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:

☒ Medicare Advantage (Fallon Medicare Plus, Fallon Medicare Plus Central)

☒ MassHealth ACO

☒ NaviCare HMO SNP, NaviCare SCO

☒ PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)

☒ Community Care

Organ transplants require prior authorization. Only those plan members accepted for transplant 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.

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

Fallon Health Clinical Coverage Criteria

Liver Transplantation

Effective for dates of service on or after March 1, 2025, Fallon Health will use InterQual® Criteria when making medical necessity determinations for adult (age ≥ 18 years) liver transplantation.

For coverage criteria, refer to the InterQual® Criteria in effect on the date of service:

- InterQual® CP:Procedures, Transplantation, Liver

Fallon Health makes InterQual® criteria available through the Transparency Tool on our website, effective January 1, 2024.

Fallon Health will review requests for pediatric (age < 18 years) liver transplantation on an individual case-by-case basis in in accordance with medical necessity.

Kidney Transplantation

Effective for dates of service on or after March 1, 2025, Fallon Health will use InterQual® Criteria when making medical necessity determinations for adult (age ≥ 18 years) renal (kidney) transplantation.

For coverage criteria, refer to the InterQual® Criteria in effect on the date of service:

- InterQual® CP:Procedures, Transplantation, Renal

Fallon Health makes InterQual® criteria available through the Transparency Tool on our website, effective January 1, 2024.

Fallon Health will review requests for pediatric (age < 18 years) kidney transplantation on an individual case-by-case basis in in accordance with medical necessity.

Pancreas Transplantation

Simultaneous Pancreas-Kidney (SPK) Transplantation

Simultaneous pancreas-kidney transplantation (SPK) is considered medically necessary for members with insulin dependent diabetes mellitus (IDDM) and end stage renal disease (Holt et al., 2021; ADA. Standards of Medical Care in diabetes—2025; Amara et al., 2022). The member must meet coverage criteria for a kidney transplant [see Renal (Kidney) Transplantation criteria above].
The criteria for coverage of a pancreas transplant alone are not applicable when a kidney is also being transplanted.

Pancreas After Kidney (PAK) Transplantation
Pancreas transplantation is considered medically necessary for members with insulin dependent diabetes mellitus (IDDM) after having had a prior successful kidney transplant.
The criteria for coverage of a pancreas transplant alone are not applicable when the member has already had a kidney transplant.

Pancreas Transplant Alone (PTA)
In the absence of indications for kidney transplantation, pancreas transplant alone (PTA) is considered medically necessary for members with insulin dependent diabetes mellitus (IDDM) and all of the following:
(1) a history of frequent, acute, and severe metabolic complications (hypoglycemia, marked hyperglycemia, ketoacidosis) requiring medical attention;
(2) clinical and emotional problems with exogenous insulin therapy that are so severe as to be incapacitating; and
(3) consistent failure of insulin-based management to prevent acute complications (Robertson et al., 2004).

Improved outcomes are found when PTA is performed in people who are relatively young (< 50 years) and do not have obesity (< 30 kg/m^2) or coronary artery disease. These selection criteria minimize operative mortality (<1%) (Holt et al., 2021).

Patients with end-stage kidney disease receiving simultaneous pancreas-kidney (SPK) or pancreas after kidney (PAK) transplants are already required to take immunosuppressive therapy for the kidney graft, and therefore the incremental effect of immunosuppressive therapy on quality of life is small. However, for patients receiving PTA, who have not yet developed advanced nephropathy, the benefit of preventing or slowing the progression of secondary complications must be balanced with the adverse effects of the immunosuppressive agents used in transplantation (Robertson et al., 2004).

Intestinal and Multivisceral Transplantation
An intestinal (small bowel) transplant may be 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 parenteral nutrition (TPN) and who have developed evidence of one or more severe complications due to TPN (Iyer et al., 2022; McLaughlin and Kato, 2014; Cheesman et al., 2025; Sudan et al., 2010; Seetharam and Rodrigues, 2011).

Evidence of intolerance to TPN includes, but is not limited to, multiple and prolonged hospitalizations to treat TPN-related complications, inability to maintain venous access, 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.

A small bowel and liver transplant may be 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 parenteral nutrition (TPN) and who have developed evidence of one or more severe complications due to TPN, and there is evidence of impending end-stage liver failure.

Adult Heart Transplantation
Effective for dates of service on or after March 1, 2025, Fallon Health will use InterQual® Criteria when making medical necessity determinations for adult (age ≥ 18 years) heart transplants.

For coverage criteria, refer to the InterQual® Criteria in effect on the date of service:

- InterQual® CP:Procedures, Transplantation, Cardiac

Fallon Health makes InterQual® criteria available through the Transparency Tool on our website, effective January 1, 2024

Pediatric Heart Transplantation

Fallon Health Clinical Coverage Criteria for pediatric heart transplantation apply to Community Care members only.

Heart transplantation for pediatric members (age < 18 years) is considered medical necessary for the following American Heart Association (AHA) Class I Recommendations (Canter et al., 2007):

1. Stage D heart failure associated with systemic ventricular dysfunction in pediatric patients with cardiomyopathies or previous repaired or palliated congenital heart disease.
2. Stage C heart failure in pediatric heart disease associated with severe limitation of exercise and activity. If measurable, such patients would have a peak maximum oxygen consumption 50% predicted for age and sex.
3. Stage C heart failure associated with systemic ventricular dysfunction in pediatric patients with cardiomyopathies or previously repaired or palliated congenital heart disease when heart failure is associated with significant growth failure attributable to the heart disease.
4. Stage C heart failure in pediatric heart disease with associated near sudden death and/or life-threatening arrhythmias untreatable with medications or an implantable defibrillator.
5. Stage C heart failure in pediatric restrictive cardiomyopathy disease associated with reactive pulmonary hypertension.
6. In the presence of other indications for heart transplantation, heart transplantation is feasible in patients with pediatric heart disease and an elevated pulmonary vascular resistance index 6 Woods units/m2 and/or a transpulmonary pressure gradient 15 mm Hg if administration of inotropic support or pulmonary vasodilators can decrease pulmonary vascular resistance to 6 Woods units/m2 or the transpulmonary gradient to 15 mm Hg.

AHA Class I Recommendations are defined as: Conditions for which there is evidence and/or general agreement that heart transplantation is useful and effective.

Heart Failure Staging in Pediatric Heart Disease

The International Society for Heart and Lung Transplantation (ISHLT) stratified pediatric heart failure into four stages (Stages A–D) which is useful to identify those at risk for heart failure and who are currently asymptomatic (Stage A) versus those on the other end of the spectrum (Stage D), who have advanced heart failure and, thus, would require therapeutic interventions for maintenance of end-organ function (Rosenthal et al., 2004).

Stage	Interpretation
A	Patients with increased risk of developing heart failure, but who have normal cardiac function and no evidence of cardiac chamber volume overload. Examples: previous exposure to cardiotoxic agents, family history of heritable cardiomyopathy, univentricular heart, congenitally corrected transposition of the great arteries
B	Patients with abnormal cardiac morphology or cardiac function, with no symptoms of HF, past or present. Examples: aortic insufficiency with LV enlargement, history of anthracycline with decreased LV systolic function.
C	Patients with underlying structural or functional heart disease, and past or current symptoms of HF.
D	Patients with end-stage HF requiring continuous infusion of inotropic agents, mechanical circulatory support, cardiac transplantation or hospice care.

OPTN Allocation of Pediatric Hearts

The OPTN Policies that address organ allocation are available at:
https://optn.transplant.hrsa.gov/policies-bylaws/policies/

Heart-Lung Transplantation

Fallon Health Clinical Coverage Criteria for heart-lung transplantation apply to Community Care members only.

Heart-lung transplantation is considered medically necessary for adult (age ≥ 18 years) plan members with end-stage heart and end-stage lung disease due to one of the following:

- 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
- Pulmonary fibrosis with uncontrollable pulmonary hypertension or heart failure

Fallon Health will review requests for pediatric (age < 18 years) heart-lung transplantation on an individual case-by-case basis in in accordance with medical necessity.

Medicare Variation

Medicare regulations at 42 CFR Part 482 Subpart E §§ 482.68-482.104 contain Condition of participation requirements for Transplant Centers.[1] Unless specified otherwise, these requirements apply to heart, heart-lung, intestine, kidney, liver, lung, and pancreas centers. Medicare covers the following organ transplants: kidney, heart, lung, heart/lung, liver, pancreas, pancreas/kidney, and intestinal/multi-visceral. Medicare has the following NCDs related to solid organ transplants:

- NCD for Adult Liver Transplantation (260.1) – Coverage criteria for adult liver transplantation are fully established by Medicare for end-stage liver disease and hepatocellular carcinoma. Coverage criteria for adult liver transplantation for the following malignancies are not fully established by Medicare and coverage will be determined on an individual case-by-case basis by the Plan:
  - (1) extrahepatic unresectable cholangiocarcinoma (CCA);
  - (2) liver metastases due to a neuroendocrine tumor (NET); and,
  - (3) hemangioendothelioma (HAE).

  All other malignancies continue to remain nationally non-covered (R146NCD).
- NCD for Pediatric Liver Transplant (260.2) – Coverage criteria for pediatric liver transplantation are fully established by Medicare, therefore the Plan's coverage criteria are not applicable.
- NCD for Pancreas Transplants (260.3) – Coverage criteria for pancreas transplantation are fully established by Medicare, therefore the Plan's coverage criteria are not applicable.
- NCD for Islet Cell Transplantation in the Context of a Clinical Trial (260.3.1) – Coverage criteria for islet cell transplantation are fully established by Medicare, therefore the Plan's coverage criteria are not applicable. Original Medicare will pay for the routine costs, as well as transplantation and appropriate related items and services, for Medicare beneficiaries participating in a National Institutes of Health (NIH)-sponsored clinical trial. The term 'routine costs' means reasonable and necessary routine patient care costs, including immunosuppressive drugs and other follow-up care, as defined in section 310.1 of the NCD Manual. The transplant is performed on patients with Type I diabetes. Islet cell transplantation performed outside the context of a clinical trial continues to be noncovered by Medicare.
- NCD for Intestinal and Multi-Visceral Transplantation (260.5) – Coverage criteria for intestinal and multi-visceral transplantation are fully established by Medicare, therefore the Plan's coverage criteria are not applicable.
- NCD for Dental Examination Prior to Kidney Transplantation (260.6) – Coverage criteria for dental examination prior to kidney transplantation are fully established by Medicare, therefore the Plan's coverage criteria are not applicable.

[1] Final Rule: Hospital Conditions of Participation Requirements for Approval and Re-Approval of Transplant Centers to Perform Organ Transplants (CMS–3835–F) establishes, for the first time, Medicare conditions of participation for heart, heart-lung, intestine, kidney, liver, lung, and pancreas transplant centers. This rule sets forth clear expectations for safe, high quality transplant service delivery in Medicare-participating facilities.

- NCD for Lymphocyte Immune Globulin, Anti-Thymocyte Globulin (Equine) (260.7) – Coverage criteria for lymphocyte immune globulin, anti-thymocyte globulin (equine) are fully established by Medicare, therefore the Plan's coverage criteria are not applicable.
- NCD for Heart Transplants (260.9) – Coverage criteria for heart transplants are fully established by Medicare, therefore the Plan's coverage criteria are not applicable.
- NCD for Heartsbreath Test for Heart Transplant Rejection (260.10) – Effective for dates of service on or after December 8, 2008, Heartsbreath testing to predict heart transplant rejection is not reasonable and necessary under section 1862(a)(1)(A) of the Social Security Act and is nationally non-covered.

Coverage criteria for kidney transplantation are described in Medicare Benefit Policy Manual, Chapter 11 – End Stage Renal Disease, Section 140 – Transplantation. Coverage criteria for kidney transplantation are fully established by Medicare therefore the Plan's coverage criteria are not applicable.

Coverage criteria for Medicare coverage of heart-lung transplantation are described in Federal Register (FR) 6537 February 2, 1995. Medicare will "cover heart-lung transplants for beneficiaries with progressive end-stage cardiopulmonary disease when they are provided in a facility that has been approved by Medicare for both heart and lung transplantation."

National Government Services, Inc., the Part A and B Medicare Administrative Contractor (MAC) with jurisdiction in the Plan's service area, does not have any LCDs related to solid organ transplantation (Medicare Coverage Database search 01/24/2025).

See Medicare Claims Processing Manual, Chapter 3, Section 90 – Billing Transplant Services for claims processing information.

All Medicare-covered organ transplants must be performed in a hospital that has a CMS-Approved Organ Transplant Program. As of February 11, 2019, the List of CMS-Approved Organ Transplant Programs is now available on the Quality, Certification and Oversight Reports (QCOR) web site. The List may be downloaded in Microsoft Excel format. Click "Resources" at the top of the main QCOR page. Select "List of CMS-Approved Organ Transplant Programs" link.

MassHealth Variation

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.

Link: Guidelines for Medical Necessity Determination for Organ Transplant Procedures

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.

Summary of Evidence

N/A

Analysis of Evidence (Rationale for Determination)

N/A

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Policy history

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Instructions for Use

Fallon Health complies with CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations for Medicare Advantage members. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health may create internal coverage criteria under specific circumstances described at § 422.101(b)(6)(i) and (ii).

Fallon Health follows Medical Necessity Guidelines published by MassHealth when making medical necessity determinations for MassHealth members. In the absence of Medical Necessity Guidelines published by MassHealth, Fallon Health may create clinical coverage criteria in accordance with the definition of Medical Necessity in 130 CMR 450.204.

For plan members enrolled in NaviCare, Fallon Health first follow's CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, or if the NaviCare member does not meet coverage criteria in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health then follows Medical Necessity Guidelines published by MassHealth when making necessity determinations for NaviCare members.

Each PACE plan member is assigned to an Interdisciplinary Team. PACE provides participants with all the care and services covered by Medicare and Medicaid, as authorized by the interdisciplinary team, as well as additional medically necessary care and services not covered by Medicare and Medicaid. With the exception of emergency care and out-of-area urgently needed care, all care and services provided to PACE plan members must be authorized by the interdisciplinary team.

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.