Molina Clinical Policy
Pancreas Transplantation Procedures: Policy No. 017

Last Approval: 6/8/2022
Next Review Due By: June 2023

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Pancreas transplantation is used to treat Type 1 diabetes. The ultimate goal is to improve the overall quality of life for the recipient. Successful transplantation can eliminate the need for exogenous insulin, renal dialysis, and the associated primary and secondary complications that result from diabetes mellitus and renal failure (e.g., retinopathy, neuropathy, and vasculopathy). Nephropathy is a frequent major complication associated with type 1 and type 2 diabetes and often ends in end-stage renal disease. (Alhamad & Stratta, 2021; Bloom, 2021; [1-2] Hayes, 2020; Robertson, 2020; Hayes, 2017; [1-2] DynaMed, n.d.). There are several types of pancreas transplantation:

Pancreas Transplant Alone (PTA). Performed in labile diabetics with hypoglycemic unawareness and frequent ketoacidotic episodes without end stage renal disease. The goal is to limit or prevent complications that could cause permanent disability that may result from uncontrolled glucose levels (e.g., retinopathy, neuropathy, nephropathy, and vasculopathy).

Simultaneous Pancreas Kidney (SPK) Transplantation. Performed in Type I diabetes with end stage renal disease. Both organs come from the same living or deceased donor. The objectives are to restore glucose-regulated endogenous insulin secretion, arrest progression of complications, protect kidney damage from hyperglycemia and improve quality of life.

Pancreas After Kidney (PAK) Transplantation. Performed in Type I diabetic patients with end stage renal disease. Two operations are required. Treatment of choice for candidates with a living donor for a kidney transplant.

Allogeneic Pancreas Islet Cell Transplantation. Transplanting islet cells from a donor pancreas are infused into the patient's portal vein during the open procedure or postoperatively by a percutaneous approach.

Autologous Pancreas Islet Cell Auto Transplantation. Transplanting islet cells from the patient's own resected pancreas are infused into the patient's portal vein during the open procedure or postoperatively by a percutaneous approach. Autologous islet cell transplantation as an adjunct to a total or near-total pancreatectomy is used to salvage and transplant beta cells which may prevent complications of chronic diabetes in individuals with chronic pancreatitis.

COVERAGE POLICY

All transplants require prior authorization from the Corporate Transplant Department. Solid organ transplant requests will be reviewed by the Corporate Senior Medical Director or qualified clinical designee. All other transplants will be reviewed by the Corporate Senior Medical Director or covering Medical Director. If the criteria are met using appropriate NCD and/or LCD guidelines, State regulations, and/or MCP policies the Corporate Senior Medical Director's designee can approve the requested transplant.

Office visits with participating Providers do NOT require prior authorization. Providers should see the Member in office visits as soon as possible and without delay. Failure to see the Member in office visits may be considered a serious quality of care concern.

Pre-Transplant Evaluation

(ADA, 2021; AMR, 2020; Zhang et al., 2020; FDA, 2009; [1-2] CMS, 2006; Robertson et al., 2006; CMS, 2004)

Please see *MCP-323 Pre-Transplant Evaluation* for additional criteria and information.

Criteria for transplant evaluation include:

1. History and physical examination; **AND**

2. Psychosocial evaluation and clearance:
   a. No behavioral health disorder by history or psychosocial issues:
      - If history of behavioral health disorder, no severe psychosis or personality disorder;
      - Mood/anxiety disorder must be excluded or treated;
      - Member has understanding of surgical risk and post procedure compliance and follow-up required.

   AND
   b. Adequate family and social support.

AND

3. EKG; **AND**

4. Chest x-ray; **AND**

5. Cardiac clearance in the presence of any of the following:
   a. Chronic smokers; **OR**
   b. Members > 50 years age; **OR**
   c. Those with a clinical or family history of heart disease or diabetes.

AND

6. Pulmonary clearance if evidence of pulmonary artery hypertension (PAH) or chronic pulmonary disease; **AND**

7. Neurological exam and clearance for transplant including **ONE** of the following:
   a. Normal exam by H&P; **OR**
   b. Abnormal neurological exam with positive findings including **ONE** of the following:
      - Lumbar puncture normal cytology; **OR**
      - Lumbar puncture with cytological exam abnormal: CNS disease treated prior to clearance.

AND

8. A Performance Status that includes **ONE** of the following:
   a. Karnofsky score 70-100%; **OR**
   b. Eastern Cooperative Oncology Group (ECOG) Grade 0-2.

AND

9. Lab studies that include:
   a. Complete blood count; kidney profile (blood urea nitrogen, creatinine); electrolytes; calcium; phosphorous; albumin; liver function tests; and coagulation profile (prothrombin time, and partial thromboplastin time);*
   b. Serologic screening for: HIV; Epstein Barr virus (EBV); Hepatitis virus B (HBV); Hepatitis C (HCV); cytomegalovirus (CMV); RPR and/or FTA:*
      - If HIV positive **ALL** of the following must be met:
        i. CD4 count >200 cells/mm-3 for >6 months; **AND**
        ii. HIV-1 RNA undetectable; **AND**
        iii. On stable anti-retroviral therapy >3 months; **AND**
        iv. No other complications from AIDS (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioides mycosis, resistant fungal infections, Kaposi's sarcoma, or other neoplasm).
      - If abnormal serology, need physician plan to address and/or treatment as indicated.
        i. Antinuclear antibody, smooth muscle antibody, antimitochondrial antibody

ii. Ceruloplasmin, α1-antitrypsin phenotype
iii. Alpha-fetoprotein

c. Urine drug screen (UDS) if Member is current or gives a history of past drug abuse.

AND

10. Colonoscopy (if indicated or if Member is age ≥ 50) with complete workup and treatment of abnormal results as indicated; an initial screening colonoscopy after initial negative screening requires a follow-up colonoscopy every 10 years).*

AND

11. Gynecological examination with Pap smear for women ages ≥ 21 to ≤ 65 years of age or if indicated (not indicated in women who have had a total abdominal hysterectomy [TAH] or a total vaginal hysterectomy [TVH]) within the last three years with complete workup and treatment of abnormal results as indicated.

Within the last 12 months:

1. Dental examination or oral exam showing good dentition and oral care or no abnormality on panorex or plan for treatment of problems pre- or post-transplant; **AND**
2. Mammogram (if indicated or > age 40) with complete workup and treatment of abnormal results as indicated;* **AND**
3. PSA if history of prostate cancer or previously elevated PSA with complete workup and treatment of abnormal results as indicated.*

* Participating Centers of Excellence may waive these criteria.

Transplant Criteria

Pancreas alone, simultaneous pancreas-kidney transplantation, and pancreas after kidney organ transplantation from a donor **may be considered medically necessary** in adult members that have met **ALL** of the following:

1. All pre-transplant criteria are met; **AND**

2. Optimally managed for at least 12 months by an endocrinologist or pancreas transplant surgeon; **AND**

3. Documentation of insulin dependent Type 1 diabetes showing abnormal beta cell functioning:
   a. Beta cell autoantibody positive; **OR**
   b. Fasting C-peptide undetectable (e.g., ≤ 110% of the laboratory's lower limit of normal and with a concurrently obtained fasting glucose ≤ 225mg/dl).

AND

4. Documented history of frequent medically uncontrolled labile (brittle) insulin dependent diabetes mellitus, with recurrent, acute and severe life-threatening metabolic complications that have required previous hospitalization. (e.g., ketoacidosis, hypoglycemia or hyperglycemia attacks); **AND**

5. Consistent failure of aggressive insulin management (e.g., insulin pump, adjusting amounts and frequencies of injected insulin, multiple daily blood glucose levels, and strict diet and exercise); **AND**

6. A partial pancreas transplant from a living donor may be considered medically necessary as an acceptable alternative to cadaveric transplant for individuals who meet medical necessity criteria for pancreas transplant alone (PTA); **AND**

7. Pancreas re-transplantation after a failed primary pancreas transplant may be considered medically necessary for individuals who meet medical necessity criteria for pancreas transplant above.

AND

1. The requesting transplant recipient should not have any of the following **absolute contraindications**:
   a. Cardiac, pulmonary, and nervous system disease that cannot be corrected and is a prohibitive risk for surgery; **OR**
   b. Malignant neoplasm with a high risk for reoccurrence, non-curable malignancy (excluding localized skin cancer); **OR**
   c. Systemic and/or uncontrolled infection; **OR**
   d. AIDS (CD4 count < 200cells/mm3); **OR**
   e. Unwilling or unable to follow post-transplant regimen as evidenced by **ONE** of the following:
      - Documented history of non-compliance; **OR**
      - Inability to follow through with medication adherence or office follow-up.

   OR
   f. Chronic illness with one year or less life expectancy; **OR**
   g. Limited, irreversible rehabilitation potential; **OR**
   h. Active untreated substance abuse issues (requires documentation supporting that Member is free from addiction for minimally 6 months if previous addiction was present); **OR**
   i. No adequate social or family support.

AND

2. The requesting transplant recipient should be evaluated carefully and potentially treated if any of the relative contraindications below are present. (Irreversible lung disease patients require consultation and clearance by a Pulmonologist prior to consideration of transplantation).
   a. Smoking, documentation supporting free from smoking for 6 months; **OR**
   b. Active peptic ulcer disease; **OR**
   c. Active gastroesophageal reflux disease; **OR**
   d. CVA with long term impairment that is not amendable to rehabilitation or a patient with CVA/transient ischemic attack within past 6 months; **OR**
   e. Obesity with body mass index of >30 kg/m^2 may increase surgical risk; **OR**
   f. Chronic liver disease such as Hepatitis B/C/D, or cirrhosis which increases the risk of death from sepsis and hepatic failure requires consultation by a gastroenterologist or hepatologist; **OR**
   g. Gall bladder disease requires ultrasound of the gall bladder with treatment prior to transplantation.

The following pancreas transplantation specific requirements by transplantation type must also be met:

For Pancreas Transplant Alone, all of the above main criteria are met and **ALL** of the following criteria:
1. The presence of minimally one secondary complication that has not progressed to end-organ failure such as proliferative diabetic retinopathy, neuropathy, gastroparesis, accelerated atherosclerosis; **AND**
2. Creatinine clearance glomerular filtration rate of ≥ 80ml/min; **AND**
3. Minimum proteinuria.

For Simultaneous Pancreas-Kidney Transplant, all of the above main criteria are met and **ALL** of the following:
1. The presence of minimally one secondary complication that has not progressed to end-organ failure such as proliferative diabetic retinopathy, neuropathy, gastroparesis, accelerated atherosclerosis; **AND**
2. The Member has renal insufficiency with uremia or impending/ current end stage renal disease (ESRD) with poor renal function and **ONE** of the following:
   a. Currently on dialysis; **OR**
   b. Anticipated date of the member requiring dialysis would be within the next 6 months or demonstrates 50% or more decline in renal function in the past year.

For Pancreas After Kidney Transplant, all of the above main criteria are met and **ALL** of the following criteria:
1. The presence of minimally one secondary complication that has not progressed to end-organ failure such as proliferative diabetic retinopathy, neuropathy, gastroparesis, accelerated atherosclerosis; **AND**
2. The Member has a living organ donor for the kidney transplant procedure otherwise SPK should be considered; **AND**
3. Previously successful kidney transplant as evidenced by stable function of previous renal allograft; **AND**
4. Stable adequate kidney function as evidenced by creatinine clearance glomerular filtration rate of ≥ 45ml/min; **AND**

5. Minimum proteinuria.

Autologous Pancreatic Islet Cell Transplantation may be considered medically necessary as an adjunct to a total or near total pancreatectomy in patients with chronic pancreatitis.

Continuation of Therapy

When extension of a previously approved transplant authorization is requested, review using updated clinical information is appropriate.

1. If Molina Healthcare has authorized prior requests for transplantation, **ALL** of the following information is required for medical review:
   a. Presence of no absolute contraindication as listed above; **OR**
   b. History and physical within the last 12 months; **OR**
   c. Kidney profile within the last 12 months; **OR**
   d. Cardiac update if history of cardiac disease within two years (≥ 50 years of age); **OR**
   e. Psychosocial evaluation or update within the last 12 months; **OR**
   f. Per initial and updated history and physical, any other clinically indicated tests and/or scans as determined by transplant center physician or Molina Medical Director.

2. If authorized prior requests for transplantation were obtained from another insurer, **ALL** of the following information is required for medical review:
   a. Authorization letter/documentation from previous insurer; **OR**
   b. Presence of no absolute contraindication as listed above; **OR**
   c. History and physical within the last 12 months; **OR**
   d. Cardiac update if history of cardiac disease within two years (≥ 50 years of age); **OR**
   e. Psychosocial evaluation or update within the last 12 months; **OR**
   f. Per initial and updated history and physical, any other clinically indicated tests and/or scans as determined by transplant center physician or Molina Medical Director.

For Members with Significant or Daily Marijuana Use

1. Documentation of compliance with a physician prescribed and managed program of abstinence, and a reasonable expectation that the Member will be abstinent from marijuana use during the transplant and immediate post-transplant time period. Daily marijuana use is an absolute contraindication for both transplant and pre-transplant evaluation unless there is a state mandate applicable for medical marijuana use and transplants, and there is documentation of Member compliance with a physician prescribed plan of care for prescribed marijuana use.
2. If the Member's marijuana use is in compliance with a formal, State-based program for managed medical marijuana, the request should include:
   - Documentation of the Plan of Care for medical marijuana (including the medical decision making that supports the use of medical marijuana); **AND**
   - Transplant Provider agreement with the Plan of Care (including agreement to be accountable for managing the Member's use of medical marijuana).

Limitations and Exclusions

Any of the following conditions **are considered experimental, investigational and unproven** due to insufficient evidence in the peer reviewed published literature:

1. Type II diabetes
2. Allogeneic pancreas islet cell transplantation for any condition or xenotransplantation
3. Bioartificial pancreas device

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

The Food and Drug Administration (FDA) (2009) have provided guidance to industry regarding investigational new drug development (IND) for allogeneic pancreatic islet cell products. To date, there is no FDA approved biologic license for allogeneic pancreatic islet cell products or for a bioartificial pancreas device.

Autologous Islet Cell Transplantation for Chronic Pancreatitis

Results of the peer reviewed published studies suggest that autologous islet cell transplantation may provide durable improvements in patient-reported pain, reduce narcotic use, provide adequate glycemic control and insulin independence in many patients, improve quality of life in patients with intractable and debilitating symptoms from chronic pancreatitis and improve survival with an acceptable level of mortality. Several systematic reviews of the literature on islet auto-transplantation (IAT) after total pancreatectomy (TP) or partial pancreatectomy (PP) have been published. A summary of the most relevant publications is outlined below.

Kempeneers et al. (2019) identified 15 observational studies with a total of 1255 individuals who had chronic pancreatitis who underwent total pancreatectomy with islet autotransplant. The pooled 30-day mortality rate was 2% and the 1-year mortality rate was 4%. Four studies assessed the insulin-free rate at 1 year and the other 11 studies reported the insulin-free rate at last follow-up. In pooled analyses, the insulin-free rate at 1 year was 30% (95% confidence interval [CI], 20-43%) and at last follow-up the insulin-free event rate was 1.31 (95% CI, 0.74 to 2.31) per 10 person-years. In the 5 studies that reported this outcome, pain assessed by a 100-point visual analogue scale (VAS) decreased by a mean of 58 points (from a preoperative mean of 79 to a post-operative mean of 22). In 6 studies, the pooled 1-year opioid-free rate was 63% (95% CI, 46-77%).

Wu et al. (2015) performed a systematic review and meta-analysis evaluating outcomes of IAT after TP. A total of 12 studies with a total of 677 subjects were included. The insulin independent rate for IAT after TP at last follow-up was 3.72 per 100 person-years (95% CI, 1.00-6.44). The 30-day mortality was 2.1% (95% CI, 1.2-3.8%). The mortality at last follow-up was 1.09 per 100 person-years (95% CI, 0.21-1.97). Factors associated with incidence density of insulin independence in univariate meta-regression analyses included islet equivalents per kg body weight.

Sutherland et al. (2012) reported data from a single center series of 409 individuals with chronic pancreatitis who were treated between 1977 and 2011 with TP and IAT to relieve pain and preserve β-cell mass. Fifty-three of the 409 participants (13%) were children between the ages of 5 and 18 years. Post TP and IAT actuarial survival at 1 year was 96% in adults and 98% in children, and 5-year survival was 89% in adults and 98% in children. Overall, at 15 years post-surgery, two-thirds (66%) of the individuals were reported alive. Insulin independence at 3 years was noted in 30% of individuals (25% of adults and 55% of children), while partial function was reported in 33%. Surgical complications requiring reoperation during the initial admission occurred in a total of 15.9% of the individuals, with bleeding as the most common reason for reoperation experienced in 9.5%. There were a total of 5 (1.2%) in-hospital deaths, and 53 deaths following initial discharge with 3 of those deaths related to chronic pancreatitis disease processes. Insulin independence at 6 months was observed in 25% of individuals, 33% had partial islet function and less than one-fifth were dependent on insulin. Narcotic use for pain control declined after TP and IAT. The proportion of individuals requiring narcotics were, 91%, 61%, 54% and 51% at 3, 6, 12 and 24 months, respectively. A survey of integrated quality-of-life outcomes showed that at 1 year of the 191 participants, 85% reported improvement compared to the prior year. The authors concluded TP alleviates pain caused by chronic pancreatitis and IAT can help to preserve glycemic control in most individuals.

The **American Diabetes Association** (2021) *Standards of Medical Care in Diabetes* which recommends that islet auto-transplantation should be considered for patients requiring total pancreatectomy for medically refractory chronic pancreatitis to prevent postsurgical diabetes. The standards state that approximately one-third of patients undergoing total pancreatectomy with islet auto-transplantation are insulin free 1 year postoperatively, and observational studies from different centers have demonstrated islet graft function up to a decade after the surgery in some patients. Both patient and disease factors should be carefully considered when deciding the indications and timing of this surgery. Surgeries should be performed in skilled facilities that have demonstrated expertise in islet auto-transplantation.

SUPPLEMENTAL INFORMATION

None.

CODING & BILLING INFORMATION

CPT Codes

CPT	Description
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
48160	Pancreatectomy, total or subtotal, with autologous transplantation of 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
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
50323	Backbench standard preparation of cadaver donor renal allograft prior to transplantation, including dissection and removal of perinephric fat, diaphragmatic and retroperitoneal attachments, excision of adrenal gland, and preparation of ureter(s), renal vein(s), and renal artery(s), ligating branches, as necessary
50325	Backbench standard preparation of living donor renal allograft (open or laparoscopic) prior to transplantation, including dissection and removal of perinephric fat and preparation of ureter(s), renal vein(s), and renal artery(s), ligating branches, as necessary
50327	Backbench reconstruction of cadaver or living donor renal allograft prior to transplantation; venous anastomosis, each
50340	Recipient nephrectomy (separate procedure)
50360	Renal allotransplantation, implantation of graft; without recipient nephrectomy
50365	Renal allotransplantation, implantation of graft; with recipient nephrectomy
50370	Removal of transplanted renal allograft

HCPCS Codes

HCPCS	Description
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

ICD-10 Codes

ICD-10 CM	Description
E10.10	Type 1 DM with ketoacidosis without coma
E10.11	Type 1 DM with ketoacidosis with coma
E10.21	Type 1 DM with diabetic nephropathy
E10.39	Type 1 DM with other diabetic ophthalmic comp
E10.40	Type 1 DM with diabetic neuropathy, unspecified
E10.51	Type 1 DM with diabetic peripheral angiopathy without gangrene
E10.65	Type 1 DM with hyperglycemia
E10.69	Type 1 DM with other specified complication
E10.8	Type 1 DM with unspecified complications
K86.0-K86.1	Chronic pancreatitis
N18.5	Chronic kidney disease Stage V
N18.6	End stage renal disease
N18.9	Chronic kidney disease unspecified
Z99.2	Dependence on renal dialysis

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

6/8/2022	Policy reviewed, no changes to criteria; included section on marijuana use; updated Overview, Summary of Medical Evidence and Reference sections.
6/9/2021	Policy reviewed, updated references. Added CPT codes: 48551, 48552, 50323, 50325, 50327.
4/23/2020	Policy updated with medically necessary criteria for autologous pancreatic islet cell transplantation when used as an adjunct to a total or near total pancreatectomy in patients with chronic pancreatitis. Updated references, guidelines; added three new 2020 CPT codes (0584T, 0585T, 0586T) and one new ICD-10 code (K86.0-K86.1) for chronic pancreatitis.
9/18/2019	Policy reviewed, updated references only.
9/13/2018	Policy reviewed, updated references only.
6/22/2017	Policy reviewed, no changes.
12/14/2016	Policy reviewed, no changes.
5/26/2015	Policy updated with new pretransplant criteria and one new exclusion for bioartificial pancreas devices; Summary of Medical Evidence section was condensed.
10/31/2012	Policy updated (criteria for pre-transplant evaluation and HIV/AIDS patients). Summary of Medical Evidence was updated.
8/25/2010	Policy updated; some of the contraindications were moved from absolute to relative contraindications. The pancreas transplant alone (PTA) section includes a new requirement of glomerular filtration rate (GFR) of > 80ml/min and minimal proteinuria (based on recent studies that demonstrated improved outcomes). Document reviewed by an AMR board certified physician in General Surgery and Transplant Surgery.
8/28/2007	Policy reviewed by a board-certified Endocrinologist and Pancreas Transplant Surgeon. Pancreas transplant alone criteria added.
6/14/2006	New policy.

REFERENCES

Government Agencies

1. [1] Centers for Medicare and Medicaid Services (CMS). Medicare coverage database: National coverage determination – pancreas transplants (260.3). Available from CMS. Effective April 26, 2006. Accessed May 27, 2022.
2. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database: National coverage determination – islet cell transplantation in the context of a clinical trial (260.3.1). Available from CMS. Effective October 1, 2004. Accessed May 27, 2022.
3. [2] Centers for Medicare and Medicaid Services (CMS). Decision memo for pancreas transplants. Available from CMS. Effective April 26, 2006. Accessed May 27, 2022.
4. Food and Drug Administration (FDA). Guidance document: Considerations for allogeneic pancreatic islet cell products (guidance for industry). Available from FDA. Published September 2009. Accessed May 27, 2022.

National and Specialty Organizations

1. American Diabetes Association (ADA). 4. Comprehensive medical evaluation and assessment of comorbidities: Standards of medical care in diabetes 2021. Diabetes Care. 2021 Jan;44(Suppl 1):S40-S52. doi: 10.2337/dc21-S004. Accessed June 2, 2022.

2. Robertson RP, Davis C, Larsen J, Stratta R, Sutherland DER, American Diabetes Association (ADA). Position statement: Pancreas and islet transplantation in type 1 diabetes. Diabetes Care. 2006 Apr;29(4):935. doi: 10.2337/diacare.29.04.06.dc06-9908. Accessed June 2, 2022.

Peer Reviewed Publications

1. Kempeneers MA, Scholten L, Verkade CR, van Hooft JE, van Santvoort HC, Busch OR, et al. Efficacy of total pancreatectomy with islet auto-transplantation on opioid and insulin requirement in painful chronic pancreatitis: A systematic review and meta-analysis. Surgery. 2019 Sep;166(3):263-270. doi: 10.1016/j.surg.2019.03.014. Accessed June 2, 2022.
2. Sutherland DER, Radosevich DM, Bellin MD, Hering BJ, Beilman GJ, Dunn TB, et al. Total pancreatectomy and islet auto-transplantation for chronic pancreatitis. J Am Coll Surg. 2012 Apr;214(4):409-24; discussion 424-6. doi: 10.1016/j.jamcollsurg.2011.12.040. Accessed June 2, 2022.
3. Wu Q, Zhang M, Qin Y, et al. Systematic review and meta-analysis of islet auto-transplantation after total pancreatectomy in chronic pancreatitis patients. Endocr J. 2015;62(3):227-34. doi: 10.1507/endocrj.EJ14-0510. Accessed June 2, 2022.
4. Zhang YJ, Duan DD, Yuan H. Efficacy and safety of islet auto-transplantation after total pancreatectomy in chronic pancreatitis: A systematic review and meta-analysis including 17 studies. Clin Res Hepatol Gastroenterol. 2020 Sep;44(4):598-608. doi: 10.1016/j.clinre.2019.08.004. Accessed June 2, 2022.

Evidence Based Reviews and Publications

1. Alhamad T, Stratta RJ. Pancreas-kidney transplantation in diabetes mellitus: Patient selection and pretransplant evaluation. Available from UpToDate. Updated October 5, 2021. Accessed June 6, 2022. Registration and login required.
2. AMR Peer Review. Policy reviewed in January 2020 by an Advanced Medical Reviews (AMR) practicing, board-certified physician in the areas of Surgery, Transplant.
3. Bloom RD. Kidney function and non-kidney solid organ transplantation. Available from UpToDate. Updated July 9, 2021. Accessed June 6, 2022. Registration and login required.
4. [1] DynaMed. Management of type 1 diabetes. Available from DynaMed. Accessed June 3, 2022. Registration and login required.
5. [2] DynaMed. Pancreas transplant. Available from DynaMed. Accessed June 3, 2022. Registration and login required.
6. [1] Hayes. Pancreas transplant alone (PTA) for pediatric patients with diabetes mellitus. Published December 22, 2015. Updated January 17, 2020. Available from Hayes. Archived January 22, 2021. Accessed June 2, 2022. Registration and login required.
7. [2] Hayes. Total pancreatectomy with islet auto-transplantation for chronic pancreatitis. Available from Hayes. Published December 22, 2015. Updated January 17, 2020. Archived January 22, 2021. Accessed June 2, 2022. Registration and login required.
8. Hayes. Simultaneous pancreas-kidney (SPK) transplantation in diabetic patients. Available from Hayes. Published March 27, 2013. Updated February 21, 2017. Archived April 27, 2018. Accessed June 2, 2022. Registration and login required.
9. Robertson RP. Pancreas and islet transplantation in diabetes mellitus. Available from UpToDate. Updated August 27, 2020. Accessed June 6, 2022. Registration and login required.

Other Peer Reviewed and National Organization Publications (used in the development of this policy)

1. Bellin MD, Beilman GJ, Dunn TB, Pruett TL, Sutherland DER, Chinnakotla S, et al. Sitagliptin treatment after total pancreatectomy with islet auto-transplantation: A randomized, placebo-controlled study. Am J Transplant. 2017 Feb;17(2):443-450. doi: 10.1111/ajt.13979. Accessed June 6, 2022.
2. Colling KP, Bellin MD, Schwarzenberg SJ, Berry L, Wilhelm JJ, Dunn T, et al. Total pancreatectomy with intraportal islet auto-transplantation as a treatment of chronic pancreatitis in patients with CFTR mutations. Pancreas. 2018 Feb;47(2):238-244. doi: 10.1097/MPA.0000000000000968. Accessed June 2, 2022.
3. Fazlalizadeh R, Moghadamyeghaneh Z, Demirjian AN, Imagawa DK, Foster CE, Lakey JR, et al. Total pancreatectomy and islet auto-transplantation: A decade nationwide analysis. World J Transplant. 2016 Mar 24;6(1):233-8. doi: 10.5500/wjt.v6.i1.233. Accessed June 6, 2022.
4. 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. https://pubmed.ncbi.nlm.nih.gov/26644812/. Accessed June 6, 2022.
5. Kesseli SJ, Wagar M, Jung MK, Smith KD, Lin YK, Walsh RM, et al. Long-term glycemic control in adult patients undergoing remote vs. local total pancreatectomy with islet auto-transplantation. Am J Gastroenterol. 2017 Apr;112(4):643-649. doi: 10.1038/ajg.2017.14. Accessed June 2, 2022.
6. Kizilgul M, Wilhelm JJ, Beilman GJ, et al. Effect of intrapancreatic fat on diabetes outcomes after total pancreatectomy with islet auto-transplantation. J Diabetes. 2018 Apr;10(4):286-295. doi: 10.1111/1753-0407.12589. Accessed June 6, 2022.
7. Lane A, Hodges JS, Ptacek P, Berry KL, Beilman GJ, Dunn TB, et al. Low prevalence of diabetes distress following total pancreatectomy with islet auto-transplantation. Clin Transplant. 2018 May;32(5):e13237. doi: 10.1111/ctr.13237. Accessed June 6, 2022.
8. Maffi P, Nano R, Monti P, Melzi R, Sordi V, Mercalli A, et al. Islet allotransplantation in the bone marrow of patients with type 1 diabetes: A pilot randomized trial. Transplantation. 2019 Apr;103(4):839-851. doi: 10.1097/TP.0000000000002416. Accessed June 6, 2022.
9. Morgan KA, Lancaster WP, Owczarski SM, Wang H, Borckardt J, Adams DB. Patient selection for total pancreatectomy with islet auto-transplantation in the surgical management of chronic pancreatitis. J Am Coll Surg. 2018 Apr;226(4):446-451. doi: 10.1016/j.jamcollsurg.2017.12.018. Accessed June 6, 2022.
10. Shahbazov R, Naziruddin B, Salam O, Saracino G, Levy MF, Beecherl E, Onaca N. The impact of surgical complications on the outcome of total pancreatectomy with islet auto-transplantation. Am J Surg. 2020 Jan;219(1):99-105. doi: 10.1016/j.amjsurg.2019.04.007. Accessed June 6, 2022.
11. Steinman TI, Becker BN, Frost AE, Olthoff KM, Smart FW, Clinical Practice Committee American Society of Transplantation, et al. Guidelines for the referral and management of patients eligible for solid organ transplantation. Transplantation. 2001 May 15;71(9):1189-204. doi: 10.1097/00007890-200105150-00001. Accessed June 6, 2022.
12. Wilson GC, Sutton JM, Abbott DE, Smith MT, Lowy AM, Matthews JB, et al. Long-term outcomes after total pancreatectomy and islet cell auto-transplantation: Is it a durable operation? Ann Surg. 2014 Oct;260(4):659-65; discussion 665-7. doi: 10.1097/SLA.0000000000000920. Accessed June 6, 2022.
13. Wilson GC, Sutton JM, Smith MT, Schmulewitz N, Salehi M, Choe KA, et al. Completion pancreatectomy and islet cell auto-transplantation as salvage therapy for patients failing previous operative interventions for chronic pancreatitis. Surgery. 2015 Oct;158(4):872-8; discussion 879-80. doi: 10.1016/j.surg.2015.04.045. Accessed June 6, 2022.
14. Wilson GC, Sutton JM, Smith MT, Schmulewitz N, Salehi M, Choe KA, et al. Total pancreatectomy with islet cell auto-transplantation as the initial treatment for minimal-change chronic pancreatitis. HPB (Oxford). 2015 Mar;17(3):232-8. doi: 10.1111/hpb.12341. Accessed June 6, 2022.

APPENDIX

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*