



Transplants, Solid Organ Clinical Coverage Criteria

Overview

In the United States, the United Network for Organ Sharing (UNOS) collects and reports data on organ donors, transplant candidates, recipients and post-transplant outcomes. The data is used to study and advance transplantation, inform the transplant policy development process and help transplant professionals make informed decisions. In total, 39,719 solid organ transplants, from both deceased and living donors, were performed in 2019. In addition, the U.S. Organ Procurement and Transplantation Network (OPTN) and the Scientific Registry of Transplant Recipients (SRTR) produce an annual report on data and trends for each of the solid organ transplants. The OPTN/SRTR Annual Data Report (ADR) is accessible on the Health Resources and Services Administration (HRSA) website.

Liver represents the second most commonly transplanted organ in the United States (kidney transplant is the most common). In 2019, 8,896 liver transplants were performed in the United States, a 7.8% increase over 2018 (8,250). From 2012 to 2018, the number of liver transplants in the U.S. increased by 27.8%. Deceased donor made up the vast majority (7,849 transplants or 95%) of liver transplants in 2018, with living donor accounting for only 5% (401). Data on adult waiting list candidates in 2018 are notable for a sharp decline in candidates with a primary diagnosis of hepatitis C virus, while the proportion of candidates with alcoholic liver disease and hepatocellular carcinoma (HCC) increased.

Liver transplantation plays a major role in the treatment of end-stage liver disease. The success of liver transplantation over the past years has been remarkable, with 1 and 5-year survival rates of 89.8% and 77.7%, respectively (HRSA, 2018 ADR). Such success comes as a consequence of the absence of alternative therapies. Limited organ availability and an increasing demand for organ transplantation has extended transplant waiting times and thus increased morbidity and mortality for potential recipients on these waiting lists. Timing of liver is crucial since patients who should be transplanted for end-stage liver disease need to undergo surgery before life-threatening systemic complications occur (Fayek et al., 2016).

There is strong evidence to suggest that living donor liver transplant facilitates timely transplantation to patients; however, information on the relative morbidity and death risks after living donor liver transplant as compared with deceased donor liver transplant is limited. In regions with low deceased donation rates, living donor liver transplantation reduces wait list mortality. However, previous reports have suggested that technical complications are higher after living donor liver transplantation (especially when performed at inexperienced centers) potentially resulting in graft failure (Freise et al., 2008, Kulik et al., 2012). Accurate information on the relative morbidity and death risks comparing living donor and deceased donor liver transplantation has been difficult to obtain because of the confounding effects of differences in the living donor liver transplant population who tend to be younger, have lower MELD (Model for End-Stage Liver Disease) scores, and have shorter follow-up (Reichman et al., 2013). In a matched cohort comparison, Reichman et al. (2013) reported the 3- and 5-year graft and patient survival for living donor versus deceased donor were similar (85% versus 83% and 83% versus 79%, respectively).

Kidney is the most commonly transplanted organ in the United States. In 2019 there were 23,401 kidney transplants compared to 21,167 in 2018, representing an increase of 10.6%. Despite the ongoing severe mismatch between organ need and supply, data from 2018 revealed some promising trends. For the fourth year in a row (since its peak at nearly 100,000 in 2014), the number of patients waiting for a kidney transplant in the United States declined and numbers of both deceased and living donor kidney

transplants increased. These encouraging trends are tempered by ongoing challenges, such as a large proportion of listed patients with dialysis time longer than 5 years. The proportion of candidates aged 65 years or older continued to rise, and the proportion undergoing transplant within 5 years of listing continues to vary dramatically nationwide, from 10% to nearly 80% across service areas. Kidney transplant provides significant quality of life and mortality benefits over dialysis for the treatment of end-stage kidney disease, but optimizing access to kidney transplant and graft survival are ongoing challenges.

Policy

This Policy applies to the following Fallon Health products:

- Commercial
- Medicare Advantage
- MassHealth ACO
- NaviCare
- PACE

Note: Lung transplants are addressed in Fallon Health's Lung Transplants Clinical Coverage Criteria policy.

Fallon Health follows guidance from the Centers for Medicare and Medicaid Services (CMS) for organization (coverage) determinations for Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and guidance in the Medicare manuals are the basis for coverage determinations. When there is no NCD, LCD, LCA or manual guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations.

Medicare has the following NCDs related to solid organ transplants:

- NCD for Adult Liver Transplantation (260.1)
- NCD for Pediatric Liver Transplant (260.2)
- NCD for Pancreas Transplants (260.3)
- NCD for Islet Cell Transplantation in the Context of a Clinical Trial (260.3.1)
- NCD for Intestinal and Multi-Visceral Transplantation (260.5)
- NCD for Dental Examination Prior to Kidney Transplantation (260.6)
- NCD for Lymphocyte Immune Globulin, Anti-Thymocyte Globulin (Equine) (260.7)
- NCD for Heart Transplants (260.9)
- NCD for Heartbreath Test for Heart Transplant Rejection (260.10)

National Government Services, Inc. does not have an LCD or LCA related to solid organ transplantation. (MCD search 07-08-2021). Coverage for kidney transplantation is described in Medicare Benefit Policy Manual, Chapter 11 – End Stage Renal Disease, Section 140 – Transplantation.

Medicare grants approval for heart, liver and lung transplantation at the facility level. In order for a transplant facility to obtain Medicare coverage for organ transplantation, it must meet pre-approved guidelines. These guidelines differ for heart, liver, and lung transplantation. The criteria are set forth in Federal Register notices concerning heart, liver, and lung transplants, respectively (52 FR 10935, dated April 6, 1987, 56 FR 15008, dated April 12, 1991, and 60 FR 6537, dated February 2, 1995) (Program Memorandum Intermediaries/Carriers Transmittal AB-01-150, Date: October 25, 2001). Medicare requires that facilities have written patient selection criteria that they follow in determining suitable candidates for transplants.

For plan members enrolled in NaviCare and PACE plans, Fallon Health follows Medicare guidance for coverage determinations. In the event that there is no Medicare guidance or if the plan member does not meet medical necessity criteria in Medicare guidance, Fallon Health will follow guidance published by

MassHealth. When there is no Medicare or MassHealth guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations for NaviCare members. Each PACE plan member is assigned to an Interdisciplinary Team. When there is no Medicare or MassHealth guidance, the member's Interdisciplinary Team is responsible for coverage determinations.

MassHealth has Guidelines for Medical Necessity Determination for Organ Transplant Procedures. These Guidelines apply to the following single- or double-organ transplants: liver, heart, lung, pancreas, and small bowel. Fallon Health's criteria can be no more restrictive than the MassHealth Medical Necessity Guidelines. The following are excerpts from these Guidelines:

- MassHealth evaluates individual medical circumstances for medical necessity in accordance with 130 CMR 450.204: Medical Necessity, for the use of these organ transplants for treatment of irreversible end-stage organ failure. MassHealth is guided by current scientific literature and the likelihood of benefit to the member. Transplantation should be curative, lead to prolonged survival, and an improved quality of life.
 - All organ transplants must be performed in a facility that is certified by the United Network of Organ Sharing (UNOS)/Organ Procurement and Transplantation Network (OPTN)
 - The member must meet the transplanting institution's selection criteria. Transplant center criteria should be based on clinical indicators and processes specific to the disease state and the organ to be transplanted (e.g., for liver transplant, the Model for End-Stage Liver Disease (MELD) or Pediatric End-Stage Liver Disease (PELD) score, with exception scoring to the National Liver Review Board.
 - Specific organs have both relative and absolute contraindications to transplant. MassHealth does not ordinarily consider organ transplants to be medically necessary under certain circumstances that include, but are not limited to, the following.
 1. The member has a systemic bacterial or fungal infection that is not adequately treated.
 2. The member has a metastatic malignancy.
 3. There is significant failure of one or more of the member's other organs or systems. In some circumstances, transplantation may be considered in the face of a second organ failure if a combined transplant is medically necessary and not investigational in nature.
 4. The member has an active substance use disorder, or uses substances that are illicit or contraindicated.
 5. The member has irreversible disease that significantly impairs or limits quality or duration of life.
 6. The member has psychological or social conditions that make the member unable or unlikely to be able to actively participate in the disciplined medical regimens required by transplantation.
 7. Current non-adherence to medical therapy or a history of repeated or prolonged episodes of non-adherence to medical therapy that are perceived to increase the risk of non-adherence after transplantation.

Prior authorization is required for organ transplants. Only those plan members accepted for transplantation by a Transplant Center and actively listed for transplant will be considered for prior authorization. The plan member must meet the eligibility criteria for the Transplant Center performing the transplant and be willing and capable of following the post-transplant treatment plan.

A Transplant Program (also referred to as a Transplant Center) is defined as a component within a transplant hospital that provides transplantation of a particular type of organ. All organ transplants must be performed by a Transplant Center located in a hospital that is a member of the Organ Procurement and Transplantation (OPTN) network. OPTN approved Transplant Centers are listed in the [OPTN Member Directory](#).

Liver Transplant

Medicare members: Adult liver transplantation is covered for Medicare members in accordance with Medicare NCD for Adult Liver Transplantation (260.1).

Nationally Covered Indications

Effective July 15, 1996, adult liver transplantation is covered for plan members with end-stage liver disease other than hepatitis B or malignancies when performed in a facility which is approved by the Centers for Medicare & Medicaid Services (CMS) as meeting institutional coverage criteria.

Effective December 10, 1999, adult liver transplantation is covered for plan members with end-stage liver disease other than malignancies when performed in a facility which is approved by CMS as meeting institutional coverage criteria (exclusion for hepatitis B removed, see Decision Memo for Liver transplantation CAG-00053N for rationale for removing this exclusion).

Effective September 1, 2001, adult liver transplantation is covered for hepatocellular carcinoma (HCC) when the following conditions are met:

- The plan member is not a candidate for subtotal liver resection;
- The plan member's tumor(s) is less than or equal to 5 cm in diameter;
- There is no macrovascular involvement;
- There is no identifiable extrahepatic spread of tumor to surrounding lymph nodes, lungs, abdominal organs or bone; and,
- The transplant is furnished in a facility that is approved by CMS as meeting institutional coverage criteria for liver transplants (see 65 FR 15006).

Effective June 21, 2012, Medicare Administrative Contractors acting within their respective jurisdictions may determine coverage of adult liver transplantation for the following malignancies: (1) extrahepatic unresectable cholangiocarcinoma (CCA); (2) liver metastases due to a neuroendocrine tumor (NET); and, (3) hemangioendothelioma (HAE) (See Transmittal R146NCD and MLN Matters Article MM7908 for additional information). At this time, National Government Services, Inc. does not have an LCD or LCA for adult liver transplantation.

Nationally Non-Covered Indications

Adult liver transplantation for other malignancies is excluded from coverage.

Other

Follow-up care or re-transplantation required as a result of a covered liver transplant is covered, provided such services are otherwise reasonable and necessary. Follow-up care is also covered for plan member who has been discharged from a hospital after receiving non-covered liver transplant. Coverage for follow-up care is for items and services that are reasonable and necessary as determined by Medicare guidelines.

Immunosuppressive drugs that have been specifically labeled as such and approved for marketing by the FDA are covered under Part B (See the Medicare Benefit Policy Manual, Chapter 15, Section 50.5.1 - Immunosuppressive Drugs and Medicare Claims Processing Manual, Chapter f17, Section 80.3 - Billing for Immunosuppressive Drug, for additional information),

Pediatric liver transplantation is covered for Medicare members in accordance with Medicare NCD for Pediatric Liver Transplantation (260.2).

Nationally Covered Indications

Liver transplantation is covered for children (under age 18) with extrahepatic biliary atresia or any other form of end stage liver disease, except that coverage is not provided for children with a malignancy extending beyond the margins of the liver or those with persistent viremia.

Liver transplantation is covered when performed in a pediatric hospital that performs pediatric liver transplants if the hospital submits an application which CMS approves documenting that: The hospital's pediatric liver transplant program is operated jointly by the hospital and another facility that has been found by CMS to meet the institutional coverage criteria in the "Federal Register" notice of April 12, 1991;

- The unified program shares the same transplant surgeons and quality assurance program (including patient protocol, patient selection criteria, and oversight committee.); and
- The hospital is able to provide the specialized facilities, personnel and services that are required by pediatric liver transplant patients.

Liver Transplant

Commercial and MassHealth plan members: MassHealth has Guidelines for Medical Necessity Determination for Organ Transplant Procedures. These MassHealth Guidelines apply to liver transplants.

Cadaveric or living donor liver transplant is considered medically necessary for plan members with:

- Cirrhosis with hepatic decompensation and serious complications, or
- Cirrhosis with non-metastatic hepatocellular carcinoma (HCC), single tumor ≤ 5 cm or < 4 tumors ≤ 3 cm each, or
- Acute hepatic failure (urgent) with Total bilirubin >5 mg/dL, INR >2.3 , or creatinine >2 mg/dL, or
- Primary biliary cirrhosis (PBC), or
- Primary sclerosing cholangitis (PSC).

AND

- No active infection
- No nicotine, alcohol, and other drugs documented by random tests for prior 6 months if past history of misuse
- No cancer (except localized non-melanoma skin cancer) or cancer free ≥ 5 years or cleared by oncologist
- No other organ system failure

Kidney Transplant

Medicare members: Kidney transplantation is covered for Medicare members in accordance with guidance in Medicare Benefit Policy Manual, Chapter 11 – End Stage Renal Disease, Section 140 – Transplantation.

“After a plan member is diagnosed as having end-stage renal disease (ESRD), the physician should determine if the plan member is suitable for kidney transplantation. If the plan member is a suitable transplant candidate, a live donor transplant is considered first because of the high success rate in comparison to a cadaveric transplant (Section 140.1).”

Sections 140.2-140.8 describe coverage for services provided in preparation for a live-donor kidney transplant.

Section 140.9 describes post-transplant services provided to a live donor.

Sections 140.11-140.15 describe coverage for services related to a cadaver transplant.

Section 140.16 describes noncovered transplant related items and services. These include:

- Travel, room, and board expenses incurred by a live donor;
- Travel, room, and board expenses (to any transplant center) incurred by the recipient;
- Reimbursement for the kidney itself when the live donor or the cadaver donor's next of kin sells the kidney;

- Transportation of the potential cadaveric donor to the transplant hospital (only transportation of the organ is reimbursable as part of the organ procurement charge); or
- Pronouncement of death and burial expenses for the cadaveric donor.

Dental Exam Prior to Kidney Transplant

A dental exam is covered for Medicare members prior to a kidney transplant in accordance with NCD for Dental Examination Prior to Kidney Transplantation (260.6):

Despite the dental services exclusion in §1862(a)(12) of the Act (see the Medicare Benefit Policy Manual, Chapter 16, "General Exclusions from Coverage," §140), **an** oral or dental examination performed on an inpatient basis as part of a comprehensive workup prior to renal transplant surgery is a covered service. This is because the purpose of the examination is not for the care of the teeth or structures directly supporting the teeth. Rather, the purpose for the examination is for the identification, prior to a complex surgical procedure, of existing medical problems where the increased possibility of infection would not only reduce the chances for successful surgery but would also expose the patient to additional risks in undergoing such surgery.

Such a dental or oral examination would be covered under Part A of the program if performed by a dentist on the hospital's staff, or under Part B if performed by a physician. (When performing a dental or oral examination, a dentist is not recognized as a physician under §1861(r) of the Act. See the Medicare General Information, Eligibility, and Entitlement Manual, Chapter 5, "Definitions," §70.2.)

Lymphocyte Immune Globulin, Anti-Thymocyte Globulin

Lymphocyte Immune Globulin, Anti-Thymocyte Globulin (Equine) is covered for Medicare members for the management of allograft rejection episodes in renal transplantation in accordance with NCD for Lymphocyte Immune Globulin, Anti-Thymocyte Globulin (Equine) (260.7).

Other forms of lymphocyte globulin preparation which the FDA approves for this indication in the future may be covered under Medicare.

Kidney Transplant

Commercial and MassHealth members: Kidney transplantation is preferred to dialysis for treating end-stage renal disease.

Kidney transplant is considered medically necessary for plan members with end-stage renal disease when all the following criteria are met:

1. The plan member is on dialysis or has a glomerular filtration rate (GFR) ≤ 20 mL/min/1.73 m².
2. The plan member has no drug or alcohol misuse by history or has been drug and alcohol free for ≥ 6 months.
3. The plan member has no active infection.
4. The plan member has no other organ system failure.
5. The plan member has no cancer except localized non-melanoma skin cancer or has been cancer free ≥ 5 years.
6. The plan member understands post-transplant care including anti-rejection medication and complications.

Pancreas Transplant

Medicare members: Pancreas transplantation is covered for Medicare members in accordance with Medicare NCD for Pancreas Transplants (260.3).

Nationally Covered Indications

Effective for services performed on or after July 1, 1999, whole organ pancreas transplantation is covered when performed simultaneous with or after a kidney transplant. If the pancreas transplant occurs after the

kidney transplant, immunosuppressive therapy begins with the date of discharge from the inpatient stay for the pancreas transplant.

Effective for services performed on or after April 26, 2006, pancreas transplants alone are covered for in the following limited circumstances:

1. Pancreas transplants alone will be limited to those facilities that are Medicare-approved for kidney transplantation. (Approved centers can be found at http://www.cms.gov/ESRDGeneralInformation/02_Data.asp#TopOfPage)¹
2. Patients must have a diagnosis of type I diabetes:
 - Patient with diabetes must be beta cell autoantibody positive; or
 - Patient must demonstrate insulinopenia defined as a fasting C-peptide level that is less than or equal to 110% of the lower limit of normal of the laboratory's measurement method. Fasting C-peptide levels will only be considered valid with a concurrently obtained fasting glucose \leq 225 mg/dL;
3. Patients must have a history of medically-uncontrollable labile (brittle) insulin-dependent diabetes mellitus with documented recurrent, severe, acutely life-threatening metabolic complications that require hospitalization. Aforementioned complications include frequent hypoglycemia unawareness or recurring severe ketoacidosis, or recurring severe hypoglycemic attacks;
4. Patients must have been optimally and intensively managed by an endocrinologist for at least 12 months with the most medically-recognized advanced insulin formulations and delivery systems;
5. Patients must have the emotional and mental capacity to understand the significant risks associated with surgery and to effectively manage the lifelong need for immunosuppression; and,
6. Patients must otherwise be a suitable candidate for transplantation.

Nationally Non-Covered Indications

Transplantation of partial pancreatic tissue or islet cells (except in the context of a clinical trial (see section 260.3.1 of the National Coverage Determinations Manual).

Islet Cell Transplantation in the Context of a Clinical Trial (NCD 260.3.1)

Medicare members: Islet cell transplantation is performed for the treatment of type 1 diabetes. One of the desired outcomes is insulin independence. Elimination of clinically significant hypoglycemia episodes and improved glucose control are other important patient outcomes.

Under NCD 260.3.1, Medicare covers the routine costs of islet cell transplantation for Medicare beneficiaries participating in qualifying clinical trials as defined in NCD for Routine Costs of Qualifying Clinical Trials (310.1). Coverage includes the cost of acquisition and delivery of the pancreatic islet cells, as well as medically necessary inpatient and outpatient medical care and immunosuppressants.

Original Medicare pays for the routine costs of qualifying clinical trials for all Medicare beneficiaries, including those enrolled in Medicare Advantage plans. The Medicare Administrative Contractors will reimburse providers on a fee-for-service basis for services related to qualifying clinical trials for Medicare Advantage members. Fallon Health will reimburse the difference between Original Medicare cost-sharing incurred for qualified clinical trial items and services and the Plan's in-network cost-sharing for the same category of items and services. Refer to Fallon Health's Clinical Trials Payment Policy for additional information.

¹ The lists of Medicare approved transplant centers as authorized by the National Coverage Determinations (NCDs) have been moved. The NCD listings were for heart, liver, lung and intestinal transplant centers, and they have been merged with the complete transplant center listings. The lists include heart, liver, lung, intestines, as well as kidney and pancreas (go to: https://www.cms.gov/Medicare/Transplantation/01_overview; then use the Transplant Center link in the Related Links section: then on the Transplant Centers webpage use The Organ Procurement and Transplantation Network link to go to the OPTN website; then search Member Directory.)

Partial pancreatic tissue transplantation or islet cell transplantation performed outside the context of a qualifying clinical trial is noncovered by Medicare and is not covered by Fallon Health.

Intestinal and Multi-Visceral Transplantation

Medicare members: Intestinal and multi-visceral transplantation are covered for Medicare members when criteria in NCD for Intestinal and Multi-Visceral Transplantation (260.5) are met.

Medicare covers intestinal and multi-visceral transplantation for the purpose of restoring intestinal function in patients with irreversible intestinal failure. Intestinal failure is defined as the loss of absorptive capacity of the small bowel secondary to severe primary gastrointestinal disease or surgically induced short bowel syndrome. It may be associated with both mortality and profound morbidity. Multi-visceral transplantation includes organs in the digestive system (stomach, duodenum, pancreas, liver and intestine).

Nationally Covered Indications

Effective for services performed on or after April 1, 2001, intestinal and multi-visceral transplantation is covered only when performed for Medicare beneficiaries who have failed total parenteral nutrition (TPN) and only when performed in centers that meet approval criteria.

1. Failed TPN

The TPN delivers nutrients intravenously, avoiding the need for absorption through the small bowel. TPN failure includes the following:

- Impending or overt liver failure due to TPN induced liver injury. The clinical manifestations include elevated serum bilirubin and/or liver enzymes, splenomegaly, thrombocytopenia, gastroesophageal varices, coagulopathy, stomal bleeding or hepatic fibrosis/cirrhosis.
- Thrombosis of the major central venous channels; jugular, subclavian, and femoral veins. Thrombosis of two or more of these vessels is considered a life threatening complication and failure of TPN therapy. The sequelae of central venous thrombosis are lack of access for TPN infusion, fatal sepsis due to infected thrombi, pulmonary embolism, Superior Vena Cava syndrome, or chronic venous insufficiency.
- Frequent line infection and sepsis. The development of two or more episodes of systemic sepsis secondary to line infection per year that requires hospitalization indicates failure of TPN therapy. A single episode of line related fungemia, septic shock and/or Acute Respiratory Distress Syndrome are considered indicators of TPN failure.
- Frequent episodes of severe dehydration despite intravenous fluid supplement in addition to TPN. Under certain medical conditions such as secretory diarrhea and non-constructable gastrointestinal tract, the loss of the gastrointestinal and pancreaticobiliary secretions exceeds the maximum intravenous infusion rates that can be tolerated by the cardiopulmonary system. Frequent episodes of dehydration are deleterious to all body organs particularly kidneys and the central nervous system with the development of multiple kidney stones, renal failure, and permanent brain damage.

2. Approved Transplant Facilities

Intestinal transplantation is covered by Medicare if performed in an approved facility.

Nationally Non-covered Indications

All other indications remain non-covered.

Cardiac (Heart) Transplant

Medicare members

Heart transplantation is covered for Medicare members in accordance with the Medicare NCD for Heart Transplants (NCD 260.9).

Adult heart transplantation is covered when performed in a facility that is approved by Medicare for heart transplantation (see April 6, 1987 [CMS Ruling 87-1 Criteria for Heart Transplants](#)). A facility must have written patient selection criteria and an implementation plan as part of their application (guidelines for patient selection criteria appear in Section D. of CMS Ruling 87-1.)

Medicare grants approval for transplantation at the facility level. Heart transplants in adults are considered medically necessary when performed in carefully selected patients at facilities meeting Medicare criteria (Decision Memo for Transplant Centers: Re-Evaluation of Criteria for Medicare Approval CAG-00061N).

Pediatric cardiac transplantation is covered for Medicare beneficiaries when performed in a pediatric hospital that performs pediatric heart transplants if the hospital submits an application which CMS approves as documenting that:

- The hospital's pediatric heart transplant program is operated jointly by the hospital and another facility that has been found by CMS to meet the institutional coverage criteria in CMS Ruling 87-1;
- The unified program shares the same transplant surgeons and quality assurance program (including oversight committee, patient protocol, and patient selection criteria); and
- The hospital is able to provide the specialized facilities, services, and personnel that are required by pediatric heart transplant patients.

Follow-up care required as a result of a covered heart transplant is covered, provided such services are otherwise reasonable and necessary. Follow-up care is also covered for plan members who have been discharged from a hospital after receiving a noncovered heart transplant. Coverage for follow-up care would be for items and services that are reasonable and necessary, as determined by Medicare guidelines. (See the Medicare Benefit Policy Manual, Chapter 16, "General Exclusions From Coverage," §180.)

Immunosuppressive drugs that have been specifically labeled as such and approved for marketing by the FDA are covered under Part B (See the Medicare Benefit Policy Manual, Chapter 15, Section 50.5.1 - Immunosuppressive Drugs and Medicare Claims Processing Manual, Chapter 17, Section 80.3 - Billing for Immunosuppressive Drug, for additional information),

Heartsbreath Test for Heart Transplant Rejection

The Heartsbreath Test is not covered by Fallon Health for Medicare members in accordance with NCD 260.10.

Effective for services performed on or after December 8, 2008, the Centers for Medicare & Medicaid Services has determined that the evidence does not adequately define the technical characteristics of the test nor demonstrate that Heartsbreath testing to predict heart transplant rejection improves health outcomes in Medicare beneficiaries. Thus, we conclude that the Heartsbreath test is not reasonable and necessary under section 1862(a)(1)(A) of the Social Security Act and is non-covered.

Cardiac (Heart) Transplant Commercial and MassHealth members

Heart transplant is considered medically necessary for adult plan members with:

- Ejection fraction (EF) \leq 35%, or
- Maximal VO₂ \leq 10 mL/kg/min OR VO₂ \geq 11mL/kg/min and \leq 14 mL/kg/min despite optimal medical treatment and significant limitations of the member's activities, or
- New York Heart Association Class IV heart failure with continued symptoms despite optimal medical treatment.

AND

- No active infection
- No nicotine, alcohol, and other drugs documented by random tests for prior 6 months if past history of misuse

- No cancer (except localized non-melanoma skin cancer) or cancer free \geq 5 years or cleared by Oncologist
- No other organ system failure

Heart transplant is considered medically necessary for pediatric members with:

- Require circulatory or ventilator support, or
- Severe limitation of exercise and activity, or
- Near sudden death and/or life-threatening arrhythmias untreatable with medications or an implantable defibrillator, or
- Reactive pulmonary hypertension.

Heart and Lung Transplant

Heart and lung transplant is considered medically necessary for adult plan members with:

- Irreversible primary pulmonary hypertension with heart failure, or
- Non-specific severe pulmonary fibrosis, or
- Eisenmenger complex with irreversible pulmonary hypertension and heart failure or
- Cystic fibrosis with severe heart failure, or
- Chronic obstructive pulmonary disease with heart failure, or
- Emphysema with severe heart failure, or
- Pulmonary fibrosis with uncontrollable pulmonary hypertension or heart failure.

AND

- No active infection
- No nicotine, alcohol, and other drugs documented by random tests for prior 6 months if past history of misuse
- No cancer (except localized non-melanoma skin cancer) or cancer free \geq 5 years or cleared by oncologist
- No other organ system failure

Exclusions

- Heartsbreath Test for Heart Transplant Rejection is considered experimental and is not covered (CPT 0085T). See the NCD for [Heartsbreath Test for Heart Transplant Rejection](#) (260.10).
- Allogeneic islet cell transplantation for the treatment of type 1 diabetes is considered experimental and investigational.

References

1. United Network for Organ Sharing (UNOS). Transplants by Organ Type. Available at: <https://unos.org/data/transplant-trends/>. Accessed May 25, 2020.
2. Health Resources and Services Administration (HRSA) OPTN/SRTR 2018 Annual Data Report. Available at: https://srtr.transplant.hrsa.gov/annual_reports/2018_ADR_Preview.aspx. Accessed May 25, 2020.
3. Medicare National Coverage Determinations Manual. Chapter 1, Part 4, Section 260 – Transplantation – solid Organ Transplants. Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1_Part4.pdf. Accessed May 25, 2020.
4. MassHealth Guidelines for Medical Necessity Determination for Organ Transplant Procedures. Available at: <https://www.mass.gov/doc/organ-transplant-procedures/download>. Accessed May 25, 2020.
5. Steinman TI, Becker BN, Frost AE, et al. Guidelines for the referral and management of patients eligible for solid organ transplantation. *Transplantation*. 2001;71(9):1189-1204.
6. Samuel D, Coilly A. Management of patients with liver diseases on the waiting list for transplantation: a major impact to the success of liver transplantation. *BMC Med*. 2018;16(1):113.
7. EASL. EASL clinical practice guidelines: liver transplantation. *J Hepatol*. 2016;64:433–85.

8. Fayek SA, Quintini C, Chavin KD and Marsh CL. The Current State of Liver Transplantation in the United States: Perspective From American Society of Transplant Surgeons (ASTS) Scientific Studies Committee and Endorsed by ASTS Council. *Am J Transplant.* 2016;16(11):3093-3104.
9. Freise CE, Gillespie BW, Koffron AJ, et al. Recipient morbidity after living and deceased donor liver transplantation: findings from the A2ALL Retrospective Cohort Study. *Am J Transplant.* 2008;8(12):2569-2579.
10. Kulik LM, Fisher RA, Rodrigo DR, et al. Outcomes of living and deceased donor liver transplant recipients with hepatocellular carcinoma: results of the A2ALL cohort. *Am J Transplant.* 2012;12(11):2997-3007.
11. Squires RH, Ng V, Romero R, et al. Evaluation of the pediatric patient for liver transplantation: 2014 Practice Guideline by The American Association for the Study of Liver Diseases, American Society of Transplantation and The North American Society for Pediatric Gastroenterology, Hepatology and Nutrition. *Hepatology.* 2014 Jul; 60(1):362-98.
12. Martin P et al. Evaluation for liver transplantation in adults: 2013 Practice Guideline by the American Association for the Study of Liver Disease and the American Society of Transplantation. *Hepatology.* 2014;59(3):1144-1166.
13. Reichman TW, Katchman H, Tanaka T, et al. Living donor versus deceased donor liver transplantation: a surgeon-matched comparison of recipient morbidity and outcomes. *Transpl Int.* 2013;26(8):780-787.
14. Charlton, M, Levitsky, J, Aql B, et al. International Liver Transplantation Society Consensus Statement on Immunosuppression in Liver Transplant Recipients. *Transplantation.* 2018;102: 727–743).
15. Mazzaferro V, Regalia E, Doci R, et al. Liver transplantation for the treatment of small hepatocellular carcinomas in patients with cirrhosis. *N Engl J Med.* 1996;334(11):693-699.
16. Singh S, Osna NA, Kharbanda KK. Treatment options for alcoholic and non-alcoholic fatty liver disease: A review. *World J Gastroenterol.* 2017;23(36):6549-6570.
17. Mazzaferro V, Llovet JM, Miceli R, et al. Predicting survival after liver transplantation in patients with hepatocellular carcinoma beyond the Milan criteria: a retrospective, exploratory analysis. *Lancet Oncol.* 2009;10(1):35-43.
18. Costanzo MR, Augustine S, Bourge R et al. Selection and treatment of candidate for heart transplantation. A statement for health professionals from the Committee on Heart Failure and Cardiac Transplantation of the Council on Clinical Cardiology, American Heart Association. *Circulation.* 1995; 92(12):3593-612.
19. Mehra MR, Canter CE, Hannan MM, et al. The 2016 International Society for Heart Lung Transplantation Listing Criteria for Heart Transplantation: A 10-year update. *J Heart Lung Transplant.* 2016;35(1):1-23.
20. Mehra MR, Kobashigawa J, Starling R, et al. Listing criteria for heart transplantation: International Society for Heart and Lung Transplantation guidelines for the care of cardiac transplant candidates--2006. *J Heart Lung Transplant.* 2006;25(9):1024-1042.
21. Hunt SA, Abraham WT, Chin MH, et al. 2009 focused update incorporated into the ACC/AHA 2005 Guidelines for the Diagnosis and Management of Heart Failure in Adults: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines: developed in collaboration with the International Society for Heart and Lung Transplantation. *Circulation.* 2009;119(14):e391-479.
22. Hunt SA, Abraham WT, Chin MH, et al. ACC/AHA 2005 Guideline Update for the Diagnosis and Management of Chronic Heart Failure in the Adult: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Update the 2001 Guidelines for the Evaluation and Management of Heart Failure): developed in collaboration with the American College of Chest Physicians and the International Society for Heart and Lung Transplantation: endorsed by the Heart Rhythm Society. *Circulation.* 2005;112(12):e154-e235.

23. Kirk R, Dipchand AI, Davies RR, et al. ISHLT consensus statement on donor organ acceptability and management in pediatric heart transplantation. *J Heart Lung Transplant.* 2020;39(4):331-341.
24. Kirk R, Dipchand AI, Rosenthal DN, et al. The International Society for Heart and Lung Transplantation Guidelines for the management of pediatric heart failure: Executive summary. *J Heart Lung Transplant.* 2014;33(9):888-909.
25. Canter CE, Shaddy RE, Bernstein D, et al. Indications for heart transplantation in pediatric heart disease: a scientific statement from the American Heart Association Council on Cardiovascular Disease in the Young; the Councils on Clinical Cardiology, Cardiovascular Nursing, and Cardiovascular Surgery and Anesthesia; and the Quality of Care and Outcomes Research Interdisciplinary Working Group [published correction appears in *Circulation.* 2007 Apr 3;115(13):e385. Friedman, Allen H [corrected to Friedman, Alan H]]. *Circulation.* 2007;115(5):658-676. 2):1313-1333.
26. Bia M, Adey DB, Bloom RD, Chan L, Kulkarni S, Tomlanovich S. KDOQI US commentary on the 2009 KDIGO clinical practice guideline for the care of kidney transplant recipients. *Am J Kidney Dis.* 2010;56(2):189-218.
27. Dew MA, Rosenberger EM, Myaskovsky L, et al. Depression and Anxiety as Risk Factors for Morbidity and Mortality After Organ Transplantation: A Systematic Review and Meta-Analysis. *Transplantation.* 2015;100(5):988-1003.
28. Heldal K, Hartmann A, Lønning K, et al. Should patients older than 65 years be offered a second kidney transplant? *BMC Nephrol.* 2017;18(1):13.
29. Lemoine M, Titeca Beauport D, Lobbedez T, et al. Risk Factors for Early Graft Failure and Death After Kidney Transplantation in Recipients Older Than 70 Years. *Kidney Int Rep.* 2019;4(5):656-666.

Policy history

Origination date: 01/01/2014

Approval(s): Technology Assessment Committee 10/23/2013 (Adopted Interqual Criteria) 01/28/2015 (annual review), 01/27/2016 (annual review), 01/25/2017 (annual review), 01/24/2018 (annual review), 01/23/2019 (annual review); 5/27/2020 (adopted Fallon Health criteria)

07/10/2021 (Added clarifying language related to Medicare Advantage, NaviCare and PACE under policy section)

Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully-insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans.