TUFTS Health Plan

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

Effective: October 21, 2020

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request.	**Yes** ☒ **No** ☐

Applies to:

COMMERCIAL Products

☒ Tufts Health Plan Commercial products; Fax: 617.972.9409

☒ Tufts Health Freedom Plan products; Fax: 617.972.9409

- CareLink[SM] – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

TUFTS HEALTH PUBLIC PLANS Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax:888.415.9055

☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax: 888.415.9055

☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax: 857.304.6404

☒ Tufts Health Unify* – OneCare Plan (a dual-eligible product); Fax: 857.304.6304

*The MNG applies to Tufts Health Unify members unless a less restrictive LCD or NCD exists.

SENIOR Products

- Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product) – Refer to the Tufts Health Plan SCO Prior Authorization List
- Tufts Medicare Preferred HMO, (a Medicare Advantage product) – Refer to the Tufts Medicare Preferred HMO Prior Authorization and Inpatient Notification List

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to make sure that prior authorization has been obtained.

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 COVERAGE CRITERIA

Pancreas Transplantation Alone:

Tufts Health Plan may authorize pancreas transplantation alone for Members with Type I DM who meet all of the following:

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

Simultaneous Pancreas-Kidney Transplant (SPK):
Tufts Health Plan may authorize a simultaneous pancreas-kidney transplant (SPK) for Members with end stage renal disease from Type I diabetic nephropathy for Members age 18 to 55 who meet all of the criteria for a kidney transplant.

Pancreas Transplantation after a previous kidney transplant:
Tufts Health 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:
Tufts Health 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

Tufts Health Plan will not authorize coverage of a pancreas-kidney, pancreas or pancreas islet cell transplant for Members with one of the following:

- History of malignancy within past 5 years of transplantation
- Advanced ileo-femoral vascular disease
- Serious conditions that create an inability to tolerate transplant surgery or post-transplant care
- Any unresolved psychosocial concerns or history of noncompliance with medical management.
- 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
- Obesity. Patients' weight over 130% of ideal (BMI 25-28 to encompass NIH and CDI guidelines) or BMI ≥ 35
- Active drug, substance, or alcohol abuse within the last 6 months
- Active tobacco use within the last 6 months such as actively smoking cigarettes, or using any nicotine delivery system products (e.g., gum, patches, electronic cigarettes)
- Tufts Health Plan will not authorize coverage of an Islet cell transplant alone for diabetes mellitus because it is considered to be experimental and investigational
- Human immunodeficiency virus (HIV) disease unless ALL of the following are met:
  - CD4 count greater than 200 cells/mm3
  - Undetectable HIV-1 ribonucleic acid (RNA)
  - Stable anti-retroviral therapy for > than three months
  - 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)

CODES

The following HCPCS/CPT code(s) require prior authorization:

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

Code	Description
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
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. American Diabetes Association. Pancreas transplantation in type I diabetes. Diabetes Care.2004; 27:S105.
2. Bloom RD, Goldberg LR, Wang AY, Faust TW, Kotloff RM. An overview of solid organ transplantation. Clin Chest Med. 2005;26(4):529-43, v.
3. Bolton WK. Renal physicians association clinical practice guideline: appropriate patient preparation for renal replacement therapy: guideline number 3. J Am Soc Nephrol. 2003;14(5):1406-10.
4. Robertson R, Klein CL, Brennan DC, et al. Patient selection for and immunological issues relating to kidney-pancreas transplantation in diabetes mellitus. UpToDate®. December 2006. Updated November 2014.

APPROVAL HISTORY

January 2004: Reviewed by the Clinical Coverage Criteria Committee

Subsequent endorsement date(s) and changes made:

- April 14, 2007: Criteria placed in new format
- April 25, 2008: Reviewed and renewed without changes
- May 4, 2009: Clarification of guideline for coverage of a simultaneous pancreas-kidney transplant
- November 1, 2009: Reviewed by Medical Affairs Medical Policy Committee, no changes.
- November 2010: Reviewed by MCMC. Coverage Guidelines, First Group, Bullet One clarified by adding: "despite documented diligent patient compliance with transplant program recommendations"; Bullet Three clarified by re-writing to "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." Under Limitations, Recurrent Infection clarified by re-writing to: "Add: 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." CABG, PTCA and MI limitation removed. Obesity limitation added. Effective date July 1, 2011.

- December 14, 2011: Reviewed by Integrated Medical Policy Advisory Committee (IMPAC), no changes.
- December 12, 2012: Reviewed by IMPAC. Advanced ileo-femoral vascular disease added to Limitations.
- August 6, 2013: Active tobacco use clarified
- December 11, 2013: Reviewed by IMPAC, renewed without changes
- October 15, 2014: Adopted by Tufts Health Plan – Network Health Commercial Plans and Tufts Health Plan – Network Health Medicaid Plans.
- December 10, 2014: Reviewed by IMPAC, renewed without changes
- February 23, 2015: Administrative update.
- August 12, 2015: Reviewed by IMPAC, renewed without changes
- September 2015: Branding and template change to distinguish Tufts Health Plan products in "Applies to" section. Added Tufts Health Freedom Plan products, effective January 1, 2016.
- July 20, 2016: Reviewed by IMPAC, renewed without changes
- December 13, 2016: Contact information updated
- April 2017: Added RITogether Plan product to template. For MNGs applicable to RITogether, effective date is August 1, 2017
- July 20, 2017: Reviewed by IMPAC, renewed without changes
- September 18, 2017: Administrative update
- October 10, 2018: Reviewed by IMPAC, renewed without changes
- October, 2018: Template and disclaimer updated
- October 16, 2019: Reviewed by IMPAC, renewed without changes
- October 21, 2020: Reviewed by IMPAC, renewed without changes
- December 8, 2020: Fax number for Unify updated

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.

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.