement and Transplantation Network (OPTN). View Data Reports

Palepu S, Prasad GV. New-onset diabetes mellitus after kidney transplantation: Current status and future directions. World J Diabetes. 2015 Apr 15;6(3):445-55. doi: 10.4239/wjd.v6.i3.445. PMID: 25897355.

Parajuli S, Arunachalam A, Swanson KJ, Aziz F, Garg N, Bath N, Redfield RR, Kaufman D, Djamali A, Odorico J, Mandelbrot DA. Pancreas Retransplant after Pancreas Graft Failure in Simultaneous Pancreas-kidney Transplants Is Associated with Better Kidney Graft Survival. Transplant Direct. 2019 Aug; 5(8): e473. doi: 10.1097/TXD.0000000000000919. PMID: 31576369.

Parajuli S, Arunachalam A, Swanson KJ, Aziz F, Garg N, Redfield RR, Kaufman D, Djamali A, Odorico J, Mandelbrot DA. Outcomes after simultaneous kidney-pancreas versus pancreas after kidney transplantation in the current era. Clin Transplant. 2019 Dec; 33(12):e13732. doi: 10.1111/ctr.13732. Epub 2019 Nov 6. PMID: 31628870.

Pérez-Sáez MJ and Pascual J. Kidney Transplantation in the Diabetic Patient. J Clin Med. 2015 Jun;4(6):1269–80. doi: 10.3390/jcm4061269. PMID: 26239558.

Ramphul R, Fernandez M, Firoozi S, Kaski JC, Sharma R, Banerjee D. Assessing cardiovascular risk in chronic kidney disease patients prior to kidney transplantation: clinical usefulness of a standardized

cardiovascular assessment protocol. BMC Nephrol. 2018 Jan 8;19(1):2. doi: 10.1186/s12882-017-0795-z. PMID: 29310598.

Redfield RR, Scalea JR, Odorico JS. Simultaneous pancreas and kidney transplantation: current trends and future directions. Curr Opin Organ Transplant. 2015 Feb; 20(1):94–102. doi: 10.1097/MOT.0000000000000146. PMID: 25565444.

The Renal Association. Guidelines and Commentaries.

Rossi AP, Klein CL. Kidney transplantation in adults: Evaluation of the potential renal transplant recipient. UptoDate. 2020 Feb 19

Scientific Registry of Transplant Recipients (SRTR) and Organ Procurement and Transplantation Network (OPTN). The SRTR/OPTN Annual Data Report. Statistics on donation and transplantation in the United States. Current report and archived reports. 2020 Jan 2.

Shah AP, Mangus RS, Powelson JA, Samy KP, Taber TE, Goble ML, Fridell JA. Impact of recipient age on whole organ pancreas transplantation. Clin Transplant. 2013 Jan-Feb; 27(1):E49-55. doi: 10.1111/ctr.12047. Epub 2012 Dec 11.PMID: 23228216.

Shin S, Jung CH, Choi JY, Kwon HW, Jung JH, Kim YH, Han DJ. Long-term effects of pancreas transplant alone on nephropathy in type 1 diabetic patients with optimal renal function. PLoS One. 2018 Jan 29;13(1):e0191421. doi: 10.1371/journal.pone.0191421. PMID: 29377901.

Smith JM, Biggins SW, Haselby DG, Kim WR, J. Wedd J, Lamb K, Thompson B, Segev DL, Gustafson S, Kandaswamy R, Stock PG, Matas AJ, Samana CJ, Sleeman EF, Stewart D, Harper A, Edwards E, Snyder JJ, Kasiske BL, Israni AK. Kidney, pancreas and liver allocation and distribution in the United States. Am J Transplant. 2012 Dec;12(12):3191-212. doi: 10.1111/j.1600-6143.2012.04259.x. Epub 2012 Nov 16. PMID: 23157207.

Stratta RJ, Rogers J, Farney AC, Orlando G, El-Hennawy H, Gautreaux MD, Reeves-Daniel A, Palanisamy A, Iskandar SS, Bodner JK. Pancreas transplantation in C-peptide positive patients: does "type" of diabetes really matter? J Am Coll Surg. 2015 Apr; 220(4):716-27. doi: 10.1016/j.jamcollsurg.2014.12.020. Epub 2014 Dec 20. PMID: 25667140.

United Network for Organ Sharing (UNOS). Annual Reports.

United Network for Organ Sharing (UNOS). Data.

United Network for Organ Sharing (UNOS). Policy.

United Network for Organ Sharing (UNOS). Transplant Trends.

Usatin DJ, Perito ER, Posselt AM, Rosenthal P. Under Utilization of Pancreas Transplants in Cystic Fibrosis Recipients in the United Network Organ Sharing (UNOS) Data 1987–2014. Am J Transplant. 2016 May;16(5): 1620–5. doi: 10.1111/ajt.13630. Epub 2016 Feb 15. PMID: 26603034.

U.S. Food and Drug Administration. Vaccines, Blood & Biologics. Information and Recommendations for Physicians Involved in the Co-Culture of Human Embryos with Non-Human Animal Cells. 2019 Mar 28.
U.S. Food and Drug Administration. Vaccines, Blood & Biologics. Xenotransplantation. 2018 Feb 5.
Weems P, Cooper M. Pancreas transplantation in type II diabetes mellitus. World J Transplant. 2014 Dec 24; 4(4):216–21. doi: 10.5500/wjt.v4.i4.216. PMID: 25540731.

Wiseman AC, Gralla J. Simultaneous pancreas kidney transplant versus other kidney transplant options in patients with type 2 diabetes. Clin J Am Soc Nephrol. 2012 Apr; 7(4):656-64. doi: 10.2215/CJN.08310811. Epub 2012 Feb 16. PMID: 22344508.

Policy History

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

*Effective Date for the BMC HealthNet Plan Commercial Product: 01/01/12
*Effective Date of the WellSense New Hampshire Medicaid Product: 01/01/13
*Effective Date for Senior Care Options Product: 01/01/16
*Effective Date for the WellSense Medicare Advantage HMO Product: 01/01/22

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date and Version Number**	**Approved by**
07/11/07	Updated template, added coding, and added references.	Version 2	07/11/07: MPCTAC 07/24/07: Utilization Management Committee (UMC) 08/13/07: QIC
09/09/08	No changes.	Version 3	09/09/08: MPCTAC 09/30/08: UMC 10/22/08: QIC
08/25/09	Review for effective date 12/01/09.	12/01/09	08/25/09: MPCTAC

Policy Revisions History			
	Updated references and coding. Added AIDS criteria to the contraindications section.	Version 4	08/25/09: UMC 09/23/09: QIC
09/01/10	Updated references and coding.	Version 5	09/15/10: MPCTAC 10/27/10: QIC
09/01/11	Updated clinical criteria for type 2 diabetics and updated references.	Version 6	09/21/11: MPCTAC 10/26/11: QIC
08/01/12	Off cycle review for WellSense New Hampshire Medicaid product, revised Summary statement, reformatted Medical Policy Statement, revised Applicable Coding introduction, updated code list.	Version 7	08/13/12: MPCTAC 09/06/12: QIC
09/01/12	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.	Version 8	09/19/12: MPCTAC 10/24/12: QIC
03/01/13	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 > 35 to BMI $\geq$ 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.	07/01/13 Version 9	03/20/13: MPCTAC 04/18/13: QIC
08/14/13 and	Off cycle review for WellSense New	Version 10	08/14/13: MPCTAC

Policy Revisions History			
08/15/13	Hampshire Medicaid product and merged policy format. Incorporate policy revisions dated 03/01/13 (as specified above) for the WellSense New Hampshire Medicaid product; these policy revisions were approved by MPCTAC on 03/20/13 and QIC on 04/18/13 for applicable Plan products.		(electronic vote) 08/15/13: QIC
03/01/14	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.	07/01/14 Version 11	03/19/14: MPCTAC 04/16/14: QIC
03/01/15	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.	07/01/15 Version 12	03/18/15: MPCTAC 04/08/15: QIC
11/25/15	Review for effective date 01/01/16. Updated template with list of applicable products and notes. Revised language in the Applicable Coding section.	01/01/16 Version 13	11/18/15: MPCTAC 11/25/15: MPCTAC (electronic vote) 12/09/15: QIC
03/01/16	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.	07/01/16 Version 14	03/16/16: MPCTAC 04/13/16: QIC
03/01/17	Review for effective date 06/07/17. Updated Summary, Definitions, Clinical	06/07/17 Version 15	03/15/17: MPCTAC

Policy Revisions History			
	Background Information, and References sections. Revised criteria in the Medical Policy Statement section. Plan note added to the Applicable Coding section.		
03/01/18	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.	04/01/18 Version 16	03/21/18: MPCTAC
03/01/19	Review for effective date 06/01/19. Revised criteria in the Medical Policy Statement and Limitations sections. Administrative changes made to the Definitions, References, Other Applicable Polices, and Reference to Applicable Laws and Regulations sections.	03/20/19 Version 17	03/20/19: MPCTAC
03/01/20	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.	04/01/20 Version 18	03/12/20: MPCTAC (electronic vote)
03/01/21	Review for effective date 06/01/21. Criteria revised in the Medical Policy Statement and Limitations sections. Administrative changes made to the References section.	06/01/21 Version 19	03/17/21: MPCTAC
11/01/21	Review for effective date 12/01/21. Adopted new medical policy template; removed administrative sections, the Medical Policy Statement section renamed the Clinical Criteria section, and the Limitations section renamed the Limitations and Exclusions section. Added WellSense Medicare Advantage HMO as an applicable product effective 01/01/22. Administrative changes made to the Policy Summary, Clinical Criteria, Limitations and Exclusions, Applicable Coding, and References	12/01/21 Version 20	11/17/21: MPCTAC

Policy Revisions History			
	sections.		

Next Review Date

03/01/22

Authorizing Entity

MPCTAC

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.