

Subject: Pancreas Transplantation Procedures (Pancreas Alone, Simultaneous Pancreas and Kidney, Pancreas after Kidney and Pancreatic Islet Cell and Retransplantation)		Original Effective Date: 6/14/06
Policy Number: MCP-017	Revision Date(s): 8/28/07, 8/25/10, 10/31/12, 5/26/15	
Review Date: 12/16/15, 12/14/16, 6/22/17, 9/13/18, 9/18/19		
MCPC Approval Date: 6/22/17, 9/13/18, 9/18/19		

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. 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 (i.e., 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 Molina Clinical Policy (MCP) document and provide the directive for all Medicare members.^{1 2 3}

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

Pancreas transplantation is used to treat type 1 diabetes. The ultimate goal for pancreas transplantation is to improve the overall quality of life for the recipient. Transplantation, when successful, 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 both type 1 and type 2 diabetes and often ends in end-stage renal disease.

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 transplantation (SPK): 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 transplantation (PAK): Performed in Type I diabetic patients with end stage renal disease. Two operations are required for this procedure. This is the treatment of choice for candidates with a living donor for a kidney transplant.

Pancreas Islet Cell Transplantation (PICT): Transplanted islets (small clusters of endocrine cells found in the pancreas that include insulin producing beta cells) are infused into the portal vein through a catheter and anchored in the liver.

RECOMMENDATION

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 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.

Members must meet UNOS guidelines for transplantation and the diagnosis must be made by a *Specialist in the Disease* and or Transplant Surgeon.

Pre-Transplant Evaluation:

Criteria for transplant evaluation include all of the following:

- History and physical examination
- Psychosocial evaluation and clearance:
 - 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
 - Adequate family and social support
- EKG
- Chest x-ray
- Cardiac clearance in the presence of any of the following:
 - chronic smokers
 - > 50 years age
 - those with a clinical or family history of heart disease or diabetes
- Pulmonary clearance if evidence of pulmonary artery hypertension (PAH) or chronic pulmonary disease
- Lab studies:
 - *Complete blood count, Kidney profile (blood urea nitrogen, creatinine), electrolytes, calcium, phosphorous, albumin, liver function tests, Coagulation profile (prothrombin time, and partial thromboplastin time)
 - *Serologic screening for HIV, Epstein Barr virus (EBV), Hepatitis virus B (HBV), and Hepatitis C(HCV), cytomegalovirus (CMV), RPR and/or FTA:
 - If HIV positive all of the following are met:
 - CD4 count >200 cells/mm-3 for >6 months
 - HIV-1 RNA undetectable
 - On stable anti-retroviral therapy >3 months

- 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
 - UDS (urine drug screen) if patient is current or gives a history of past drug abuse
- ❑ *Colonoscopy (if indicated or if patient is 50 ≥ older should have had an initial screening colonoscopy, after initial negative screening requires follow up colonoscopy every ten years) with complete workup and treatment of abnormal results as indicated
- ❑ *GYN examination with Pap smear for women ≥ 21 to ≤ 65 years of age or indicated (not indicated in women who have had a TAH or TVH) with in the last three year with complete workup and treatment of abnormal results as indicated

Within the last 12 months:

- ❑ 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
- ❑ *Mammogram (if indicated or > age 40) with complete workup and treatment of abnormal results as indicated
- ❑ *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**

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 criteria: ^{1-3 38 41-45} [ALL]

- ❑ All pre-transplant criteria are met; and
- ❑ Optimally managed for at least 12 months by an endocrinologist or pancreas transplant surgeon; and
- ❑ Documentation of insulin dependent Type 1 diabetes showing abnormal beta cell functioning: ¹
 - Beta cell autoantibody positive; or
 - Fasting C-peptide undetectable (e.g., than or equal to 110% of the laboratory's lower limit of normal and with a concurrently obtained fasting glucose < 225mg/dl); and
- ❑ 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); ¹ and
- ❑ 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)

The requesting transplant recipient should not have any of the following **absolute contraindications**:

- ❑ Cardiac, pulmonary, and nervous system disease that cannot be corrected and is a prohibitive risk for surgery
- ❑ Malignant neoplasm with a high risk for reoccurrence, non-curable malignancy (excluding localized skin cancer)

- Systemic and/or uncontrolled infection
- AIDS (CD4 count < 200cells/mm3)
- Unwilling or unable to follow post-transplant regimen
 - Documented history of non-compliance
 - Inability to follow through with medication adherence or office follow-up
- Chronic illness with one year or less life expectancy
- Limited, irreversible rehabilitation potential
- Active untreated substance abuse issues, requires documentation supporting free from addiction for minimally 6 months if previous addiction was present
- No adequate social/family support

The requesting transplant recipient should be evaluated carefully and potentially treated if the following **relative contraindications** are present:

- Irreversible lung disease patients require consultation and clearance by a Pulmonologist prior to consideration of transplantation, this includes the following:
 - Smoking, documentation supporting free from smoking for 6 months
 - Active peptic ulcer disease
 - Active gastroesophageal reflux disease
- CVA with long term impairment that is not amendable to rehabilitation or a patient with CVA/transient ischemic attack within past 6 months
- Obesity with body mass index of >30 kg/m² may increase surgical risk
- 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
- Gall bladder disease requires ultrasound of the gall bladder with treatment prior to transplantation

AND

The following Pancreas transplantation specific requirements by transplantation type must also be met: ³⁸

Pancreas Transplant Alone: [ALL]

- All of the above outlined main criteria are met AND all of the following criteria are present:
- 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
- Creatinine clearance glomerular filtration rate of ≥ 80 ml/min, and
- Minimum proteinuria

Simultaneous pancreas-kidney transplant: [ALL]

- All of the above outlined main criteria are met AND all of the following criteria are present:
- 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
- The member has renal insufficiency with uremia or impending/ current end stage renal disease (ESRD) with poor renal function and one of the following: [ONE]

- Currently on dialysis; or
- 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

Pancreas after kidney Transplant: [ALL]

- All of the above outlined main criteria are met AND all of the following criteria are present:
- 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
- The member has a living organ donor for the kidney transplant procedure otherwise SPK should be considered; and
- Previously successful kidney transplant as evidenced by stable function of previous renal allograft; and
- Stable adequate kidney function as evidenced by creatinine clearance glomerular filtration rate of \geq 45ml/min; and
- Minimum proteinuria

CONTINUATION OF THERAPY

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

- If Molina Healthcare has authorized prior requests for transplantation, the following information is required for medical review: [ALL]
 - Presence of no absolute contraindication as listed above;
 - History and physical within the last 12 months;
 - Kidney profile within the last 12 months;
 - Cardiac update if history of cardiac disease within two years (\geq 50 years of age);
 - Psychosocial evaluation or update within the last 12 months;
 - 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.
- If authorized prior requests for transplantation were obtained from another insurer, the following information is required for medical review: [ALL]
 - Authorization letter/documentation from previous insurer;
 - Presence of no absolute contraindication as listed above;
 - History and physical within the last 12 months;
 - Cardiac update if history of cardiac disease within two years (\geq 50 years of age);
 - Psychosocial evaluation or update within the last 12 months;
 - 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.

COVERAGE EXCLUSIONS ^{1-3 38}

Any requests that do not meet the above outlined criteria for pancreas alone, simultaneous pancreas-kidney transplantation and pancreas after kidney transplantation and any of the following conditions:

- Type II diabetes
- Pancreas Islet Cell Transplantation
- Any transplant beyond one retransplantation
- Bioartificial pancreas device
- Chronic pancreatitis & Islet Cell Auto-transplantation

SUMMARY OF MEDICAL EVIDENCE⁵⁻³⁷

The published medical evidence and outcomes for pancreas transplantation in the United States consists of registry data obtained from transplant centers that perform pancreas transplantation procedures and is available from the United Network for Organ Sharing (UNOS) database. Registry data demonstrates graft survival rates and outcomes comparable to other organ transplants.

Pancreatic islet cell transplantation is considered investigational because the peer reviewed published evidence is insufficient to conclude that islet cell transplantation shows net benefits in type I diabetes or for any other indication. The U.S. Food and Drug Administration (FDA) have provided guidance to industry regarding investigational new drug development (IND) for allogeneic pancreatic islet cell products. However, to date, there is no FDA approved biologic license for allogeneic pancreatic islet cell products or for a bioartificial pancreas device.

CODING INFORMATION THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

CPT	Description
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
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
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
50380	Renal autotransplantation, reimplantation of kidney

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
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ICD-10 CM	Description: [For dates of service on or after 10/01/2015]
E10.10	Type 1 DM w/ketoacidosis w/o coma
E10.11	Type 1 DM w/ketoacidosisw/coma
E10.21	Type 1 DM w/diabetic nephropathy
E10.39	Type 1 DM w/oth diab ophthalmic comp
E10.40	Type 1 DM w/diab neuropathy unspec
E10.51	Type 1 DM w/diab periph angiopathy w/o gangrene
E10.65	Type 1 DM w/hyperglycemia
E10.69	Type 1 DM w/oth specified complication
E10.8	Type 1 DM w/unspec complications
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

RESOURCE REFERENCES

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45. Advanced Medical Review (AMR): Policy reviewed by MD board certified in Surgery, Transplant. August 30, 2012

Review/Revision History:

6/14/06: New Policy

8/28/07: Policy reviewed by a Board certified Endocrinologist and Board Certified Pancreas Transplant Surgeon. Pancreas transplant alone criteria was added.

8/25/10: Policy reviewed and the changes include: Some of the contraindications were moved from absolute to the relative contraindications section. The pancreas transplant alone (PTA) section has a new requirement of glomerular filtration rate (GFR) of > 80ml/min and minimal proteinuria. This was based upon recent studies that demonstrated improved outcomes in patients meeting these criteria. The document was reviewed by an AMR physician Board certified in General Surgery General, and Transplant Surgery.

10/31/12: Policy reviewed and the changes include updated criteria for pre-transplant evaluation and HIV and AIDS patients. Summary of medical evidence section was updated.

5/26/15: This policy was reviewed and was updated with new pretransplant criteria and one new exclusion for bioartificial pancreas devices. The medical evidence section was condensed.

12/14/16, 6/22/17: Policy reviewed, no changes

9/13/18 & 9/18/19: Policy reviewed, no changes to criteria, updated references