MEDICAL POLICY

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

CLINICAL BENEFIT	☐ MINIMIZE SAFETY RISK OR CONCERN. ☐ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☒ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	**12/1/2024**

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 individuals who meet criteria for kidney transplantation**.**

Kidney transplant is considered **investigational** for all other situations. There is insufficient evidence to support a general 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

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 individuals. 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 individuals with uremia.

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

Pancreas transplant alone may be considered **medically necessary** in individuals 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 individuals who meet criteria for pancreas transplantation**.**

Pancreas transplant is considered **investigational** in all other situations. There is insufficient evidence to support a general 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 individuals 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 ≤32 kg/m^2). In 2018, individuals with type 2 diabetes accounted for 14.8% of all pancreas transplants, according to data from the Organ Procurement and Transplantation Network and the Scientific Registry of Transplant Recipients.

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 Blue Cross. Please see additional information below, and subject to benefit variations as discussed in Section VI below.

FEP PPO- Refer to FEP Medical Policy Manual. 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

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KIDNEY TRANSPLANT

Solid organ transplantation offers a treatment option for patients with different types of end-stage organ failure that can be lifesaving or provide significant improvements to a patient's quality of life. Many advances have been made in the last several decades to reduce perioperative complications. Available data supports improvement in long-term survival as well as improved quality of life particularly for liver, kidney, pancreas, heart, and lung transplants.

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Allograft rejection remains a key early and late complication risk for any organ transplantation. Transplant recipients require life-long immunosuppression to prevent rejection. Patients are prioritized for transplant by mortality risk and severity of illness criteria developed by Organ Procurement and Transplantation Network (OPTN) and United Network of Organ Sharing (UNOS).

Kidney Transplant

In 2022, 42,889 transplants were performed in the United States procured from almost 36,421 deceased donors and 6,468 living donors. Kidney transplants were the most common procedure with 25,000 transplants performed from both deceased and living donors in 2022. Since 1988, the cumulative number of kidney transplants is 553,905. Of the cumulative total, 67% of the kidneys came from deceased donors and 33% from living donors.

Kidney transplant, using kidneys from deceased or living donors, is an accepted treatment of end-stage renal disease (ESRD). 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 chronic kidney disease stage 5 and is defined as a glomerular filtration rate (GFR) less than 15 mL/min/1.73 m2. Patients with advanced chronic kidney disease, mainly stage 4 (GFR 15 to 29 mL/min/1.73 m2) and stage 5 (GFR <15 mL/min/1.73 m2), should be evaluated for transplant. Being on dialysis is not a requirement to be considered for kidney transplant. Severe non-compliance and substance abuse serve as contraindications to kidney transplantation but even those could be overcome with clinician support and patient motivation. All kidney transplant candidates receive organ allocation points based on waiting time, age, donor-recipient immune system compatibility, prior living donor status, distance from donor hospital, and survival benefit.

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

Solid organ transplants are a surgical procedure and, as such, are not subject to regulation by the U.S. Food and Drug Administration (FDA).

The FDA 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. Solid organs used for transplantation are subject to these regulations.

ALLOGENEIC PANCREAS TRANSPLANT

Solid organ transplantation offers a treatment option for patients with different types of end-stage organ failure that can be lifesaving or provide significant improvements to a patient's quality of life. Many advances have been made in the last several decades to reduce perioperative complications. Available data supports improvement in long-term survival as well

as improved quality of life particularly for liver, kidney, pancreas, heart, and lung transplants. Allograft rejection remains a key early and late complication risk for any organ transplantation. Transplant recipients require life-long immunosuppression to prevent rejection. Patients are prioritized for transplant by mortality risk and severity of illness criteria developed by Organ Procurement and Transplantation Network and United Network of Organ Sharing.

Allogeneic Pancreas Transplant

In 2022, 42,889 transplants were performed in the United States procured from more than 36,400 deceased donors and 6,400 living donors. Pancreas-kidney transplants were the fifth most common procedure, with 810 transplants performed in 2019. Pancreas-alone transplants were the sixth most common procedure, with 108 transplants performed in 2022.

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 transplant ; (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 pancreas transplant alone.

Data from the United Network for Organ Sharing and the International Pancreas Transplant Registry indicate that the proportion of simultaneous pancreas plus kidney transplant recipients worldwide who have type 2 diabetes has increased over time, from 6% of transplants between 2005 and 2009 to 9% of transplants between 2010 and 2014. Between 2010 and 2014, approximately 4% of pancreas after kidney transplants and 4% of pancreas alone transplants were performed in patients with type 2 diabetes. In 2019, patients with type 2 diabetes accounted for 20.6% of all pancreas transplants, according to data from the Organ Procurement and Transplantation Network and the Scientific Registry of Transplant Recipients. Patients with type 2 diabetes accounted for 6.2%, 1%, and 22.4% of pancreas alone, pancreas after kidney, and simultaneous pancreas plus kidney transplants, respectively.

Regulatory Status

Solid organ transplants are a surgical procedure and, as such, are not subject to regulation by the U.S. Food and Drug Administration (FDA).

The FDA 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. Solid organs used for transplantation are subject to 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 retrospective studies and registry studies. Relevant outcomes are overall survival (OS), 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 94.5%). Single-center retrospective studies have found similar patient survival and death-censored pancreas graft survival rates with a pancreas transplant after a kidney transplant or a simultaneous pancreas and kidney (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 retrospective studies and registry studies. Relevant outcomes are OS, 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 versus 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 OS, 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 94.9%). 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 retrospective studies and registry studies. Relevant outcomes are OS, 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.

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 Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

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Capital Blue Cross' 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 Blue Cross' Provider Services or Member Services. Capital Blue Cross 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:

Procedure Codes								
S2065	S2152	48550	48551	48552	48554	48556	50300	50320
50323	50325	50327	50328	50329	50340	50360	50365	50380
50547								

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

ICD-10-CM Diagnosis Codes	Description
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
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

TOP

MP 9.005	**08/24/2020 Consensus Review.** Policy Statement unchanged. FEP and Product Variation Statements updated. References reviewed, updated. Coding reviewed, no changes.
	07/12/2021 Consensus Review. No change to policy statement. Coding reviewed. Background, rationale, and References updated.
	12/14/2022 Consensus Review. No change to policy statement. FEP, background, references updated. No coding changes.
	09/12/2023 Consensus Review. No change to policy statement. Background updated. References reviewed and updated. Coding reviewed, no changes.
	01/19/2024 Administrative Update. Clinical benefit added.
	07/25/2024 Consensus Review. No change to policy statements. References reviewed and updated. Coding reviewed with no coding changes.

Top