



## 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

Prior authorization is required. 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 has a National Coverage Determination (NCD) for Adult Liver Transplantation (NCD 260.1) and for Pediatric Liver Transplantation (NCD 260.1).

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  $\leq 5$  cm or  $< 4$  tumors  $\leq 3$  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  $\geq 5$  years or cleared by oncologist
- No other organ system failure

### Cardiac (Heart) Transplant

Medicare has a National Coverage Determination (NCD) for Heart Transplants (NCD 260.9).

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

- Ejection fraction (EF)  $\leq 35\%$ , or
- Maximal  $VO_2 \leq 10$  mL/kg/min OR  $VO_2 \geq 11$  mL/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

### **Renal (Kidney) Transplant**

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

- End stage Renal disease (ESRD) on dialysis or Glomerular filtration rate (GFR) $<20$

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).

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## Policy history

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*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. For Medicare and Medicaid members, this policy will apply unless Medicare and Medicaid policies extend coverage beyond this policy.*