Medical Policy Reference Manual
Medical Policy

7.03.001 Human Organ Transplants

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Description

Human organ transplants include the following: Heart, Heart/Lung, Lung/Lobar Lung, Combined Pancreas/Kidney, Pancreas, Liver, Small Bowel, Combined Small Bowel/Liver, and Multivisceral.

Such organs are surgically removed from a human cadaver or live human donor (in some cases) and surgically transplanted into a recipient in need of a new organ, secondary to trauma, disease, or congenital disorder.

NOTE: Kidney, cornea, and bone marrow transplants are not addressed in this policy.

Policy

NOTE: Certain contracts contain specific wording with regard to coverage of this service. Benefits provided by the member's contract supersede the statements of Medical Policy. Therefore, one should refer to the contract language to be certain of limitations of coverage prior to quoting benefits, adjudicating claims, preauthorizing or performing treatment.

Heart transplantation is considered **medically necessary** for patients with *end-stage heart failure,* secondary to conditions such as:

- Idiopathic cardiomyopathy,
- Valvular disease,
- Congenital heart disease,
- Non-resectable cardiac tumors, or
- Hemochromatosis.

Heart/Lung transplantation is considered **medically necessary** for patients with *end-stage cardiac and pulmonary disease,* including but not limited to the following diagnoses:

- Irreversible primary pulmonary hypertension with heart failure,
- Non-specific severe pulmonary fibrosis,
- Eisenmenger complex with irreversible pulmonary hypertension and heart failure,

- Cystic fibrosis with severe heart failure,
- Chronic obstructive pulmonary disease with heart failure,
- Emphysema with severe heart failure, or
- Pulmonary fibrosis with uncontrollable pulmonary hypertension or heart failure.

Lung/Lobar Lung transplantation is considered **medically necessary** for patients with irreversible, progressively disabling *end-stage pulmonary disease,* including but not limited to the following conditions:

- Bilateral bronchiectasis,
- Alpha-1 antitrypsin deficiency,
- Primary pulmonary hypertension,
- Cystic fibrosis (both lungs to be transplanted),
- Bronchopulmonary dysplasia,
- Interstitial pulmonary fibrosis,
- Idiopathic pulmonary fibrosis,
- Sarcoidosis,
- Scleroderma,
- Lymphangiomyomatosis,
- Emphysema,
- Eosinophilic granuloma,
- Bronchiolitis obliterans,
- Recurrent pulmonary embolism,
- Pulmonary hypertension due to cardiac disease,
- Chronic obstructive pulmonary disease, or
- Eisenmenger's syndrome.

Combined Pancreas/Kidney transplantation is considered **medically necessary** for patients with *uremic diabetes.*

Pancreas transplantation is considered **medically necessary** for patients who exhibit one of the following criteria:

- a history of frequent, acute, and severe metabolic complications (hypoglycemia, hyperglycemia, ketoacidosis) requiring medical attention; or
- clinical and emotional problems with exogenous insulin therapy that are so severe as to be incapacitating; or
- consistent failure of insulin-based management to prevent acute complications.

In some cases, these patients will have received a prior successful kidney transplant.

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

Due to the scarcity of donor livers, a variety of strategies have been developed to expand the donor pool. For example, split graft refers to dividing a donor liver into 2 segments that can be used for 2 recipients. Living donor transplantation of the left lateral segment is now commonly performed between parent and child. Recently, adult-to-adult living donor transplantation has been investigated, using the right lobe of the liver from a related or unrelated donor. In addition to addressing the problem of donor organ scarcity, living donation allows the procedure to be scheduled electively, shortens the preservation time for the donor liver, and allows time to optimize the recipient's condition pretransplant.

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

- Intrinsic liver diseases,
- Inborn errors of metabolism,
- Alpha-1 antitrypsin deficiency,
- Protoporphyria,
- Wilson's disease,
- Liver disease caused by external agents:
  - Trauma
  - Alcoholic cirrhosis
  - Viral hepatitis
  - Toxic reactions
- Systemic diseases:
  - Primary biliary cirrhosis
  - Sclerosing cholangitis
  - Secondary biliary cirrhosis
  - Budd-Chiari syndrome
  - Biliary atresia

Small Bowel transplantation is considered **medically necessary** in *pediatric and adult* patients with intestinal failure, who have established long-term dependency on total parenteral nutrition (TPN) **and** have developed severe life-threatening complications due to TPN. Complications include, but are not limited to, impending or overt liver failure, thrombosis of the major central veins (and therefore lack of TPN access), frequent central line infection and sepsis, and frequent episodes of severe dehydration.

Small Bowel/Liver Transplantation is considered **medically necessary** for *pediatric and adult* patients with intestinal failure, who have been managed with long-term total parenteral nutrition (TPN) and who have developed evidence of impending *end-stage liver failure.*

Multivisceral transplantation (combined small bowel, liver, and/or stomach, duodenum, jejunum, ileum, pancreas and/or colon) (HCPCS codes S2054, S2055) is considered **medically necessary** in both *pediatric and adult patients* with intestinal failure, liver failure, and/or other gastrointestinal problems such as pancreatic failure, thromboses of the celiac axis and the superior mesenteric artery, or pseudo-obstruction affecting the entire gastrointestinal tract.

Policy Guidelines

Rationale:

Evidence has shown that human organ transplants for the heart, heart/lung, lung/lobar lung, pancreas/kidney, pancreas, liver, small bowel, combined small bowel and liver and multivisceral, can increase the survival of individuals with end stage organ failure and/or impending mortality for patients meeting the criteria as identified in the above policy.

Update 2008:

A search of the peer-reviewed literature was performed for the period of July 2006 through July 2008. Findings in the recent literature do not change the conclusions on the use of human organ transplantation for conditions other than those medically necessary indications listed in the Policy section of this document. Therefore, the policy statements are unchanged.

Update 2012:

A search of the peer-reviewed literature was performed through May 2012. Findings in the recent literature do not change the conclusions on the use of human organ transplantation for conditions other than those medically necessary indications listed in the Policy section of this document. Therefore, the policy statements are unchanged.

Update 2014:

A search of the peer-reviewed literature was performed for the period of September 2012 through July 2014. Findings in the recent literature do not change the conclusions on the use of human organ transplantation for conditions other than those medically necessary indications listed in the Policy section of this document. Therefore, the policy statements are unchanged.

Update 2016:

A search of the peer-reviewed literature was performed for the period of August 2014 through September 2016. Findings in the recent literature do not change the conclusions on the use of human organ transplantation for conditions other than those medically necessary indications listed in the Policy section of this document. Therefore, the policy statements are unchanged.

Update 2018:

A search of the peer-reviewed literature was performed for the period of October 2016 through November 2018. Findings in the recent literature do not change the conclusions on the use of human organ transplantation for conditions other than those medically necessary indications listed in the Policy section. Therefore, the policy statement remains unchanged.

Update 2021:

A search of the peer-reviewed literature was performed for the period of December 2018 through December 2020. Findings in the recent literature do not change the conclusions on the use of human organ transplantation for conditions other than those medically necessary indications listed in the Policy section. Therefore, the policy statement remains unchanged.

Benefit Applications

Certain contracts contain specific wording with regard to coverage of this service. Benefits provided by the member's contract supersede the statements of Medical Policy. Therefore, one should refer to the contract language before treatment. The following are some examples of transplant related services and issues that may vary by individual contract:

- Types of covered transplants

- Related Expenses (examples: transportation, lodging, meals)
- Related Medications (example: anti-rejection drugs)
- Retransplantation

Benefits **are not provided** for search of a population or mass screening in order to identify potential organ donors. Benefits for screening are only provided for the actual organ donor. Check member's contract.

Separate benefits are provided for back bench preparation of a donor organ for medically necessary transplantation.

If determined to be experimental / investigational, benefits for human organ transplant may be allowed as part of a clinical trial. Check the member's contract and *Clinical Trials, Operating Procedure # 10.01.001A.*

NOTE: For FEP business, check the member's contract for benefits.

Provider Guidelines

When the recipient is an eligible member and the contract specifically includes a requirement for preauthorization for human organ transplantation, written notice must be received by the Plan prior to surgery. The Plan reserves the right to approve only those covered procedures performed at transplant centers which comply with established criteria and have been designated as approved transplant centers.

If benefits exist, the following information must be submitted for review:

- A completed Preservice Review Request for Authorization Form. This form may be obtained by sending a faxed request to 410-720-3061 or on the CareFirst website at: https://provider.carefirst.com/carefirst-resources/provider/pdf/precertification-request-for-authorization-of-services-cut9233.pdf.

- Clinical information to support the need for transplant should include a letter of medical necessity, all pertinent test results, consults and the proposed treatment plan.

The above clinical information must be faxed to 410-720-3061 or mailed to:
CareFirst BlueCross BlueShield
Preservice Review Department
1501 S. Clinton Street
8th Floor, Mail Stop CT-08-02
Baltimore, Md. 21224

Cross References to Related Policies and Procedures

Archived Allogeneic Bone Marrow Transplantation for Malignant and Non-Malignant Conditions, Procedure 7.03.003A
Archived High-Dose Chemotherapy/Radiation Therapy with Autologous Bone Marrow/Peripheral Stem Cell Support, Procedure 7.03.002A
Clinical Trial Mandates, Maryland and Virginia, Procedure 10.01.001A
High-Dose Chemotherapy/Radiation Therapy with Allogeneic Stem Cell Support and Allogenic Stem Cell Transplantation for Non-Malignant Conditions, Policy 7.03.003
High-Dose Chemotherapy/Radiation Therapy with Autologous Stem Cell Support and Autologous Stem Cell Transplantation for Non-Malignant Conditions, Policy 7.03.002
Islet Cell Transplantation, Policy 7.03.007
Archived Molecular Genetic Expression Test for Identification of Heart Transplant Rejection, 11.01.034
Nonmyeloablative Allogeneic Hemopoietic Stem Cell Transplantation for Hematologic Malignancies, 7.03.006
Archived Oral-Facial Pathology or Trauma, 7.01.022
Oral-Facial Trauma/Accidental Injury 7.01.136
Oral-Facial Pathology 7.01.137
Pulmonary Rehabilitation Programs, 8.01.010
Private Room, 10.01.007
Therapeutic Apheresis, 7.01.030

References

The following were among the resources reviewed and considered in developing this policy. By reviewing and considering the resources, CareFirst does not in any way endorse the contents thereof nor assume any liability or responsibility in connection therewith. The opinions and conclusions of the authors of these resources are their own and may or may not be in agreement with those of CareFirst.

Agency for Health Care Policy and Research. (1993, August). *Health technology review No.5: Small intestine and combined liver-small intestine transplantation* (DHHS AHCPR Publication No. 93-0067). Rockville: Author. Retrieved August 13, 2001 from the World Wide Web: http://hstat.nlm.nih.gov/ftrs/dbaccess/htr93-5

Agency for Health Care Policy and Research. (1995, August). *Health technology review No.11: Isolated pancreas transplantation (DHHS AHCPR Publication* No. 95-0068). Rockville: Author. Retrieved August 13, 2001 from the World Wide Web: http://hstat.nlm.nih.gov/ftrs/dbaccess/htr95-11

Agency for Health Care Policy and Research. (1995, March). Health technology review No.9: Combined liver-kidney transplantation (DHHS AHCPR Publication No. 95-0012). Rockville: Author. Retrieved August 13, 2001 from the World Wide Web: http://hstat.nlm.nih.gov/ftrs/dbaccess/htr95-9

Agency for Health Care Policy and Research. (1996, September). Health technology review No.13: Living related liver transplantation (DHHS AHCPR Publication No. 96-0059). Rockville: Author. Retrieved August 13, 2001 from the World Wide Web: http://hstat.nlm.nih.gov/ftrs/dbaccess/htr96-13

American Diabetes Association. (2004). *Position statement: Pancreas Transplantation in type 1 Diabetes.* Retrieved August 24, 2004 from the World Wide Web: http://care.diabetesjournals.org/cgi/content/full/27/suppl_1/s105

American Diabetes Association. (2001). *Position statement: Pancreas transplantation for patients with type 1 diabetes* [On-line]. Alexandria, VA: Author. Retrieved August 13, 2001 from the World Wide Web: http://www.diabetes.org/clinicalrecommendations/Supplement101/S93.htm

Aycart, M.A., Alhefzi, M., Kueckelhaus, M., Krezdorn, N., Bueno, E.M., …& Pomahac, B. (2016, October). A retrospective analysis of secondary revisions after face transplantation: assessment of outcomes, safety and feasibility. *Plastic Reconstructive Surgery*, Oct;138(4):690e-701e.

BlueCross BlueShield of the National Capital Area. (1995, December). *Human Organ and Tissue Transplantation* (Medical Policy Manual, Section IV [Surgery], p.12). Washington, DC: Author.

Salam, S., Kotloff, R., Garcha, P., Krishnan, S., Joshi, D. …& Duggal, A. (2016, September). Lung transplantation after 125 days on ECMO for severe refractory hypoxemia with no prior lung disease. *ASAIO Journal*, DOI: 10.1097/MAT.0000000000000450. Retrieved from the World Wide Web https://www.ncbi.nlm.nih.gov/pubmed/?term=Schlegel%20A%5BAuthor%5D&cauthor=true&cauthor_uid=27676319

Schlegel, A., Linecker, M., Kron, P., Györi, G., De Oliveira, M.L., …& Dutkowski, P. (2016, September). Risk assessment in high and low MELD liver transplantation. *American Journal of Transplantation,* Sep 27. doi: 10.1111/ajt.14065.

Date, H., Aoe, M., Nagahiro, I., et. al. (2003, August) Living-donor lobar lung transplantation for various lung diseases. *Journal of Thoracic and Cardiovascular Surgery,* 126, (2), 476-481.

Gilroy, R. & Sudan, D. (2000). Liver and small bowel transplantation: therapeutic alternatives for the treatment of liver disease and intestinal failure. *Seminars in Liver Disease, 20*(4), 437-450.

Hayes Directory (2009, November; updated 2012, December 31: Archived 2014, December). *Lung transplantation.* Lansdale, PA: Hayes, Inc.

Hayes Directory (2008, January; updated 2012, February; updated 2014, March 20: 2016, February). *Simultaneous pancreas-kidney (SPK) transplantation in diabetic patients.* Lansdale, PA: Hayes, Inc.

Hayes Directory (2012, July 26). *Small bowel transplant from living donors for intestinal failure.* Lansdale, PA: Hayes, Inc.

Hayes Directory (2014, June; 2016, April). Living related donor small bowel transplantation for intestinal failure. Lansdale, PA: Hayes, Inc.

Hayes Medical Technology Directory. (2013, March; 2017, February-annual review; 2018, April-archived). Simultaneous pancreas-kidney (SPK) transplantation in diabetic patients. (March 27, 2013). Lansdale, PA: Hayes, Inc.

Hayes Search & Summary. (2017, February; 2018, March- archived). Pancreas after kidney transplant (PAK) for pediatric patients with diabetes mellitus. (February 16, 2017). Lansdale, PA: Hayes, Inc.

Hayes Search & Summary. (2017, February; 2018, March-archived). Pancreas transplant alone (PTA) for pediatric patients with diabetes mellitus. February 9, 2017. Lansdale, PA: Hayes, Inc.

Hayes Search & Summary. (2017, February; 2018 March-archived). Simultaneous pancreas and kidney transplant (SPK) for pediatric patients with diabetes mellitus. (February 16, 2017). Lansdale, PA: Hayes, Inc.

Health Technology Assessment. (2015, December; 2020, January- annual review). Total Pancreatectomy With Islet Autotransplantation For Chronic Pancreatitis. (December 22, 2015). Lansdale, PA: Hayes, Inc.

Lamour, J.M., Hsu, D.T., et. al. (2004, August). Heart transplantation to a physiologic single lung in patients with congenital heart disease. *Journal Heart Lung Transplant*, 23 (8), 948-953.

National Institute of Diabetes and Digestive and Kidney Diseases. (2003, November). Pancreatic Islet Transplantation. Retrieved from the World Wide Web, August 24, 2004: http://diabetes.niddk.nih.gov/dm/pubs/pancreaticislet

National Institute of Diabetes and Digestive and Kidney Diseases. (1998, March 17). Pancreatic islet cell transplantation [On-line]. Retrieved August 13, 2001 from the World Wide Web: http://www.niddk.nih.gov/health/diabetes/summary/pancisl/pancisl.htm

Orens, J.B., Estenne, M., Arcasoy, S., et al (2006, July). International Guidelines for the Selection of Lung Transplant Candidates: 2006 Update-A Consensus Report from the Pulmonary Scientific Council of the International Society for Heart and Lung Transplantation. *The Journal of Heart and Lung Transplantation.* 25(7): 745-755.

Prabhudesai, A. & Kumar, D. (2001). Surgery on the small bowel. *Current Opinions in Gastroenterology, 17*(2), 127-131.

Toyoda, Y., Guy, T.S., & Kashem, A. (2013, April 3). Present status and future perspectives of heart transplantation. *Circulation Journal, 77*. doi: 10.1253/circj.CJ-13-0296