COVERAGE:

A **simultaneous or combined pancreas-kidney transplant (SPK)** from a cadaver donor or a **simultaneous pancreas and living donor kidney (SPLK)** where the pancreas is obtained from a cadaver donor and a kidney is obtained from a living donor, may be considered medically necessary for dialysis dependent diabetic ESRD (End Stage Renal Disease) patients. SPK or SPLK are primarily indicated for those select patients who cannot be adequately controlled on any standard insulin regimen and in which this poor control represents a significant threat to life.

**Pancreas transplant after a prior kidney transplant (PAK)** may be considered medically necessary in patients with insulin dependent diabetes mellitus.

**Pancreas transplant alone (PTA)** may be considered medically necessary in patients with severely disabling and potentially life threatening complications due to hypoglycemia unawareness and labile-diabetes that persists in spite of optimal medical management. See the description for typical symptoms of hypoglycemia unawareness.

**Pancreas retransplantation (PR)** (after failure of a primary pancreas allograft) is medically necessary in patients who meet eligibility criteria for primary transplantation. Third or subsequent pancreas transplantation is experimental/investigative.

**Autologous pancreas islet cell transplantation** may be considered medically necessary as an adjunct to a total or near total pancreatectomy in patients with chronic pancreatitis.

**Allogenic pancreas islet cell transplantation** is considered experimental/investigative.

The following procedure is considered experimental/investigative:

- transplantation of a segment of a pancreas from a living related donor (i.e., head or tail sections).

DESCRIPTION:

**Pancreas transplant** is the surgical removal of the pancreas from a deceased donor and the implantation of the pancreas into a recipient patient. Pancreas transplantation is unique among vascularized organ transplants because it is not considered a life-saving treatment. In a small subset of patients who experience life-threatening complications from insulin-dependent diabetes (IDDM), pancreas transplantation could be considered life saving. Achievement of insulin independence with resultant decreased morbidity and increased quality of life is the primary health outcome of pancreas transplant.
Pancreas alone or Pancreas/Kidney transplant candidates include patients with the following:

1. Uncontrollable insulin dependent diabetes despite documentation of patient compliance with a “tight control” regimen;

2. IDDM patients with renal failure [may be given a cadaveric simultaneous pancreas/kidney transplant (SPK)];

3. IDDM patients who may be given a cadaveric pancreas transplant at a period of time following a kidney transplantation from either a cadaveric or a living related donor pancreas after kidney (PAK); and

4. Non-uremic IDDM patients with specific severely disabling and potentially life threatening diabetic problems may be offered a pancreas transplant alone (PTA).

Patients who meet the criteria listed above should also meet the following physical status criteria (for any type of pancreas transplant):

- Adequate cardiopulmonary status and a functional urinary bladder
- Absence of active infection
- Absence of HIV infection
- No history of malignancy within 5 years of transplantation; excluding non melanomatous skin cancers
- Documentation of patient compliance with medical management.

Candidates for pancreas transplant alone (PTA) should additionally meet one of the following severity of illness criteria:

- Documentation of severe hypoglycemia unawareness as evidenced by chart notes or emergency room visits. (Typical symptoms of hypoglycemic unawareness include: sweating, anxiety, palpitations, tremors, dizziness, tingling, faintness, or blurred vision); OR

- Documentation of potentially life-threatening labile diabetes as evidenced by chart notes or hospitalization for diabetic ketoacidosis.

Autologous Pancreas Islet cell transplantation – Patients with chronic pancreatitis may experience intractable pain that can only be relieved with a total or near total pancreatectomy. However the pain relief must be balanced against the certainty that the patient will be rendered an insulin dependent diabetic. Autologous islet cell transplantation has been investigated as a technique to prevent this serious morbidity. Specifically, during the pancreatectomy procedure a suspension of isolated islet cells is created from the resected pancreas specimen and then injected into the portal vein of the liver, where the cells function as a free graft.

Allogenic Pancreas Islet cell transplantation– A donor pancreas can either be used for a pancreas transplant or it can be processed further and used for islet transplant. The first step is to get the islets out of the pancreas without damaging them. This is a very
difficult and expensive process because the islets are only 1% of the pancreas. After the islets have been isolated from the rest of the pancreas, the islets are infused into the portal vein of the transplant recipient and the cells drain into the liver.

**Segmental pancreas transplantation** from a living related donor (LRD) has also been performed. The early rationale for LRD pancreas transplant was to reduce the rejection rate. LRD represents a very small proportion of all pancreas transplants.

A **Pancreas Kidney transplant (SPK)** is the simultaneous surgical removal of a pancreas and kidney from the same cadaver, and the subsequent implantation of the pancreas and kidney into a single recipient patient. This surgery is done for insulin dependent diabetics with end-stage renal failure.

Note: Experience with SPK transplants is more extensive than that of other transplant options.

**RATIONALE:**

This policy is based in part on a 1998 TEC Assessment, which focused on the pancreas graft survival and health outcomes associated with both pancreas transplant alone (PTA) and pancreas after kidney transplant (PAK). The assessment offered the following conclusions:

1. **Pancreas after Kidney (PAK) Transplant**

Based on current pancreas transplant registry data, after approximately 3 years, 64% of transplant recipients have a functioning pancreas compared to 77% among recipients of simultaneous pancreas and kidney transplants. PAK transplantation allows the uremic patient the benefits of a living related kidney graft (if available), and the benefits of a subsequent pancreas transplant that is likely to result in improved quality of life compared to a kidney transplant alone. Uremic patients for whom a cadaveric kidney graft is available but a pancreas graft is not simultaneously available benefit similarly from a subsequent pancreas transplant.

2. **Pancreas Transplant Alone (PTA)**

PTA graft survival has improved in recent years; available data suggest that 60% of grafts are functioning at 2 years with potential insulin independence. In carefully selected IDDM patients with severely disabling and potentially life threatening complications due to hypoglycemia unawareness and labile diabetes (that persists despite optimal medical management), the benefits of PTA were judged to outweigh the risks of surgery and subsequent immunosuppression. The majority of patients undergoing PTA are those with either hypoglycemic unawareness or labile diabetes. However, other exceptional circumstances may exist where nonuremic IDDM patients have significant morbidity risks due to secondary complications of diabetes (i.e., peripheral neuropathy) that exceed those of the transplant surgery and subsequent chronic immunosuppression. Because there is virtually no published evidence regarding outcomes of medical management in this very small group of exceptional diabetic patients, it is not possible to generalize about which circumstances represent appropriate indications for pancreas transplant alone (PTA). Case by case consideration of each patient’s clinical situation may be the best
option for determining the balance of risks and benefits.

3. Pancreas Retransplantation (PR)

For all three types of pancreas transplantation (i.e., pancreas transplant alone, simultaneous pancreas-kidney transplant, and pancreas after kidney transplant), the survival of a second pancreas was lower than for the primary transplant of the same type. However, patients receiving second pancreas transplants have a good chance of remaining insulin-independent for 3 years or more.

4. Autologous islet cell transplantation

Autologous islet cell transplantation has been investigated since 1977 and has grown slowly with incremental improvements in the islet cell isolation process. Researchers at the University of Minnesota have reported the largest experience, summarizing the results in 48 patients undergoing the procedure between 1977 and 1995. Of the 39 evaluable patients; 51% were insulin independent for at least 1 month with the probability of sustained insulin independence dropping to 34% after 2 years. However, of the 18 patients who received an autotransplant with islets prepared with the most recent techniques in islet cell isolation, the long term success rate was 55%. The most powerful predictor of insulin independence was the number of islets cells infused, which in turn is inversely related to the degree of fibrosis of the pancreas. Unfortunately there is currently no way to predict preoperatively the number of islet cells isolated, although patients with long standing pancreatitis and prior surgical procedures are more likely to have a fibrotic pancreas. There have been no reports of significant morbidity or mortality associated with this procedure. Although published experience with this procedure is limited, autologous islet cell transplantation appears to significantly decrease the incidence of diabetes after total or near total pancreatectomy. In addition, this procedure is not associated with serious complications itself and is performed as an adjunct to the pancreatectomy procedure.

5. Allogenic Pancreas Islet cell transplantation

Allogenic Pancreas Islet cell transplantation is considered experimental/investigative due to the lack of consistent success as a result of engraftment of too few islets to sustain a non-diabetic state and due to the toxic effect of immunosuppression drugs, most notably, steroids.

6. Other forms of pancreas transplantation were not considered separately in the TEC Assessment. However, the TEC Assessment states: “The technical failure rate with living related donor (LRD) segmental pancreas transplantation has been reported to be higher than with cadaveric pancreas, but the rejection rate is lower in technically successful transplants.” This transplant remains in the experimental/investigative status due to a lack of long term, multicentered studies showing the long-term effects on health outcomes (patient survival, graft survival, morbidity and quality of life measurements).

DISCLAIMER:

State and federal law, as well as contract language, including
definitions and specific inclusions/exclusions, takes precedence over Medical Policy and must be considered first in determining coverage. The member’s contract benefits in effect on the date that services are rendered must be used. Any benefits are subject to the payment of premiums for the date on which services are rendered. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

HMO Blue Texas physicians who are contracted/affiliated with a capitated IPA/medical group must contact the IPA/medical group for information regarding HMO claims/reimbursement information and other general polices and procedures.

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