BLUE CROSS OF NORTHEASTERN PA "BCNEPA" MEDICAL POLICY BULLETIN	**MANUAL:** MEDICAL POLICY
	REFERENCE NO.: MPO-490-0001
EFFECTIVE DATE October 1, 2014	**SUBJECT:** Transplant

Blue Cross of Northeastern Pennsylvania ("BCNEPA") Medical Policy

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical policy and claims payment policy are applied. Policies are provided for informational purposes only and are developed to assist in administering plan benefits and do not constitute medical advice. Treating providers are solely responsible for medical advice and treatment. Policies are based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and information are constantly changing and BCNEPA may review and revise its medical policies periodically. Also, due to the rapid pace of changing technology and the advent of new medical procedures, BCNEPA may not have a policy to address every procedure. In those cases, BCNEPA may review other sources of information including, but not limited to, current medical literature and other medical resources, such as Technology Evaluation Center Assessments (TEC) published by the Blue Cross Blue Shield Association. BCNEPA may also consult with health care providers possessing particular expertise in the services at issue.

I. DESCRIPTION:

Transplantation is a process by which the organ and tissue are excised from a live or cadaveric donor, then implanted to a recipient patient. The transfer of human organ and tissue from one person to another (allograft) or from one site to another in the same individual (autograft). Transplants are intended to prolong survival and improve the function of patients with severe diseases or irreversible organ damage.

II. BENEFIT POLICY STATEMENT:

BCNEPA makes decisions on coverage based on Policy Bulletins, benefit plan documents, and the member's medical history and condition. Benefits may vary based on product line, group or contract, therefore, Member benefits must be verified. In the event of a conflict between the Member's benefit plan document and topics addressed in Medical Policy Bulletins (i.e., specific contract exclusions), the Member's benefit plan document always supersedes the information in the Medical Policy Bulletins. BCNEPA determines medical necessity only if the benefit exists and no contract exclusions are applicable.

Benefits are determined by the terms of the Member's specific benefit plan document [i.e., the Fully Insured policy, the Administrative Services Only (ASO) agreement applicable to the Self-Funded Plan Participant, or the Individual Policy] that is in effect at the time services are rendered.

III. MEDICAL POLICY STATEMENT:

Coverage is subject to the terms, conditions, and limitations of the member's contract.

Allogeneic Pancreas Transplant

A. BCNEPA will provide coverage for pancreas transplant when medically necessary.

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

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

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

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

5. The following guidelines apply:

   General -

   Potential contraindications subject to the judgment of the transplant center:

   a) Known current malignancy, including metastatic cancer

   b) Recent malignancy with high risk of recurrence

   c) Untreated systemic infection making immunosuppression unsafe, including chronic infection

   d) Other irreversible end-stage disease not attributed to kidney disease

   e) History of cancer with a moderate risk of recurrence

   f) Systemic disease that could be exacerbated by immunosuppression

   g) Psychosocial conditions or chemical dependency affecting ability to adhere to therapy

Pancreas Specific -

Candidates for pancreas transplant alone should additionally meet 1 of the following severity of illness criteria:

a) Documentation of severe hypoglycemia unawareness as evidenced by chart notes or emergency room visits; OR

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

In addition, the vast majority of 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 32 or less).

Multiple Transplants -

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

a) If there is early graft loss resulting from technical factors (e.g., venous thrombosis), a retransplant may generally be performed without substantial additional risk.

b) 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.

Corneal Transplant

B. BCNEPA will provide coverage for corneal transplant (keratoplasty) when medically necessary.

1. Corneal transplant may be considered medically necessary for the following indications:

a) Pseudophakic corneal edema

b) Aphakic corneal edema

c) Stromal corneal dystrophies

d) Primary corneal endotheliopathies

e) Ectasias/thinnings

f) Congenital opacities

g) Viral/post-viral keratitis

h) Microbial/post-microbial keratitis

i) Noninfectious ulcerative keratitis or perforation

j) Corneal degenerations

k) Chemical injuries

l) Mechanical trauma, non-surgical

m) Regraft related to allograft rejection

n) Regraft unrelated to allograft rejection

o) Other causes of corneal opacification/distortion

p) Mechanical complication of corneal graft

q) Complications of transplanted organ

2. Endothelial keratoplasty (Descemet's stripping endothelial keratoplasty or Descemet's stripping automated endothelial keratoplasty) may be considered medically necessary for the treatment of endothelial dysfunction, including but not limited to Fuch's endothelial dystrophy, aphakic, and pseudophakic bullous keratopathy, and failure or rejection of a previous corneal transplant.

3. Corneal transplant for indications other than those listed above are considered not medically necessary.

Embryonic Mesencephalic Transplantation for the Treatment of Parkinson's Disease

C. BCNEPA will not provide coverage for Fetal mesencephalic transplantation for the treatment of Parkinson's Disease as it is considered investigational.

Heart Transplant

D. BCNEPA will provide coverage for human heart transplantation when medically necessary.

1. Human heart transplantation may be considered medically necessary for selected adults and children with end-stage heart failure when patient selection criteria are met.

Adult Patients

a) Accepted Indications for Transplantation

(1) Hemodynamic compromise due to heart failure demonstrated by any of the following 3 bulleted items, or

- Maximal V02 (oxygen consumption) <10 ml/kg/min with achievement of anaerobic metabolism
- Refractory cardiogenic shock
- Documented dependence on intravenous inotropic support to maintain adequate organ perfusion

(2) Severe ischemia consistently limiting routine activity not amenable to bypass surgery or angioplasty; or

(3) Recurrent symptomatic ventricular arrhythmias refractory to ALL accepted therapeutic modalities.

b) Probable Indications for Cardiac Transplantation

(1) Maximal VO2 <14 ml/kg/min and major limitation of the patient's activities; or

(2) Recurrent unstable ischemia not amenable to bypass surgery or angioplasty; or

(3) Instability of fluid balance/renal function not due to patient noncompliance with regimen of weight monitoring, flexible use of diuretic drugs, and salt restriction.

c) The following conditions are inadequate indications for transplantation unless other factors as listed above are present.

(1) Ejection fraction <20%;

(2) History of functional class III or IV symptoms of heart failure;

(3) Previous ventricular arrhythmias;

(4) Maximal VO2 >15 ml/kg/min.

Pediatric Patients

a) Patients with heart failure with persistent symptoms at rest who require one or more of the following:

(1) Continuous infusion of intravenous inotropic agents; or

(2) Mechanical ventilatory support; or

(3) Mechanical circulatory support.

b) Patients with pediatric heart disease with symptoms of heart failure who do not meet the above criteria but who have:

(1) Severe limitation of exercise and activity (if measurable, such patients would have a peak maximum oxygen consumption <50% predicted for age and sex); or

(2) Cardiomyopathies or previously repaired or palliated congenital heart disease and significant growth failure attributable to the heart disease; or

(3) Near sudden death and/or life-threatening arrhythmias untreatable with medications or an implantable defibrillator; or

(4) Restrictive cardiomyopathy with reactive pulmonary hypertension; or

(5) Reactive pulmonary hypertension and potential risk of developing fixed, irreversible elevation of pulmonary vascular resistance that could preclude orthotopic heart transplantation in the future; or

(6) Anatomical and physiological conditions likely to worsen the natural history of congenital heart disease in infants with a functional single ventricle; or

(7) Anatomical and physiological conditions that may lead to consideration for heart transplantation without systemic ventricular dysfunction.

2. Heart retransplantation after a failed primary heart transplant may be considered medically necessary in patients who meet criteria for heart transplantation.

3. Heart transplantation is considered investigational in all other situations.

4. Potential contraindications subject to the judgment of the transplant center:

a) Known malignancy, including metastatic cancer;

b) Recent malignancy with high risk of recurrence;

c) Untreated systemic infection making immunosuppression unsafe, including chronic infection;

d) Other irreversible end-stage disease not attributed to heart disease;

e) History of cancer with a moderate risk of recurrence;

f) Systemic disease that could be exacerbated by immunosuppression; or

g) Psychosocial conditions or chemical dependency affecting ability to adhere to therapy.

Policy Specific -

a) Pulmonary hypertension that is fixed as evidenced by pulmonary vascular resistance (PVR) greater than 5 Woods units, or trans-pulmonary gradient (TPG) greater than or equal to 16mm/Hg*;

b) Severe pulmonary disease despite optimal medical therapy, not expected to improve with heart transplantation*;

*Some patients may be candidates for combined heart-lung transplantation.

3. The following guidelines apply:

General -

Patients must meet UNOS guidelines for 1A, 1B, or 2 Status and not currently be Status 7.

Cardiac Specific -

The United Network for Organ Sharing (UNOS) prioritizes donor thoracic organs according to the severity of illness, with those patients who are most severely ill (status 1A) given highest priority in allocation of the available organ as follows:

Adult Patients (18 years of age or older)

Status 1A

A patient is admitted to the listing transplant center hospital and has at least one of the following devices or therapies in place:

a) Mechanical circulatory support for acute hemodynamic decompensation that includes at least one of the following:

- Left and/or right ventricular assist device implanted
- Total artificial heart
- Intra-aortic balloon pump; or
- Extracorporeal membrane oxygenator (ECMO)

b) Mechanical circulatory support

c) Mechanical ventilation

d) Continuous infusion of inotropes and continuous monitoring of left ventricular filling pressures

e) If criteria a, b, c, and d are not met, such status can be obtained by application to the applicable Regional Review Board.

Status 1B

A patient has at least one of the following devices or therapies in place:

a) Left and/or right ventricular device implanted, or

b) Continuous infusion of intravenous inotropes.

A patient that does not meet Status 1A or 1B is listed as Status 2.

Pediatric Patients

A candidate listed as Status 1A meets at least one of the following criteria:

a) Requires assistance with a ventilator;

b) Requires assistance with a mechanical assist device (e.g., ECMO);

c) Requires assistance with a balloon pump;

d) A candidate younger than 6 months old with congenital or acquired heart disease exhibiting reactive pulmonary hypertension at greater than 50% of systemic level. Such a candidate may be treated with prostaglandin E (PGE) to maintain patency of the ductus arteriosus;

e) Requires infusion of high dose (e.g., dobutamine >7.5 mcg/kg/min or milrinone >0.5 mcg/kg/min) or multiple inotropes (e.g., addition of dopamine at >5.0 mcg/kg/min); or

A candidate who does not meet the criteria specified in a, b, c, d, or e may be listed as Status 1A if the candidate has a life expectancy without a heart transplant of less than 14 days, such as due to refractory arrhythmia.

A candidate listed as Status 1B meets at least one of the following criteria:

a) Requires infusion of low dose single inotropes (e.g., dobutamine or dopamine $\leq$ 7.5 mcg/kg/min);

b) Younger than 6 months old and does not meet the criteria for Status 1A; or

c) Growth failure, i.e., greater than 5th percentile for weight and/or height, or loss of 1.5 standard deviations of expected growth (height or weight) based on the National Center for Health Statistics for pediatric growth curves.

A candidate who does not meet the criteria for Status 1A or 1B is listed as Status 2.

Note: Pediatric heart transplant candidates who remain on the waiting list at the time of their 18th birthday without receiving a transplant continue to qualify for medical urgency status based upon the pediatric criteria.

A candidate listed as Status 7 is considered temporarily unsuitable to receive a thoracic organ transplant.

Laboratory Tests for Heart Transplant Rejection

E. BCNEPA will not provide coverage for the following laboratory tests developed to assist in the detection of heart transplant rejection:

1. The measurement of volatile organic compounds with the Heartsbreath test to assist in the detection of grade 3 heart transplant rejection is considered investigational.

2. The use of peripheral blood genetic profiling tests in the management of patients after heart transplantation, including but not limited to the detection of acute heart transplant rejection or heart transplant graft dysfunction, is considered investigational.

Heart/Lung Transplant

F. BCNEPA will provide heart/lung transplantation when medically necessary.

1. Heart/lung transplantation may be considered medically necessary for carefully selected patients with end-stage cardiac and pulmonary disease including, but not limited to, one of the following diagnoses:

   a) Irreversible primary pulmonary hypertension with heart failure;

   b) Non-specific severe pulmonary fibrosis, with severe heart failure;

   c) Eisenmenger complex with irreversible pulmonary hypertension and heart failure;

   d) Cystic fibrosis with severe heart failure;

   e) Chronic obstructive pulmonary disease with heart failure;

   f) Emphysema with severe heart failure; and

   g) Pulmonary fibrosis with uncontrollable pulmonary hypertension or heart failure.

2. Potential contraindications subject to the judgment of the transplant center:

   a) Known current malignancy, including metastatic cancer;

   b) Recent malignancy with high risk of recurrence;

   c) Untreated systemic infection making immunosuppression unsafe, including chronic infection;

d) Other irreversible end-stage disease not attributed to heart or lung disease;

e) History of cancer with a moderate risk of recurrence;

f) Systemic disease that could be exacerbated by immunosuppression; or

g) Psychosocial or dependence conditions affecting ability to adhere to therapy.

3. The following guidelines apply:

General -

When the candidate is eligible to receive a heart in accordance with United Network for Organ Sharing (UNOS) guidelines for cardiac transplantation, the lung(s) shall be allocated to the heart-lung candidate from the same donor. When the candidate is eligible to receive a lung in accordance UNOS Lung Allocation System (LAS), the heart shall be allocated to the heart-lung candidate from the same donor if no suitable Status 1A isolated heart candidates are eligible to receive the heart. Status 1A is described below.

Cardiac Specific -

The United Network for Organ Sharing (UNOS) prioritizes donor thoracic organs according to the severity of illness as follows:

Status 1A

A patient is admitted to the listing transplant center hospital and has at least 1 of the following devices or therapies in place:

a) Mechanical circulatory support for acute hemodynamic decompensation that includes at least 1 of the following:

- Left and/or right ventricular assist device implanted
- Total artificial heart
- Intra-aortic balloon pump: or
- Extracorporeal membrane oxygenator (ECMO)

b) Mechanical circulatory support

c) Mechanical ventilation

d) Continuous infusion of inotropes and continuous monitoring of left ventricular filling pressures

e) If criteria a, b, c, and d are not met, such status can be obtained by application to the applicable Regional Review Board.

Status 1B

A patient has at least one of the following devices or therapies in place:

a) Left and/or right ventricular device implanted, or

b) Continuous infusion of intravenous inotropes.

A patient that does not meet Status 1A or 1B is listed as Status 2.

Status 7 patients are considered temporarily unsuitable to receive a thoracic organ transplant.

4. Heart/lung retransplantation after a failed primary heart/lung transplant may be considered medically necessary in patients who meet criteria for heart/lung transplantation.

5. Heart/lung transplantation is considered investigational in all other situations.

Islet Transplantation

G. BCNEPA will provide coverage for islet transplantation when medically necessary.

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

2. Allogeneic islet transplantation is considered investigational for the treatment of type 1 diabetes.

Isolated Small Bowel Transplant

H. BCNEPA will provide coverage for small bowel transplant when medically necessary.

1. A small bowel transplant using cadaveric intestine may be considered medically necessary in adult and pediatric patients with intestinal failure (characterized by loss of absorption and the inability to maintain protein-energy, fluid, electrolyte, or micronutrient balance), who have established long-term dependency on total parenteral nutrition (TPN) and are developing or have developed severe complications due to TPN.

2. A small bowel transplant using a living donor may be considered medically necessary only when a cadaveric intestine is not available for transplantation in a patient who meets the criteria noted above for a cadaveric intestinal transplant.

3. A small bowel retransplant may be considered medically necessary after a failed primary small bowel transplant.

4. A small bowel transplant using living donors is considered not medically necessary in all other situations.

5. A small bowel transplant is considered investigational for adults with intestinal failure who are able to tolerate TPN.

6. Candidates should meet the following criteria:

   a) Adequate cardiopulmonary status;

   b) Absence of active infection;

   c) No history of malignancy within 5 years of transplantation, excluding nonmelanomatous skin cancers;

   d) Documentation of patient compliance with medical management.

Kidney Transplant

I. BCNEPA will provide coverage for kidney transplants when medically necessary.

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

   a) Etiologies of end-stage renal disease include, but are not limited to, any of the following conditions associated with end-stage renal disease:

   - Obstructive uropathy
   - Systemic lupus erythematosus
   - Polyarteritis
   - Wegener's granulomatosis
   - Cortical necrosis
   - Henoch-Schönlein purpura
   - Hemolytic uremic syndrome
   - Acute tubular necrosis
   - Hypertensive nephrosclerosis
   - Renal artery or vein occlusion
   - Chronic pyelonephritis
   - IGA nephropathy
   - Anti-glomerular base-membrane disease
   - Focal glomerulosclerosis
   - Analgesic nephropathy with medullary necrosis
   - Heavy metal poisoning
   - Glomerulonephritis
   - Polycystic kidney disease
   - Medullary cystic disease
   - Nephritis
   - Nephrocalcinosis
   - Gout nephritis
   - Amyloid disease

- Fabry's disease
- Cystinosis
- Oxalosis
- Diabetes mellitus
- Horseshoe kidney
- Renal aplasia or hypoplasia
- Wilms' tumor
- Renal-cell carcinoma
- Myeloma in remission
- Tuberous sclerosis
- Trauma requiring nephrectomy, injury to kidney

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

   a) Known current malignancy, including metastatic cancer

   b) Recent malignancy with high risk of recurrence

   c) History of cancer with a moderate risk of recurrence

   d) Systemic disease that could be exacerbated by immunosuppression

   e) Untreated systemic infection making immunosuppression unsafe, including chronic infection

   f) Other irreversible end-stage disease not attributed to kidney disease

   g) Psychosocial conditions or chemical dependency affecting ability to adhere to therapy

3. HIV-positive patients who meet the following criteria, as stated in the 2001 guidelines of the American Society of Transplantation, could be considered candidates for kidney transplantation:

   a) CD4 count >200 cells per cubic millimeter for >6 months

   b) HIV-1 RNA undetectable

   c) On stable anti-retroviral therapy >3 months

   d) No other complications from AIDS (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidiosis mycosis, resistant fungal infections, Kaposi's sarcoma, or other neoplasm); and

   e) Meeting all other criteria for transplantation.

4. 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.

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

6. Kidney transplant is considered not medically necessary in all other situations not meeting above criteria.

Liver Transplant

J. BCNEPA will provide coverage for a liver transplant when medically necessary.

1. A liver transplant, using a cadaver or living donor, is medically necessary for carefully selected patients with end-stage liver failure due to irreversibly damaged livers.

2. Etiologies of end-stage liver disease include, but are not limited to, the following:

a) Hepatocellular diseases

- Alcoholic cirrhosis
- Viral hepatitis (either A, B, C, or non-A, non-B)
- Autoimmune hepatitis
- Alpha-1 antitrypsin deficiency
- Hemochromatosis
- Non-alcoholic steatohepatitis
- Protoporphyria
- Wilson's disease

b) Cholestatic liver diseases

- Primary biliary cirrhosis
- Primary sclerosing cholangitis with development of secondary biliary cirrhosis
- Biliary atresia

c) Vascular disease

- Budd-Chiari syndrome

d) Primary hepatocellular carcinoma

e) Inborn errors of metabolism

f) Trauma and toxic reactions

g) Miscellaneous

- Familial amyloid polyneuropathy

3. Liver transplantation may be considered medically necessary in patients with polycystic disease of the liver who have massive hepatomegaly causing obstruction or functional impairment.

4. Liver transplantation may be considered medically necessary in patients with unresectable hilar cholangiocarcinoma.

5. Liver transplantation may be considered medically necessary in pediatric patients with non-metastatic hepatoblastoma.

6. Liver *retransplantation* may be considered medically necessary in patients with:

   a) primary graft non-function

   b) hepatic artery thrombosis

   c) chronic rejection

   d) ischemic type biliary lesions after donation after cardiac death

   e) recurrent non-neoplastic disease causing late graft failure

7. Liver transplantation is considered investigational in the following patients:

   a) Patients with intrahepatic cholangiocarcinoma

   b) Patients with neuroendocrine tumors metastatic to the liver

8. Liver transplantation is considered not medically necessary in the following patients:

   a) Patients with hepatocellular carcinoma that has extended beyond the liver

   b) Patients with ongoing alcohol and/or drug abuse. (Evidence for abstinence may vary among liver transplant programs, but generally a minimum of 3 months is required.)

9. Liver transplantation is considered investigational in all other situations not described above.

10. The following guidelines apply:

    General -

    Candidates for all liver transplants should meet the following criteria:

    - Adequate cardiopulmonary status;
    - Absence of active infection;

- No history of malignancy within 5 years of transplantation, excluding nonmelanomatous skin cancers;

- Documentation of patient compliance with medical management.

Liver Specific -

The MELD and PELD scores range from 6 (less ill) to 40 (gravely ill). The MELD and PELD scores will change during the course of a patient's tenure on the waiting list.

Patients with liver disease related to alcohol or drug abuse must be actively involved in a treatment program.

Patients with polycystic disease of the liver do not develop liver failure but may require transplantation due to the anatomic complications of a hugely enlarged liver. The MELD/PELD score may not apply to these cases. One of the following complications should be present:

- Enlargement of liver impinging on respiratory function
- Extremely painful enlargement of liver
- Enlargement of liver significantly compressing and interfering with function of other abdominal organs

Patients with familial amyloid polyneuropathy do not experience liver disease, per se, but develop polyneuropathy and cardiac amyloidosis due to the production of a variant transthyretin molecule by the liver. The MELD/PELD score may apply to these cases. Candidacy for liver transplant is an individual consideration based on the morbidity of the polyneuropathy. Many patients may not be candidates for liver transplant alone due to coexisting cardiac disease. Patients with hepatocellular carcinoma are appropriate candidates for liver transplant only if the disease remains confined to the liver. Therefore, the patient should be periodically monitored while on the waiting list, and if metastatic disease develops, the patient should be removed from the transplant waiting list. In addition, at the time of transplant a backup candidate should be scheduled. If locally extensive or metastatic cancer is discovered at the time of exploration prior to hepatectomy, the transplant should be aborted, and the backup candidate scheduled for transplant.

Donor Criteria – Living-Donor Liver Transplant

Donor morbidity and mortality are prime concerns in donors undergoing right lobe, left lobe, or left lateral segment donor partial hepatectomy as part of a living-donor liver transplantation. Partial hepatectomy is a technically demanding surgery, the success of which may be related to the availability of an experienced surgical team. In 2000, the American Society of Transplant Surgeons proposed the following guidelines for living donors:

- Should be healthy individuals who are carefully evaluated and approved by a multidisciplinary team including hepatologists and surgeons to assure that they can tolerate the procedure

- Should undergo evaluation to assure that they fully understand the procedure and associated risks
- Should be of legal age and have sufficient intellectual ability to understand the procedures and give informed consent
- Should be emotionally related to the recipients
- Must be excluded if the donor is felt or known to be coerced
- Needs to have the ability and willingness to comply with long-term follow-up.

Cholangiocarcinoma -

According to the OPTN policy on liver allocation, candidates with cholangiocarcinoma (CCA) meeting the following criteria will be eligible for a MELD/PELD exception with a 10% mortality equivalent increase every three months:

- Centers must submit a written protocol for patient care to the OPTN/UNOS Liver and Intestinal Organ Transplantation Committee before requesting a MELD score exception for a candidate with CCA. This protocol should include selection criteria, administration of neoadjuvant therapy before transplantation, and operative staging to exclude patients with regional hepatic lymph node metastases, intrahepatic metastases, and/or extrahepatic disease. The protocol should include data collection as deemed necessary by the OPTN/UNOS Liver and Intestinal Organ Transplantation Committee.
- Candidates must satisfy diagnostic criteria for hilar CCA: malignant-appearing stricture on cholangiography and one of the following: carbohydrate antigen 19-9 100 U/mL, or and biopsy or cytology results demonstrating malignancy, or aneuploidy. The tumor should be considered unresectable on the basis of technical considerations or underlying liver disease (e.g., primary sclerosing cholangitis).
- If cross-sectional imaging studies (CT scan, ultrasound, MRI) demonstrate a mass, the mass should be 3 cm or less.
- Intra- and extrahepatic metastases should be excluded by cross-sectional imaging studies of the chest and abdomen at the time of initial exception and every 3 months before score increases.
- Regional hepatic lymph node involvement and peritoneal metastases should be assessed by operative staging after completion of neoadjuvant therapy and before liver transplantation. Endoscopic ultrasound-guided aspiration of regional hepatic lymph nodes may be advisable to exclude patients with obvious metastases before neoadjuvant therapy is initiated.
- Transperitoneal aspiration or biopsy of the primary tumor (either by endoscopic ultrasound, operative, or percutaneous approaches) should be avoided because of the high risk of tumor seeding associated with these procedures.

Lung and Lobar Lung Transplant

K. BCNEPA will provide coverage for lung or lobar lung transplantation when medically necessary.

1. Lung transplantation may be considered medically necessary for carefully selected patients with irreversible, progressively disabling, end-stage pulmonary disease including but not limited to one of the conditions listed below.

2. A lobar lung transplant from a living or cadaver donor may be considered medically necessary for children and adolescents with end-stage pulmonary disease including but not limited to one of the conditions listed below.

3. End-stage pulmonary diseases for which lung/lobar lung transplants may be considered medically necessary include but are not limited to one of the conditions below:

a) Bilateral bronchiectasis;

b) Alpha-1 antitrypsin deficiency;

c) Primary pulmonary hypertension;

d) Cystic fibrosis (both lungs to be transplanted);

e) Bronchopulmonary dysplasia;

f) Post inflammatory pulmonary fibrosis;

g) Idiopathic/interstitial pulmonary fibrosis;

h) Sarcoidosis;

i) Scleroderma;

j) Lymphangiomyomatosis;

k) Emphysema;

l) Eosinophilic granuloma;

m) Bronchiolitis obliterans;

n) Recurrent pulmonary embolism;

o) Pulmonary hypertension due to cardiac disease;

p) Chronic obstructive pulmonary disease; and

q) Eisenmenger's syndrome.

4. Lung or lobar lung retransplantation after a failed lung or lobar lung transplant may be considered medically necessary in patients who meet criteria for lung transplantation.

5. Lung or lobar lung transplantation is considered investigational in all other situations.

6. The following guidelines apply:

   General - Potential contraindications subject to the judgment of the transplant center:

   a) Known current malignancy, including metastatic cancer

   b) Recent malignancy with high risk of recurrence

   c) Untreated systemic infection making immunosuppression unsafe, including chronic infection

   d) Other irreversible end-stage disease not attributed to lung disease

   e) History of cancer with a moderate risk of recurrence

   f) Systemic disease that could be exacerbated by immunosuppression

   g) Psychosocial conditions or chemical dependency affecting ability to adhere to therapy

   Policy-specific -

   a) Coronary artery disease (CAD) not amenable to percutaneous intervention or bypass grafting, or associated with significant impairment of left ventricular function*; or

   b) Colonization with highly resistant or highly virulent bacteria, fungi, or mycobacteria.

   Patients must meet UNOS guidelines for lung allocation score (LAS) greater than zero.

   Lung Specific -

   Bilateral lung transplantation is typically required when chronic lung infection disease is present, i.e., associated with cystic fibrosis and bronchiectasis. Some, but not all, cases of pulmonary hypertension will require bilateral lung transplantation.

   Bronchiolitis obliterans is associated with chronic lung transplant rejection, and thus may be the etiology of a request for lung retransplantation.

   *Some patients may be candidates for combined heart-lung transplantation.

Small Bowel/Liver and Multivisceral Transplant

L. BCNEPA will provide coverage for small bowel/liver or multivisceral transplant when medically necessary.

1. A small bowel/liver transplant or multivisceral transplant may be considered medically necessary for pediatric and adult patients with intestinal failure (characterized by loss of absorption and the inability to maintain protein-energy, fluid, electrolyte, or micronutrient balance) who have been managed with long-term total parental nutrition (TPN) and who have developed evidence of impending end-stage liver failure.

2. A small bowel/liver transplant or multivisceral retransplant may be considered medically necessary after a failed primary small bowel/liver transplant or multivisceral transplant.

3. The following guidelines apply:

   General –

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

   a) Known current malignancy, including metastatic cancer

   b) Recent malignancy with high risk of recurrence

   c) History of cancer with a moderate risk of recurrence

   d) Systemic disease that could be exacerbated by immunosuppression

   e) Untreated systemic infection making immunosuppression unsafe, including chronic infection

   f) Other irreversible end stage disease not attributed to intestinal failure

   g) Psychosocial conditions or chemical dependency affecting ability to adhere to therapy

   Intestinal failure results from surgical resection, congenital defect, or disease-associated loss of absorption and is characterized by the inability to maintain protein-energy, fluid, electrolyte, or micronutrient balance. Short-bowel syndrome is one case of intestinal failure.

   Candidates should meet the following criteria:

   a) Adequate cardiopulmonary status;

   b) Documentation of patient compliance with medical management.

HIV-positive patients who meet the following criteria, as stated in the 2001 guidelines of the American Society of Transplantation, could be considered candidates for small bowel/liver or multivisceral transplantation:

a) CD4 count >200 cells per cubic millimeter for >6 months

b) HIV-1 RNA undetectable

c) On stable anti-retroviral therapy >3 months

d) No other complications from AIDS (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidiosis mycosis, resistant fungal infections, Kaposi's sarcoma, or other neoplasm), and meeting all other criteria for transplantation.

Small Bowel/Liver Specific -

Evidence of intolerance of total parenteral nutrition (TPN) includes, but is not limited to, multiple and prolonged hospitalizations to treat TPN-related complications, or the development of progressive but reversible liver failure. In the setting of progressive liver failure, small bowel transplant may be considered a technique to avoid end-stage liver failure related to chronic TPN, thus avoiding the necessity of a multivisceral transplant.

4. A small bowel/liver transplant or multivisceral transplant is considered not medically necessary in all other situations not meeting above criteria.

Total Artificial Hearts and Implantable Ventricular Assist Devices

M. BCNEPA will provide coverage for total artificial hearts and implantable ventricular assist devices when medically necessary.

Post-cardiotomy Setting/Bridge to Recovery

1. Implantable ventricular assist devices with FDA approval or clearance may be considered medically necessary in the post-cardiotomy setting in patients who are unable to be weaned off cardiopulmonary bypass.

Bridge to Transplantation

2. Implantable ventricular assist devices with FDA approval or clearance may be considered medically necessary as a bridge to heart transplantation for patients who are currently listed as heart transplantation candidates and not expected to survive until a donor heart can be obtained, or are undergoing evaluation to determine candidacy for heart transplantation.

3. Ventricular assist devices with FDA approval or clearance, including humanitarian device exemptions, may be considered medically necessary as a bridge to heart transplantation in children 16 years old or younger who are currently listed as heart transplantation candidates and not expected to survive until a donor heart can be obtained, or are undergoing evaluation to determine candidacy for heart transplantation.

4. Total artificial hearts with FDA-approved devices may be considered medically necessary as a bridge to heart transplantation for patients with biventricular failure who have no other reasonable medical or surgical treatment options, who are ineligible for other univentricular or biventricular support devices, and are currently listed as heart transplantation candidates or are undergoing evaluation to determine candidacy for heart transplantation, and not expected to survive until a donor heart can be obtained.

Destination Therapy

5. Implantable ventricular assist devices with FDA approval or clearance may be considered medically necessary as destination therapy with end-stage heart failure patients who are ineligible for human heart transplant and who meet the following "REMATCH Study" criteria:

   a) New York Heart Association (NYHA) class IV heart failure for ≥60 days, OR patients in NYHA class III/IV for 28 days, received ≥14 days' support with intra-aortic balloon pump or dependent on IV inotropic agents, with 2 failed weaning attempts

   b) In addition, patients must not be candidates for human heart transplant for 1 or more of the following reasons:

      - Age >65 years; OR
      - Insulin-dependent diabetes mellitus with end-organ damage; OR
      - Chronic renal failure (serum creatinine >2.5 mg/dL for ≥90 days; OR
      - Presence of other clinically significant condition

Other Indications

6. Other applications of implantable ventricular devices or total artificial hearts are considered investigational, including, but not limited to, the use of total artificial hearts as destination therapy. The use of non-FDA approved or cleared implantable ventricular assist devices or total artificial hearts is considered investigational.

7. Percutaneous ventricular assist devices (pVADs) (such as the TandemHeart™ and Impella® Recover LP 2.5 Percutaneous Cardiac Support System) are considered investigational for all indications.

IV. DEFINITIONS:

Chemosensitive Disease: Is defined as a tumor showing at least a 50% reduction in tumor burden in response to chemotherapy, typically measured by serial CT scans.

Kidney Transplant: Involves the surgical removal of a kidney from a living related donor or cadaver donor into a recipient.

Pancreas Transplant: Is the surgical removal of a segmental pancreas from a living donor or a whole pancreas from a deceased donor and the implantation of the pancreas into a recipient patient.

Pancreas/Kidney Transplant: Is the simultaneous surgical removal of a pancreas and kidney from the same cadaver, and the implantation of the pancreas and kidney into a recipient patient.

Pancreas/kidney transplants are performed on uremic diabetics who would otherwise undergo a kidney transplant alone.

Small Bowel Transplant: Involves the removal of the small intestine from a donor cadaver, removal of the patient's small intestine, and replacement with the donor's intestine.

Small Bowel/Liver Transplant: Involves the removal of the small intestine and liver from a cadaver, which are then placed in a recipient.

Multivisceral Transplant: Includes the small bowel and liver and can include the stomach duodenum, jejunum, ileum, pancreas or colon.

Liver Transplant: Consists of replacing an end-stage diseased liver with a healthy one. The liver is obtained from a brain-dead donor with artificially sustained cardiopulmonary function or a partial liver from a living related donor.

Lung Transplant: Refers to single-lung replacement. In a single lung transplant, only one lung from a cadaver donor is provided to the recipient. In the double-lung transplant, the recipient's lungs are removed and replaced by the donor's lungs.

Lobar Transplant: In a lobar transplant, a lobe of the donor's lung is excised, sized appropriately for the recipient's thoracic dimensions and is transplanted. Donors for lobar transplant have been primarily living related donors, with one lobe obtained from each of the two donors (e.g., mother and father) in cases where a bilateral transplant is required, there are also cases of cadaver lobe transplants.

Heart/Lung Transplant: Is intended to prolong survival and improve function in patients with end-stage cardiopulmonary or pulmonary disease.

A heart/lung transplant refers to the transplantation of one or both lungs and heart from a single cadaver donor.

In performing a heart transplant, the heart is surgically excised from the atria and main arteries of a human donor who has been pronounced dead. The recipient's heart is excised in a similar manner. The donor heart is transplanted, with anastomosis performed to connect the two pulmonary arteries, aorta, and the right atrial aperture to the vena cava.

Parkinson's Disease: A degenerative disease, which includes symptoms of resting tremor, rigidity, and bradykinesia. The condition usually appears after age 40 and progresses slowly over many years.

Fetal Mesencephalic Transplantation: In an effort to modify motor disability of advanced Parkinson's disease, embryonic mesencephalic tissue containing dopamine cells is implanted into the caudate and putamen of the candidate's brain.

LVAD: Left ventricular assist device.

NYHA: New York Heart Association.

V. CODING:

- **The identification of a code in this section does not denote coverage or separate reimbursement.**
- Covered procedure codes are dependent upon meeting criteria of the policy and appropriate diagnosis code.
- The following list of codes may not be all-inclusive, and are subject to change at any time.
- Benefits are determined by the terms of the Member's specific benefit plan document [i.e., the Fully Insured policy, the Administrative Services Only (ASO) agreement applicable to the Self-Funded Plan Participant, or the Individual Policy] that is in effect at the time services are rendered.

PROCEDURE CODES

0051T	33935	33983	44720	47147
0052T	33940	33990	44721	48146
0053T	33944	33991	47133	48160
0085T	33945	33992	47135	48550
32851	33975	33993	47136	48551
32852	33976	38232	47140	48552
32853	33977	44132	47141	48554
32854	33978	44133	47142	48556
32855	33979	44135	47143	50300
32856	33980	44136	47144	50320
33930	33981	44137	47145	50323
33933	33982	44715	47146	50325

50327	65755	Q0483	Q0495	Q0509
50328	65756	Q0484	Q0496	S2053
50329	65757	Q0485	Q0497	S2054
50340	G0341	Q0486	Q0498	S2055
50360	G0342	Q0487	Q0499	S2060
50365	G0343	Q0488	Q0500	S2061
50370	J7330	Q0489	Q0502	S2065
50380	Q0478	Q0490	Q0503	S2102
50547	Q0479	Q0491	Q0504	S2112
65710	Q0480	Q0492	Q0506	S2152
65730	Q0481	Q0493	Q0507	
65750	Q0482	Q0494	Q0508	

VI. SOURCES:

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Blue Cross and Blue Shield Association Medical Policy Reference manual, “Kidney Transplant” (7.03.01), Section: Surgery, Issue: 6: 2014: 1-15. “Allogeneic Pancreas Transplant”, (7.03.02), Section: Surgery, Issue: 2: 2014: 1-15. “Isolated Small Bowel Transplant”, (7.03.04), Section: Surgery, Issue: 5: 2014: 1-12. “Small Bowel/Liver and Multivisceral Transplant” (7.03.05), Section: Surgery, Issue: 6: 2014: 1-12. “Liver Transplant”, (7.03.06), Section: Surgery, Issue: 1: 2014: 1-36. “Lung and Lobar Lung Transplant”, (7.03.07), Section Surgery, Issue: 1: 2014: 1-16. “Heart/Lung Transplant” (7.03.08), Section: Surgery, Issue: 11: 2013: 1-12. “Heart Transplant” (7.03.09), Section: Surgery, Issue: 11: 2013: 1-21. “Embryonic Mesencephalic Transplantation for the Treatment of Parkinson’s Disease” (7.01.10), Section: Surgery, Issue: 4: 2005: 1-5. “Endothelial Keratoplasty” (9.03.22), Section: Other, Issue: 9: 2013: 1-13. “Islet Transplantation” (7.03.12), Section: Surgery, Issue: 5: 2014: 1-12. “Total Artificial Hearts Implantable Ventricular Assist Devices” (7.03.11), Section: Surgery, Issue: 2: 2013: 1-26. “Donor Leukocyte Infusion for Hematologic Malignancies That Relapse After Allogeneic Stem Cell Transplant” (2.03.03), Section: Medicine, Issue: 4: 2005: 1-4. “Laboratory Tests for Heart Transplant Rejection” (2.01.68), Section: Medicine, Issue: 4: 2014: 1-10.

BCBSA TEC Bulletin, Volume 17, No. 19, Left Ventricular Assist Devices as Destination Therapy for End-Stage Heart Failure, Issued: December, 2002: 1-13.

Highmark Medical Policy Bulletin, “Corneal Transplantation” (S-116), Effective Date: January 1, 2012. 1-3.

VII. APPROVALS:

Approved by Vice President, Clinical Operations & Chief Medical Officer:

Signature:_____
(Nina M. Taggart, MA, MD, MBA)

Date of Approval: September 17, 2014

HISTORY:

Medical Policy #PO-438-0030 was revised, placed into new format and assigned a new number (BMPO-428-0001).

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Policy developed by: Medical Policy Department