Molina Clinical Policy
Autologous Pancreatic Islet Cell Transplantation
Policy No. 440

Last Approval: 08/12/2026
Next Review Due By: August 2027

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

Pancreatitis is a condition in which digestive enzymes become activated while still in the pancreas, causing inflammation of pancreatic tissue. The most common signs and symptoms are epigastric pain, nausea, and vomiting. Episodes may occur in isolation (acute pancreatitis) or become recurring in nature (chronic pancreatitis). In chronic pancreatitis, pancreatic tissue becomes progressively damaged. The most common symptom in chronic pancreatitis is abdominal pain, which may be due to increased intrapancreatic pressure, ischemia, inflammation, neural injury and altered nociceptive signaling, or other complications. Other symptoms may include steatorrhea due to fat malabsorption, and weight loss over time. A small subset of patients may be asymptomatic and have no identifiable clinical consequences. Common complications of chronic pancreatitis include metabolic consequences of exocrine insufficiency, particularly osteopenia and osteoporosis due to malabsorption, pancreatogenic (type 3c) diabetes mellitus, and opioid dependency as a consequence of chronic pain management (Freedman & Forsmark 2026). For those with chronic pancreatitis experiencing intractable and debilitating symptoms, total or near-total pancreatectomy may be performed, and potentially in conjunction with autologous islet cell transplantation to preserve endocrine function. Islet cells are hormone-producing cells found within the pancreas that produce insulin, glucagon, and other endocrine hormones essential for regulating blood glucose and metabolic function (Hayes 2020; Kluger & Chabot 2025).

Autologous pancreatic islet cell transplantation, also referred to as islet autotransplantation, is a treatment used to preserve insulin function in select patients with chronic pancreatitis undergoing a total pancreatectomy, near-total pancreatectomy, or completion pancreatectomy after having failed previous operative interventions. In autologous transplantation, the patient becomes a self-donor, and the islet cells are harvested from the pancreas following its removal, avoiding immune rejection and the need for immunosuppression. The cells are infused into the portal vein of the liver, in which the liver then assumes the role of insulin production and thereby reducing or potentially eliminating the need for exogenous insulin. A major contraindication to autologous transplantation is malignancy of the pancreas due to the risk of transplanting malignant cells into the liver (Hayes 2020; Kluger & Chabot 2025).

Additionally, allogeneic transplantation, using islet cells from a deceased donor, is a treatment option for select patients with type 1 diabetes. Xenogeneic transplantation, using islet cells from an animal donor, remains experimental and has significant morbidity risks associated with the required immunosuppression (Robertson & Rickels 2026).

RELATED POLICIES

MCP-441: Allogeneic Pancreatic Islet Cell Transplantation with Lantidra (donislecel-jujn)

COVERAGE POLICY

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

Limitations and Exclusions

Xenotransplantation is considered **experimental, investigational, or unproven** due to insufficient evidence in the peer-reviewed medical literature to establish long-term safety, efficacy, and effect on net health outcomes

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

Systematic Reviews and Meta-Analyses

Hughes et al. (2026) conducted a systematic review and meta-analysis to evaluate the long-term metabolic outcomes following total pancreatectomy with autologous islet transplantation (TPIAT). Seventeen studies met inclusion criteria, including one randomized controlled trial (RCT), 5 prospective studies, 11 retrospective studies. All studies (n = 1,332) included patients undergoing either total, partial, or completion pancreatectomy followed by islet autotransplantation, with most being for chronic pancreatitis and some including non-pancreatitis indications, such as grade C postoperative pancreatic fistula, high-risk anastomosis, or neoplasm. The primary outcome was insulin independence after TPIAT, with a median follow-up of 1 year, and 4 studies reporting follow-up longer than 3 years. Across all 17 studies, the pooled insulin independence rate was 34% (95% confidence interval [CI] 29%-40%, I^2 = 59%). For the chronic pancreatitis subgroup, the pooled insulin independence rate was 33% (95% CI 29-38%, I^2 = 40%), while the pooled rate for non-pancreatitis indications was higher at 68% (95% CI 27-93%, I^2 = 83%) but with high heterogeneity. Additional pooled secondary outcomes included a mean hemoglobin A1c (HbA1c) of 6.9% (95% CI 6.4-7.3%, I^2 = 96%), mean fasting C-peptide of 1.0 ng/mL (95% CI 0.76-1.25, I^2 = 93%), and a severe hypoglycemic episode rate of 11% (95% CI 9.2-14%, I^2 = 0%) but with limited data. Partial graft function and graft failure were reported in 7 studies and ranged from 2.9 to 71% and 0 to 15%, respectively. Study limitations include retrospective design, small sample sizes, and substantial heterogeneity likely caused by center-specific islet isolation techniques, transplantation strategies and protocols, and inconsistent reporting of metabolic outcomes. The authors concluded that autologous islet transplantation is a safe, reproducible, and effective technique for mitigating iatrogenic diabetes following pancreatectomy. Further research is needed to define long-term metabolic outcomes for extended indications.

Carabott et al. (2026) conducted a systematic review and meta-analysis to evaluate health-related quality of life outcomes following TPIAT for chronic pancreatitis or recurrent acute pancreatitis. Twenty-nine studies (n = 4,075) met inclusion criteria, including 16 prospective and 11 retrospective cohort studies, 1 cross-sectional study, and 1 case-control study. Quality of life was measured using validated tools such as the RAND 36-Item Short Form Health Survey (SF-36) and the Pancreatitis Quality of Life Instrument, with follow-up ranging from 1 month to 10 years. For studies that reported physical component summary (PCS) and mental component summary (MCS) scores, pooled meta-analysis at 1 year showed statistically significant improvements for both, with a mean difference of 10.36 points for PCS (95% CI 7.33-13.40, $p < 0.001$, I^2 = 77.1%) and 5.54 points for MCS (95% CI 3.30-7.78, $p < 0.001$, I^2 = 68.1%). At longest follow-up, PCS improved by 16.07 points (95% CI 5.80-26.34, p = 0.002, I^2 = 98.3%) and MCS improved by 13.26 points (95% CI 3.67-22.85, p = 0.007, I^2 = 97.5%). The authors reported that quality of life improvements appeared durable at 5 years and persisted beyond 10 years in some studies. In studies that evaluated postoperative insulin requirements with quality of life, some studies reported better outcomes among insulin independent patients while others reported improvements regardless of insulin requirements. The authors suggest that patients may benefit from TPIAT even when postoperative insulin is required, as pain relief is a major driver of improved quality of life. Study limitations include low-quality observational studies, unmeasured confounding factors, responder bias, overlapping patient populations, and substantial heterogeneity. The authors concluded that TPIAT in patients with chronic pancreatitis and recurrent acute pancreatitis offers short and long-term improvements in quality of life, but further prospective research is needed to identify which patients benefit most.

Khazaaleh et al. (2023) conducted a systematic review and meta-analysis to evaluate the outcomes of TPIAT, particularly focusing on insulin and narcotic independence post-procedure. The review included 21 prospective or retrospective cohort studies published between 1980 and 2017, for a total of 1,011 patients, with 18 studies consisting of adult populations and 3 studies consisting of pediatric populations. Key outcomes showed that narcotic

independence was achieved in 53.5% of adults (95% CI 45-62, $p < 0.05$, $I^2 = 81\%$) and 51.9% of children (95% CI 17-85, $p < 0.05$, $I^2 = 84\%$) after TPIAT. Insulin independence was achieved in 31.8% of adults (95% CI 26-38, $p < 0.05$, $I^2 = 64\%$) and 47.7% in children (95% CI 20-77, $p < 0.05$, $I^2 = 82\%$) post TPIAT. Glycemic control, measured by HbA1C levels at 12 months post-procedure, was reported in 4 adult studies for a pooled mean of 6.76% ($p = 0.27$). However, there was significant heterogeneity between study data. The authors highlighted that the likelihood of insulin independence is multifactorial, with high islet yield, as measured by islet equivalents per kilogram of body weight, being a consistent predictor of better endocrine outcomes. Additionally, factors such as a lower BMI, female sex, no prior pancreatic surgery, and shorter disease duration before surgery, were associated with better insulin independence. Pediatric patients with genetic causes of chronic pancreatitis, particularly CFTR mutations, were more sensitive to prior surgical intervention and which negatively impacted islet yield and insulin independence. Pain relief was considered a key measure of success as chronic pain is the most debilitating feature in chronic pancreatitis. While most studies were deemed to be moderate or good quality, as assessed using the Newcastle-Ottawa scale and Murad tool, considerable heterogeneity across studies reduced the ability to draw definitive conclusion. Overall, the authors concluded that TPIAT offers acceptable levels of pain relief and partial preservation of endocrine function in patients with chronic pancreatitis. While insulin independence is not achieved in the majority of cases, many patients experience improved glycemic control postoperatively.

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

Witkowski et al. (2025) analyzed the 1-year outcomes from a multicenter prospective observational cohort study (POST) to identify predictors of diabetes outcomes following TPIAT. The study included 384 patients, comprised of 129 children and 255 adults who underwent TPIAT for recurrent acute or chronic pancreatitis. Primary outcomes were assessed at 6 months and 1 year, and included insulin use, HbA1c, fasting C-peptide, and islet graft function (defined as a fasting C-peptide $\geq$ 0.3 ng/mL). At 1 year, 83% of patients retained islet graft function, 20% were off insulin, and 60% had an HbA1c of < 7%. The mean insulin dose at 1 year was 0.34 units/kg/day and outcomes were favorable in children and those with normoglycemia prior to TPIAT. Among patients with preoperative diabetes, none were insulin independent at 1 year, whereas insulin independence occurred in 14% of those with prediabetes and 27% for those with normoglycemia. Children had higher odds of insulin independence than adults (odds ratio [OR] 2.3, 95% CI 1.3-4.3). Additionally, each 1% decrease in baseline HbA1c was associated with higher odds of insulin independence (OR 4.0, 95% CI 1.7-9.1). Islet graft function was associated with a higher baseline fasting C-peptide (OR 2.18, 95% CI 1.42-3.35 per 1 ng/mL increase) and lower baseline HbA1c (OR 1.89, 95% CI 1.18-3.0 per 1% decrease). There were 7 patient deaths, and 1-year survival was 98.3%. Study limitations include missing laboratory outcome data (despite nearly 95% follow-up retention), lack of stimulated islet function testing, and limited generalizability, as patients who were enrolled were already considered good clinical candidates for TPIAT. The authors concluded that most patients retained islet graft function after TPIAT, 20% were insulin independent at 1 year, and that a lower preoperative HbA1c, higher fasting C-peptide, and pediatric age predicted more favorable diabetes outcomes. The authors stated that these findings support assessing glycemia and islet function before TPIAT and offering islet autotransplantation at the time of pancreatectomy, especially in those without pancreatogenic diabetes.

Hayes (2020) performed a health technology assessment on TPIAT for chronic pancreatitis, reviewing 16 studies (4 prospective and 12 retrospective), with sample sizes ranging from 27 to 771 patients and follow-up ranging from 5.8 months to 10 years. Results suggest that TPIAT may provide durable improvements in patient-reported pain, reductions in narcotic use, and adequate glycemic control. TPIAT may also provide insulin independence in many cases, improve quality of life in patients with intractable and debilitating symptoms, and improve survival with an acceptable level of mortality. However, the authors noted that the overall quality of evidence is low, and comparative data were sparse and inconsistent for several outcomes with a lack of statistical significance data for some comparators. Despite the limitations of available evidence, TPIAT may be the only viable option for patients with debilitating chronic pancreatitis who have exhausted all available standard therapies. Higher quality evidence is needed to fully assess the effectiveness of TPIAT; however, this evidence would be difficult to obtain, and randomized controlled trials are likely not possible due to ethical concerns.

Bellin et al. (2017) performed a retrospective case series to evaluate the outcomes of TPIAT in 17 children aged 3-8 years with severe, refractory chronic pancreatitis. The median follow-up duration was 2.24 years. Most children had identifiable genetic risk factors for pancreatitis, such as proteas serine 1, protease inhibitor Kazal-type 1, cystic fibrosis transmembrane regulator genes, and chymotrypsin C. All children had failed medical and endoscopic therapies and were not candidates for less invasive surgical approaches due to diffuse pancreatic involvement and non-dilated ducts. Pain was the primary goal of surgery and was met in all patients. All 17 patients discontinued narcotic use, typically

within a median of 68 days post-surgery, and all were off opioids by one year. For glycemic outcomes, 82% of patients had at least some insulin independence post-TPIAT and 64% were completely insulin independent at last follow up. Glycemic control was excellent overall, with a median HbA1c of 5.9% postoperatively. All insulin-dependence patients retained some islet function as evidenced by positive C-peptide levels. Adverse events occurred in 7 patients, for a total of 15 complications, including gastrointestinal tube issues, wound problems, intra-abdominal hemorrhage, and bile leak. Four children required reoperation, and all complications were resolved without long-term effects. Over two years post-TPIAT, growth outcomes were positive, with children maintaining or improving height, weight, BMI Z scores, resuming normal eating and able to return to a typical childhood lifestyle. The authors concluded that young children with severe refractory chronic pancreatitis may be good candidates for TPIAT, with high rates of pain relief, insulin independence, and excellent glycemic control in the majority.

National and Specialty Organizations

The **National Institute for Health and Care Excellence (NICE)** (2008) provides evidence-based recommendations on TPIAT, specifically, how transplant can improve glycemic control after pancreatectomy. The authors note that as of 2008, evidence supports some short-term efficacy, but that most patients require insulin therapy over time. Clinicians must ensure that patients understand they may require exogenous insulin in the long term prior to performing TPIAT. Patient selection for this procedure should involve a multidisciplinary team with experience in managing the disease, and the procedure should be performed by experienced surgeons.

At the 2013 **PancreasFest**, an annual multidisciplinary meeting with leading experts in pancreatic disease, a working group provided consensus recommendations regarding the use of TPIAT in the management of chronic pancreatitis. The authors emphasized that TPIAT should be considered for individuals with disabling pain or recurrent acute episodes related to chronic pancreatitis that have not responded to other treatments, including medical therapy, endoscopy, or previous surgical interventions. It may also be considered in patients with hereditary pancreatitis who have a markedly increased risk of developing pancreatic cancer. The authors note that accurate diagnosis of chronic pancreatitis, careful patient selection, and timing of the procedure are essential. The consensus highlighted the importance of multidisciplinary evaluation, involving specialists in gastroenterology, surgery, endocrinology, pain management, nutrition, and mental health. The success of TPIAT depends on coordinated care before and after surgery. Long-term management after the procedure includes lifelong follow-up for monitoring of glycemic status, nutritional needs, pancreatic enzyme replacement therapy, and ongoing assessment and treatment of pain and psychological well-being. Finally, the authors acknowledged that although TPIAT has demonstrated benefits in pain relief and preservation of islet function in selected cases, further research is needed to clarify optimal timing, improve patient selection criteria, and better understand long-term outcomes (Bellin et al. 2014).

The **Diabetes Canada** Clinical Practice Guidelines Expert Committee (2018) recommend that individuals undergoing total pancreatectomy for benign pancreatic disease be considered for islet autotransplantation to prevent the development of diabetes where suitable facilities are accessible (Grade D, Level 4 recommendation). The guidelines highlight that islet autotransplantation does not require immunosuppression and has minimal additional operative risks for patients undergoing pancreatectomy. TPIAT can prevent diabetes and can result in durable insulin independence with no additional increase in mortality. Additionally, islet autotransplantation after partial pancreatectomy can prevent diabetes and provide superior metabolic function, which may be particularly important for patients at high risk for diabetes. While the metabolic benefits of transplantation depend on the islet yield and is generally lower than from cadaveric donors, more than 50% of patients undergoing total pancreatectomy will have a meaningful glycemic benefit.

The **American Diabetes Association** Professional Practice Committee for Diabetes (2026) published *Standards of Care in Diabetes* and recommends that islet auto-transplantation "be considered for individuals requiring total pancreatectomy for medically refractory chronic pancreatitis to prevent postsurgical diabetes." The standards state that "approximately one-third of individuals 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 individuals." Both personal factors and disease factors should be carefully considered when deciding the indications and timing of surgery. Surgeries should also be performed in skilled facilities that have demonstrated expertise in islet auto-transplantation.

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology)

Code	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

HCPCS (Healthcare Common Procedure Coding System)

Code	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

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

08/12/2026 Policy reviewed. No change to coverage criteria. Title changed to "Autologous Pancreatic Islet Cell Transplantation."
08/13/2025 Policy reviewed. No change to coverage criteria.
08/14/2024 Policy reviewed. No change to coverage criteria.
08/09/2023 Allogenic transplantation information removed from policy. Added cross-reference to new MCP on allogenic islet cell transplantation in the related policies section.
06/14/2023 Policy separated from original policy "Pancreas Transplant Procedures." Overview, Summary of Medicaid Evidence, and references updated. No changes to criteria. Policy reviewed in May 2023 by an Advanced Medical Reviews (AMR) practicing, board-certified physician in the areas of Surgery, Transplant.
06/08/2022 Policy reviewed, no changes to criteria; included section on marijuana use; updated Overview, Summary of Medical Evidence, and Reference sections.
06/09/2021 Policy reviewed, updated references. Added CPT codes: 48551, 48552, 50323, 50325, 50327.
04/23/2020 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. Policy reviewed in January 2020 by an Advanced Medical Reviews (AMR) practicing, board-certified physician in the areas of Surgery, Transplant.

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