Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines: **Solid Organ Transplant: Pancreas-Kidney Transplant, Pancreas Transplant, Pancreas Islet Cell Transplant**

Effective: November 1, 2023

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request.	Yes ☒ No ☐
Notification Required IF REQUIRED, concurrent review may apply	Yes ☐ No ☒

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; 800-232-0816
☒ Tufts Health Plan Commercial products; 617-972-9409
CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); 888-415-9055
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; 888-415-9055
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; 857-304-6404
☒ Tufts Health Unify* – OneCare Plan (a dual-eligible product); 857-304-6304
*The MNG applies to Tufts Health Unify members unless a less restrictive LCD or NCD exists.

Senior Products

☐ Harvard Pilgrim Health Care Stride Medicare Advantage; 866-874-0857
☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); 617-673-0965
☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); 617-673-0965
☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); 617-673-0965

Note: While you may not be the provider responsible for obtaining prior authorization or notifying Point32Health, as a condition of payment you will need to ensure that any necessary prior authorization has been obtained and/or Point32Health has received proper notification. If notification is required, providers may additionally be required to provide updated clinical information to qualify for continued service.

Overview

Combined transplantation of the kidney and pancreas may be indicated for those Members for whom pancreas transplant is indicated who also have concomitant diabetic ESRD. Kidney and pancreas transplant candidates might be currently on dialysis or might require dialysis in the near future. Pancreas transplant alone has specific indications for Type I diabetes that is so severe that routine exogenous insulin therapy is inefficient. Pancreas islet cell transplant may be useful as an autograft in the setting of total pancreatectomy for chronic pancreatitis. Type II diabetes is not an indication for pancreas transplantation.

To initiate the prior authorization process, it is necessary to complete and submit the Pancreas Transplant Request for Coverage Form and the Kidney Transplant Request for Coverage Form, if applicable.

Clinical Guideline Coverage Criteria

Pancreas Transplantation Alone:

The Plan may authorize pancreas transplantation alone for Members with Type I DM who meet **ALL** of the following:

1. Absence of clinical history of emotional, psychological, or behavioral events precluding diligent compliance with

insulin-based regimen to control blood sugar that has resulted in hospitalization within the two years prior to authorization; **and**

2. Consistent failure of insulin-based management to prevent acute complications, despite documented diligent Member compliance with transplant program recommendations; **and**
3. History of frequent, acute, and severe metabolic complications (hypoglycemia, marked hyperglycemia, ketoacidosis) requiring recurrent hospitalization

Simultaneous Pancreas-Kidney Transplant (SPK):

The Plan may authorize a simultaneous pancreas-kidney transplant (SPK) for Members with end stage renal disease from Type I diabetic nephropathy for Members aged 18 to 55 who meet all of the criteria for a kidney transplant.

Pancreas Transplantation after a previous kidney transplant:

The Plan may authorize pancreas transplantation after a previous kidney transplant for Members with Type I diabetes mellitus who meet all of the criteria for a simultaneous pancreas-kidney transplant (SPK).

Autologous Islet Cell Transplantation:

The Plan may authorize an autologous islet cell transplantation as an adjunct to a total or near total pancreatectomy in Members with chronic painful pancreatitis only if the Member is having the procedure performed at a center with an experimental pancreatic islet cell transplant program and appropriate islet cell extraction /purification techniques available on site.

Limitations

The Plan will not authorize coverage of a pancreas-kidney, pancreas, or pancreas islet cell transplant for Members with **ONE** of the following:

1. Active or uncontrolled alcohol use disorder or substance use disorder
2. Advanced ileo-femoral vascular disease
3. Any past history of active tuberculosis, systemic or localized solid organ fungal infection excluding candida dermatitis, solid organ viral infection (e.g., hepatitis, encephalitis, mumps) and malignant neoplasm other than basal cell carcinoma within the past five years
4. Any unresolved psychosocial concerns or history of noncompliance with medical management
5. History of malignancy within past 5 years of transplantation
6. Human immunodeficiency virus (HIV) disease unless **ALL** of the following are met:
    a. CD4 count greater than 200 cells/mm3 during 3 months prior to transplantation
    b. Undetectable HIV-1 ribonucleic acid (RNA)
    c. Stable anti-retroviral therapy for > 3 months
    d. Absence of serious complications associated with or secondary to HIV disease (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioidomycosis, resistant fungal infections; Kaposi's sarcoma; or other neoplasm)
7. Obesity: Patients' weight over 130% of ideal (BMI 25-28 kg/m^2 to encompass NIH and CDI guidelines) or BMI ≥ 35 kg/m^2
8. Serous conditions that create an inability to tolerate transplant surgery or post-transplant care
9. The Plan will not authorize coverage of an Islet cell transplant alone for diabetes mellitus because it is considered to be experimental and investigational

Note: Smoking has been strongly correlated to adverse health and surgical outcomes. There is evidence to show that smoking, both by donors and by recipients, has a major impact on outcomes after organ transplantation. Smoking cessation is strongly recommended for both donors and recipients prior to transplantation.

Codes

The following code(s) require prior authorization:

**Codes are applicable only to THP Products*

Table 1: CPT/HCPCS Codes

Code	Description
48160	Pancreatectomy, total or subtotal, with autologous transplantation or pancreas or pancreatic islet cells

Code	Description
48550	Donor pancreatectomy (including cold preservation), with or without duodenal segment for transplantation
48551	Backbench standard preparation of cadaver donor pancreas allograft prior to transplantation, including dissection of allograft from surrounding soft tissues, splenectomy, duodenotomy, ligation of bile duct, ligation of mesenteric vessels, and Y-graft arterial anastomoses from iliac artery to superior mesenteric artery and to splenic artery
48552	Backbench reconstruction of cadaver donor pancreas allograft prior to transplantation, venous anastomosis, each
48554	Transplantation of pancreatic allograft
48556	Removal of transplanted pancreatic allograft
50300	Donor nephrectomy (including cold preservation); from cadaver donor, unilateral or bilateral
50320	Donor nephrectomy (including cold preservation); open, from living donor
0584T	Islet cell transplant, includes portal vein catheterization and infusion, including all imaging, including guidance, and radiological supervision and interpretation, when performed; percutaneous
0585T	Islet cell transplant, includes portal vein catheterization and infusion, including all imaging, including guidance, and radiological supervision and interpretation, when performed; laparoscopic
0586T	Islet cell transplant, includes portal vein catheterization and infusion, including all imaging, including guidance, and radiological supervision and interpretation, when performed; open
G0341*	Percutaneous islet cell transplant, includes portal vein catheterization and infusion
G0342*	Laparoscopy for islet cell transplant, includes portal vein catheterization and infusion
G0343*	Laparotomy for islet cell transplant, includes portal vein catheterization and infusion
S2065*	Simultaneous pancreas kidney transplantation
S2102*	Islet cell tissue transplant from pancreas; allogeneic
S2152*	Solid organ(s), complete or segmental, single organ or combination of organs; deceased or living donor(s), procurement, transplantation, and related complications; including: drugs; supplies; hospitalization with outpatient follow-up; medical/surgical, diagnostic, emergency, and rehabilitative services, and the number of days of pre- and post-transplant care in the global definition

References:

1. Blumberg EA, Rogers CC; American Society of Transplantation Infectious Diseases Community of Practice. Solid organ transplantation in the HIV-infected patient: Guidelines from the American Society of Transplantation Infectious Diseases Community of Practice. Clin Transplant. 2019;33(9):e13499. doi:10.1111/ctr.13499.
2. Blumberg EA, Rogers CC; American Society of Transplantation Infectious Diseases Community of Practice. Solid organ transplantation in the HIV-infected patient: Guidelines from the American Society of Transplantation Infectious Diseases Community of Practice. Clin Transplant. 2019;33(9):e13499. doi:10.1111/ctr.13499.
3. Health Quality Ontario. Pancreas Islet Transplantation for Patients With Type 1 Diabetes Mellitus: A Clinical Evidence Review. Ont Health Technol Assess Ser. 2015;15(16):1-84. Published 2015 Sep 1.
4. Pancreas and islet transplantation in diabetes mellitus.UpToDate.com/login [via subscription only]. Published August 27, 2020. Updated July 2021. Accessed August 22, 2021.
5. Pancreas-kidney transplantation in diabetes mellitus: Patient selection and pretransplant evaluation.UpToDate.com/login [via subscription only]. Published October 29, 2020. Updated July 2021. Accessed August 22, 2021.
6. Robertson RP, Davis C, Larsen J, Stratta R, Sutherland DE; American Diabetes Association. Pancreas and islet transplantation in type 1 diabetes. Diabetes Care. 2006;29(4):935. doi:10.2337/diacare.29.04.06.dc06-9908.

Approval And Revision History

October 21, 2020: Reviewed by IMPAC, renewed without changes

Subsequent endorsement date(s) and changes made:

- December 8, 2020: Fax number for Unify updated
- November 17, 2021: Reviewed by IMPAC for integration purposes between Harvard Pilgrim Health Care and Tufts Health Plan; under the “Limitations” section changed “CD4 count >200 cells/μL” to “CD4 count >200 cells/μL during 3 months prior to transplantation”

- December 1, 2022: Reviewed by Medical Policy Approval Committee(MPAC), renewed without changes
- March 15, 2023: Reviewed by MPAC, limitations updated to remove smoking cessation and limitation modified from “Active drug, substance abuse, or alcohol abuse within the last 6 months” to “Active or uncontrolled alcohol use disorder or substance use disorder”; Codes 0584T, 0585T, and 0586T to now require PA Effective November 1, 2023

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member’s benefit document, and in coordination with the Member’s physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.