MEDICAL POLICY

POLICY TITLE	KIDNEY TRANSPLANTS, PANCREAS TRANSPLANTS, AND SIMULTANEOUS KIDNEY/PANCREAS TRANSPLANTS
POLICY NUMBER	MP- 9.005

Original Issue Date (Created):	**7/1/2002**
Most Recent Review Date (Revised):	**8/1/2019**
Effective Date:	**12/1/2020**

I. POLICY

KIDNEY TRANSPLANTS

Kidney transplants with either a living or cadaver donor may be considered **medically necessary** for carefully selected candidates with end-stage renal disease.

Kidney retransplant after a failed primary kidney transplant may be considered **medically necessary** in patients who meet criteria for kidney transplantation**.**

Kidney transplant is considered **investigational** for all other situations. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

POLICY GUIDELINES FOR KIDNEY TRANSPLANTS

Potential contraindications to solid organ transplant (subject to the judgment of the transplant center):

1. Known current malignancy, including metastatic cancer
2. Recent malignancy with high risk of recurrence
3. History of cancer with a moderate risk of recurrence
4. Systemic disease that could be exacerbated by immunosuppression
5. Untreated systemic infection making immunosuppression unsafe, including chronic infection
6. Other irreversible end-stage disease not attributed to kidney disease
7. Psychosocial conditions or chemical dependency affecting ability to adhere to therapy

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RENAL-SPECIFIC CRITERIA

Indications for renal transplant include a creatinine level of greater than 8 mg/dL, or greater than 6 mg/dL in symptomatic diabetic patients. However, consideration for listing for renal transplant may start well before the creatinine level reaches this point, based on the anticipated time that a patient may spend on the waiting list.

ALLOGENEIC PANCREAS TRANSPLANT

A combined pancreas-kidney transplant may be considered **medically necessary** in insulin-dependent diabetic patients with uremia.

Pancreas transplant after a prior kidney transplant may be considered **medically necessary** in patients with insulin-dependent diabetes.

Pancreas transplant alone may be considered **medically necessary** in patients with severely disabling and potentially life-threatening complications due to hypoglycemia unawareness and labile insulin-dependent diabetes that persists in spite of optimal medical management.

Pancreas retransplant after a failed primary pancreas transplant may be considered **medically necessary** in patients who meet criteria for pancreas transplantation**.**

Pancreas transplant is considered **investigational** in all other situations. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure

POLICY GUIDELINES FOR ALLOGENEIC PANCREAS TRANSPLANT

GENERAL CRITERIA

Potential contraindications for solid organ transplant are subject to the judgment of the transplant center include the following:

1. Known current malignancy, including metastatic cancer
2. Recent malignancy with high risk of recurrence
3. Untreated systemic infection making immunosuppression unsafe, including chronic infection
4. Other irreversible end-stage disease not attributed to kidney disease
5. History of cancer with a moderate risk of recurrence
6. Systemic disease that could be exacerbated by immunosuppression
7. Psychosocial conditions or chemical dependency affecting ability to adhere to therapy

PANCREAS SPECIFIC CRITERIA

Candidates for pancreas transplant alone 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; **or**
- Documentation of potentially life-threatening labile diabetes as evidenced by chart notes or hospitalization for diabetic ketoacidosis.

Additionally, most pancreas transplant patients will have type 1 diabetes mellitus. Those transplant candidates with type 2 diabetes mellitus, in addition to being insulin-dependent, should also not be obese (body mass index [BMI] should be $\leq$32 kg/m^2. According to International Registry data, in 2010, 7% of pancreas transplant recipients had type 2 diabetes. (Gruessner, 2011).

MULTIPLE TRANSPLANT CRITERIA

Although there are no standard guidelines regarding multiple pancreas transplants, the following information may aid in case review:

- If there is early graft loss resulting from technical factors (e.g., venous thrombosis), a retransplant may generally be performed without substantial additional risk.
- Long-term graft losses may result from chronic rejection, which is associated with increased risk of infection following long-term immunosuppression, and sensitization, which increases the difficulty of finding a negative cross-match. Some transplant centers may wait to allow reconstitution of the immune system before initiating retransplant with an augmented immunosuppression protocol

Cross-reference:

MP-9.012 Islet Transplantation

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital BlueCross. Please see additional information below, and subject to benefit variations as discussed in Section VI below.

FEP PPO- Refer to FEP Medical Policy Manual MP7.03.02; Allogenic Pancreas Transplant. The FEP Medical Policy Manual can be found at:

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https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

Refer to FEP Medical Policy Manual MP-7.03.01 Kidney Transplant. The FEP Medical Policy Manual can be found at:

https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

Note* - The Federal Employee Program (FEP) Service Benefit Plan does not have a medical policy related to these services.

III. DESCRIPTION/BACKGROUND TOP

KIDNEY TRANSPLANT

END-STAGE RENAL DISEASE

End-stage renal disease (ESRD) refers to the inability of the kidneys to perform their functions (ie, filtering wastes and excess fluids from the blood). ESRD, which is life-threatening, is also known as stage 5 chronic renal failure and is defined as a glomerular filtration rate less than 15 mL/min/1.73 m^2.[1]

Treatment

Dialysis is an artificial replacement for some kidney functions. Dialysis is used as a supportive measure in patients who do not want kidney transplants or who are not transplant candidates; it can also be used as a temporary measure in patients awaiting a kidney transplant.
Kidney transplant, using kidneys from deceased or living donors, is an accepted treatment of ESRD. Based on data from the Organ Procurement and Transplantation Network, in 2017, over 10,300 kidney transplants were performed in the United States. Since 1988, the cumulative number of kidney transplants is over 435,500.[2] Of the cumulative total, 66% of the kidneys came from deceased donors and 34% from living donors.

Combined kidney and pancreas transplants and management of acute rejection of kidney transplant using either intravenous immunoglobulin or plasmapheresis are discussed in separate evidence reviews.

REGULATORY STATUS

A kidney transplant is a surgical procedure and, as such, is not subject to regulation by the U.S. Food and Drug Administration.

The U.S. Food and Drug Administration regulates human cells and tissues intended for implantation, transplantation, or infusion through the Center for Biologics Evaluation and

Research, under Code of Federal Regulation title 21, parts 1270 and 1271. Kidney transplants are included in these regulations.

ALLOGENEIC PANCREAS TRANSPLANT

DIABETES AND PANCREATITIS

Insulin independence with resultant decreased morbidity and increased quality of life is the primary health outcome of pancreas transplantation. While pancreas transplantation is generally not considered a life-saving treatment, in a small subset of patients who experience life-threatening complications from diabetes, pancreas transplantation could be considered life-saving. Pancreas transplant alone (PTA) has also been investigated in patients following total pancreatectomy for chronic pancreatitis. In addition to the immune rejection issues common to all allograft transplants, autoimmune destruction of beta cells has been observed in the transplanted pancreas, presumably from the same mechanism responsible for type 1 diabetes.[1]

Treatment

Pancreas transplantation occurs in several different scenarios such as (1) a diabetic patient with renal failure who may receive a simultaneous cadaveric pancreas plus kidney transplants; (2) a diabetic patient who may receive a cadaveric or living-related pancreas transplant after a kidney transplantation (pancreas after kidney); or (3) a nonuremic diabetic patient with specific severely disabling and potentially life-threatening diabetic problems who may receive a PTA. The total number of adult pancreas transplants (pancreas and pancreas plus kidney) in the United States peaked at 1484 in 2004 and has since steadily declined.[2] In 2017, 213 PTAs and 789 simultaneous pancreas plus kidneys were performed in the United States.[2]

Most patients undergoing PTA are those with either hypoglycemic unawareness or labile diabetes. However, other exceptional circumstances may exist where nonuremic type 1 diabetes patients have significant morbidity risks due to secondary complications of diabetes (eg, peripheral neuropathy) that exceed those of the transplant surgery and subsequent chronic immunosuppression. Because virtually no published evidence addresses 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 PTA. Case-by-case consideration of each patient's clinical situation may be the best option for determining the balance of risks and benefits.

According to the International Pancreas Transplant Registry data, the proportion of pancreas transplant recipients worldwide who have type 2 diabetes has increased over time, from 2% in 1995 to 7% in 2010.[3] In 2010, approximately 8% of simultaneous pancreas plus kidney transplants, 5% of pancreas transplant after kidney transplant, and 1% of PTA were performed in patients with type 2 diabetes.

The approach to retransplantation varies by cause of failure. Surgical and technical complications such as venous thrombosis are the leading cause of pancreatic graft loss among

diabetic patients. Graft loss from chronic rejection may result in sensitization, increasing both the difficulty of finding a cross-matched donor and the risk of rejection of a subsequent transplant. Each transplant center has guidelines based on experience; some centers may wait to allow reconstitution of the immune system before initiating retransplant with an augmented immunosuppression protocol.

REGULATORY STATUS

Small bowel/liver and multivisceral transplantation are surgical procedures and, as such, are not subject to regulation by the U.S. Food and Drug Administration.

The U.S. Food and Drug Administration regulates human cells and tissues intended for implantation, transplantation, or infusion through the Center for Biologics Evaluation and Research, under Code of Federal Regulation title 21, parts 1270 and 1271. Pancreas transplants are included in these regulations.

IV. RATIONALE

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KIDNEY TRANSPLANT

SUMMARY OF EVIDENCE

For individuals who have end-stage renal disease without contraindications to kidney transplant who receive a kidney transplant from a living donor or deceased (cadaveric) donor, the evidence includes registry data and case series. Relevant outcomes are overall survival, morbid events, and treatment-related mortality and morbidity. Data from large registries have demonstrated reasonably high survival rates after kidney transplant for appropriately selected patients and significantly higher survival rates for patients undergoing kidney transplant compared with those who remained on a waiting list. Kidney transplantation is contraindicated for patients in whom the procedure is expected to be futile due to comorbid disease or in whom post-transplantation care is expected to significantly worsen comorbid conditions. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have a failed kidney transplant without contraindications to kidney transplant who receive a kidney retransplant from a living donor or deceased (cadaveric) donor, the evidence includes registry data and case series. Relevant outcomes are overall survival, morbid events, and treatment-related mortality and morbidity. Data have demonstrated reasonably high survival rates after kidney retransplant (eg, 5-year survival rates ranging from 87% to 96%) for appropriately selected patients. Kidney retransplantation is contraindicated for patients for whom the procedure is expected to be futile due to comorbid disease or for whom post-transplantation care is expected to significantly worsen comorbid conditions. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

ALLOGENEIC PANCREAS TRANSPLANT

SUMMARY OF EVIDENCE

For individuals who have insulin-dependent diabetes who receive a pancreas transplant after a kidney transplant, the evidence includes case series and registry studies. Relevant outcomes are overall survival, change in disease status, and treatment-related mortality and morbidity. Data from national and international registries have found relatively high patient survival rates with a pancreas transplant after a kidney transplant (eg, a 3-year survival rate of 93%). A 2012 analysis of data from a single center found similar patient survival and death-censored pancreas graft survival rates with a pancreas transplant after a kidney transplant or an SPK transplant. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have insulin-dependent diabetes with uremia who receive SPK transplants, the evidence includes registry studies. Relevant outcomes are overall survival, change in disease status, and treatment-related mortality and morbidity. Data from national and international registries have found relatively high patient survival rates after SPK transplant. A retrospective analysis found a higher survival rate in patients with type 1 diabetes who had an SPK transplant vs those on a waiting list. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have insulin-dependent diabetes and severe complications who receive pancreas transplant alone, the evidence includes registry studies. Relevant outcomes are overall survival, change in disease status, and treatment-related mortality and morbidity. Data from international and national registries have found that graft and patient survival rates after pancreas transplant alone have improved over time (eg, 3-year survival of 95%). The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have had a prior pancreas transplant who still meet criteria for a pancreas transplant who receive pancreas retransplantation, the evidence includes case series and registry studies. Relevant outcomes are overall survival, change in disease status, and treatment-related mortality and morbidity. National data and specific transplant center data have generally found similar graft and patient survival rates after pancreas retransplantation compared with initial transplantation. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

V. DEFINITIONS

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ABSOLUTE CONTRAINDICATION is a reason for not performing a particular therapeutic intervention which is so compelling or carries such a grave risk that its performance would be reasonably regarded as constituting malpractice.

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BLUE DISTINCTION CENTERS FOR TRANSPLANT (BDCT) is a cooperative effort of the Blue Cross and Blue Shield Plans, the Blue Cross and Blue Shield Association and participating medical institutions to provide patients who need transplants with access to leading centers through a coordinated, streamlined program of transplant management.

CADAVER refers to a dead body or corpse.

END-STAGE RENAL DISEASE (ESRD) is a point at which the kidney is so badly damaged or scarred that hemodialysis or transplantation is required for patient survival.

IMMUNOSUPPRESSIVE refers to any treatment used to block abnormal or excessive immune responses.

INSULIN is a hormone secreted by the beta cells of the pancreas that controls the metabolism and cellular uptake of sugars, proteins and fat.

RELATIVE CONTRAINDICATION- A relative contraindication is a condition which makes a particular treatment or procedure somewhat inadvisable but does not rule it out.

UREMIC pertains to a toxic level of urea (nitrogenous waste) in the blood.

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital BlueCross. Members and providers should consult the member's health benefit plan for information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

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Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a

provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital BlueCross' Provider Services or Member Services. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

CPT Codes®								
48550	48551	48552	48554	48556	50300	50320	50323	50325
50327	50328	50329	50340	50360	50365	50380	50547	

HCPCS Codes	Description
S2065	Simultaneous pancreas kidney transplantation
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-CM Diagnosis Codes	Description
B20	Human immunodeficiency virus [HIV] disease
E10.10	Type 1 diabetes mellitus with ketoacidosis without coma
E10.11	Type 1 diabetes mellitus with ketoacidosis with coma
E10.21	Type 1 diabetes mellitus with diabetic nephropathy
E10.22	Type 1 diabetes mellitus with diabetic chronic kidney disease
E10.29	Type 1 diabetes mellitus with other diabetic kidney complication
E10.641	Type 1 diabetes mellitus with hypoglycemia with coma
E10.649	Type 1 diabetes mellitus with hypoglycemia without coma
E10.65	Type 1 diabetes mellitus with hyperglycemia
E10.69	Type 1 diabetes mellitus with other specified complication
E10.8	Type 1 diabetes mellitus with unspecified complications

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ICD-10-CM Diagnosis Codes	Description
N18.6	End stage renal disease
T86.11	Kidney transplant rejection
T86.12	Kidney Transplant failure
T86.890	Other transplanted tissue rejection
T86.891	Other transplanted tissue failure
T86.898	Other complications of other transplanted tissue
Z79.4	Long term (current) use of insulin
Z90.5	Acquired absence of kidney
Z94.0	Kidney transplant status
Z94.8	Other transplanted organ and tissue status
Z98.85	Transplanted organ removal status

IX. REFERENCES

TOP

Kidney Transplant

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X. POLICY HISTORY

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MP 9.055	**CAC 7/27/04**
	CAC 8/30/05
	CAC 9/27/05
	CAC 7/25/06
	CAC 7/31/07
	CAC 5/27/08
	CAC 5/26/09
	CAC 5/25/10 Consensus.
	CAC 4/26/11 Consensus.
	CAC 11/22/11 Minor revision. A list of absolute contraindications for kidney transplantation considered not medically necessary added to the policy. A list of not medically necessary indications and relative contraindications were added to pancreas transplant criteria.
	04/08/2013 Administrative update. Codes reviewed
	7/18/13 Administrative update. Code review complete
	CAC 11/26/13 Minor revision. BCBSA policy adopted. Policy wording revised to state that kidney transplants with either a living or cadaver donor may be considered medically necessary for carefully selected candidates with end-stage renal disease. Kidney retransplant after a failed primary transplant was added as a new medically necessary indication. For allogeneic pancreas transplant, not medically necessary statements were removed. Policy guidelines and rationale were added. FEP variation revised. Policy coded.
	CAC 11/25 /14 Consensus review. No change to policy statements. References and rationale updated. For kidney transplants a statement was added that kidney transplant is considered investigational in all other situations. Coding reviewed 11/06/2014
	CAC 11/24/15 Consensus review. A statement was added that pancreas transplant in all other indications is considered investigational. Reference and rationale update**.** Coding updated.
	CAC 9/27/16 Consensus review. Clarification added to the Kidney and Pancreas retransplant policy statements to clarify when these retransplantations are medically necessary. No impacts to the intent of the policy statements. Product Variation, Description/Background, Rationale and

POLICY TITLE	KIDNEY TRANSPLANTS, PANCREAS TRANSPLANTS, AND SIMULTANEOUS KIDNEY/PANCREAS TRANSPLANTS
POLICY NUMBER	MP- 9.005

	Reference sections updated. Coding reviewed. New diagnosis codes added effective 10/1/16. Variation reformatting completed.
	CAC 12/19/17 Consensus review. No change to policy statements. References and rationale updated. Coding Reviewed.
	3/8/18 Coding review. Diagnosis codes updated.
	11/2/18 Consensus review. No changes to the policy statements. Guidelines, background and references updated. Rationale revised.
	08/21/2019 Consensus review. No change to policy statements. References and rationale reviewed.
	8/24/2020: Consensus Review. Policy Statement unchanged. FEP and Product Variation Statements updated. References reviewed, updated. Coding reviewed, no changes.

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