JOHNS HOPKINS HEALTH PLANS	Johns Hopkins Health Plans **Medical Policy Manual** **Medical Policy**	*Policy Number*	CMS19.05
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	Subject **Solid Organ Transplantation**	*Supersedes Date*	04/01/2024
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This document applies to the following Participating Organizations:

EHP	Johns Hopkins Advantage MD	Johns Hopkins Health Plan of Virginia Inc. (JHHPVA)	Priority Partners
US Family Health Plan			

Keywords: Organ Transplant, Solid Organ, Transplantation

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I. ACTION

	New Policy	
X	Revising Policy Number	CMS19.05
	Superseding Policy Number	
	Retiring Policy Number	

II. POLICY DISCLAIMER

Johns Hopkins Health Plans (JHHP) provides a full spectrum of health care products and services for Advantage MD, Employer Health Programs, Johns Hopkins Health Plan of Virginia Inc., Priority Partners, and US Family Health Plan. Each line of business possesses its own unique contract, benefits, regulations, and regulators' clinical guidelines that supersede the information outlined in this policy.

III. POLICY

For Advantage MD and Johns Hopkins Health Plan of Virginia LLC (JHHPVA) refer to: Medicare Coverage Database:

- National Coverage Determination (NCD) 260.1 Adult Liver Transplantation
- National Coverage Determination (NCD) 260.2 Pediatric Liver Transplantation
- National Coverage Determination (NCD) 260.3 Pancreas Transplants
- National Coverage Determination (NCD) 260.5 Intestinal and Multi-Visceral Transplantation
- National Coverage Determination (NCD) 260.9 Heart Transplants
- National Coverage Determination (NCD) 20.9.1 Ventricular Assist Devices
- Medicare Benefit Policy Manual, Chapter 11, End Stage Renal Disease (ESRD), 140 Transplantation

- Medicare Managed Care Manual, Chapter 4, Benefits and Beneficiary Protections, 10.11 Transplant Services
- CMS Provider Reimbursement Manual, Part 1, Chapter 31- Organ Donation and Transplant Reimbursement

For Employer Health Programs (EHP) refer to:

- Plan specific Summary Plan Descriptions (SPDs)

For Priority Partners (PPMCO) refer to: Code of Maryland Regulations

- Code of Maryland Regulations (COMAR) 10.67.06.09 Benefits-Transplants
- Code of Maryland Regulations (COMAR) 10.67.06.27 Benefits-Limitations

For Uniformed Services Family Health Plan (USFHP) refer to: TRICARE Policy Manuals

- TRICARE Policy Manual 6010.63-M, April 1, 2021, Chapter 4, Section 24.1 Heart-Lung and Lung Transplantation
- TRICARE Policy Manual 6010.63-M, April 1, 2021, Chapter 4, Section 24.2 Heart Transplantation
- TRICARE Policy Manual 6010.63-M, April 1, 2021, Chapter 4, Section 24.3 Combined Heart-Kidney Transplantation (CHKT)
- TRICARE Policy Manual 6010.63-M, April 1, 2021, Chapter 4, Section 24.4 Small Intestine (SI), Combined Small Intestine-Liver (SI/L) and Multivisceral Transplantation
- TRICARE Policy Manual 6010.63-M, April 1, 2021, Chapter 4, Section 24.5 Liver Transplantation
- TRICARE Policy Manual 6010.63-M, April 1, 2021, Chapter 4, Section 24.6 Combined Liver-Kidney Transplantation (CLKT)
- TRICARE Policy Manual 6010.63-M, April 1, 2021, Chapter 4, Section 24.7 Simultaneous Pancreas-Kidney (SPK), Pancreas-after-Kidney (PAK) and Pancreas Transplant Alone (PTA), and Pancreatic Islet Cell Transplantation
- TRICARE Policy Manual 6010.63-M, April 1, 2021, Chapter 4, Section 24.8 Kidney Transplantation
- TRICARE Policy Manual 6010.63-M, April 1, 2021, Chapter 11, Section 7.1 Certificate of Organ Transplant Centers
- TRICARE Reimbursement Manual 6010.64-M, April 1, 2021, Chapter 1, Section 40 Organ Acquisition Costs

IV. POLICY CRITERIA

A. When benefits are provided under the member's contract, JHHP considers solid organ transplantation medically necessary when all of the following requirements have been met:
   1. All solid organ transplants require JHHP Medical Director Review for authorization prior to listing of the potential transplant recipient for organ allocation.
   2. All transplants must be performed at a designated transplant facility as determined by a member's contract.
   3. The transplant program for the organ requested (e.g., heart, lung, liver, kidney, pancreas) must be an active member of the Organ Procurement and Transplantation Network (OPTN) for this specific organ.
   4. Clinical documentation submitted for transplant listing preauthorization review must include all of the following:
      a. Transplant Program Listing Committee (or equivalent) documented the decision to proceed with patient listing for organ allocation.
      b. Transplant Program-specific Inclusion and Exclusion Criteria indicating if the member meets the medical, surgical, and psychosocial criteria mandated by this organ transplant program.
         i. If the suitability criteria have not been met, the rationale for exception should be provided with sufficient details to assist the JHHP Medical Director in decision making without delaying review.
      c. Summary of medical and surgical pre-transplant evaluation including all of the following:
         i. Summary of clinical findings of the pre-transplant workup supporting patient's suitability for transplant.

ii. Transplant surgeon/physician's assessment of the risks and benefits of the transplant, including documentation of a member's informed consent to enter into the transplant evaluation process.

iii. Documented *absence* of absolute contraindications to a transplant, including but not limited to:

- Major systemic disease with limited life expectancy that will not be corrected with a transplant.
- Active malignancy with a high risk of recurrence or death related to the cancer.
- Severe neurological deficit that cannot be managed sufficiently to allow safe post-transplant care.
- Major psychiatric illness that cannot be managed sufficiently to allow safe post-transplant care.
- Current drug or alcohol misuse per transplant center criteria.

d. Psychosocial evaluation conducted by a designated qualified transplant team member (e.g., Clinical Social Worker, Psychologist) identifying the absence of actual and potential obstacles to successful transplantation and documenting all of the following aspects of the patient's evaluation:

i. Ability of member or proxy to make an informed decision (consent for treatment).

ii. Ability to be compliant as evidenced by adherence to a prior treatment plan.

iii. Understanding of post-procedure compliance and follow-up.

iv. Substance abuse assessment confirming transplant program-specific criteria have been met.

v. Social, personal, financial, and environmental support systems are sufficient for short and long term care associated with organ transplant.

e. Clinical documentation submitted for continued transplant listing preauthorization review by a JHHP Medical Director must include all of the following:

i. The Transplant Program Listing Committee (or equivalent) documented reevaluation summary indicating member remains eligible based on the Transplant Program-specific Wait List criteria.

ii. The Transplant Program-specific Wait List criteria. (The frequency of reevaluation assessment will be determined by each transplant center's specific organ protocols).

f. A member may be registered for an organ at multiple transplant programs within the same Donation Service Area (DSA) or different DSAs.

B. When benefits are provided under the member's contract, JHHP considers transplantation donor expenses covered under the transplant recipient's benefit plan.

C. When benefits are provided under the member's contract, JHHP considers the following devices related to heart transplantation medically necessary:

1. SynCardia™ Temporary Total Artificial Heart (TAH) (SynCardia Systems, Tucson, AZ) when it is used as a temporary measure to bridge to a heart transplant:
   a. Member is awaiting a heart transplantation, AND;
   b. Member is at imminent risk of death due to biventricular heart failure.
2. Freedom Portable Driver for SynCardia™ Temporary Total Artificial Heart:
   a. Member's condition allows for discharge to await for a heart transplant at home, AND;
   b. Member and caregiver(s) have received sufficient education on managing the above devices as documented by the care team.

V. DEFINITIONS

Donation Service Area (DSA): The geographic area designated by the Centers for Medicare and Medicaid Services (CMS) that is served by one organ procurement organization (OPO), one or more transplant hospitals, and one or more donor hospitals (OPTN, 2025a).

Estimated Post Transplant Survival Score (EPTS): The score is assigned to all adult candidates on the kidney waiting list and is based on four factors: 1. Candidate time on dialysis; 2. Current diagnosis of diabetes; 3. Prior solid organ transplants; 4. Candidate age. A candidate's EPTS score can range from 0% to 100%. The candidates with EPTS scores of 20% or less will receive offers for kidneys from donors with similar KDPI scores before other candidates. (OPTN, 2025d. UNOS, 2025a).

Kidney Donor Profile Index (KDPI): Combines a variety of donor factors into a single number that summarizes the likelihood of graft failure after a deceased donor kidney transplant. Lower KPDI scores are associated with longer estimated function, while higher KDPI scores are associated with shorter estimated function. For example, a kidney with a KDPI of 20% is expected to have shorter longevity than 20% of recovered kidneys (i.e., longer function than 80% of recovered kidneys) (OPTN, 2025c).

Match Run: A organ specific algorithm that filters and ranks waiting list candidates for potential donors. A match run is also used to generate a set of potential exchanges for kidney paired donation (KPD) donor and candidate (OPTN, 2025a).

Multiple Listing: Involves registering at two or more transplant centers for organ transplantation. A transplant program may choose whether or not to accept a candidate seeking multiple registrations for an organ (OPTN, 2025a; UNOS, 2025b).

Wait List: A computerized list of candidates registered to receive organ transplants. When a donor organ becomes available, the matching system generates a new, more specific list of potential recipients based on the criteria defined in that organ's allocation policy (e.g., organ type, geographic local and regional area, genetic compatibility measures, details about the condition of the organ, the candidate's disease severity, time spent waiting, etc.) who are waiting to be matched with specific deceased donor organs for transplant maintained by the United Network for Organ Sharing (OPTN, 2025a). Patients can be active or inactive on the waitlist. Patients can be inactivated for a variety of reasons, and if inactive, organs will not be offered.

VI. BACKGROUND

In 1984, the National Organ Transplantation Act (NOTA) directed the Secretary of Health and Human Services to establish by contract the Organ Procurement and Transplantation Network (OPTN) which shall be a private, non-profit entity that has expertise in organ procurement and transplantation. All transplant programs and organ procurement organizations throughout the country are OPTN members and are obligated to follow the policies OPTN creates for allocating organs. The OPTN policies govern the operations of all member transplant hospitals, organ procurement organizations (OPOs) and histocompatibility labs in the U.S. Policies are made through a collaborative process involving committees, the board of directors and the public. OPTN policies standardize criteria for placing patients on the waiting list for transplant and defining patient medical status. OPTN transplant organ allocation policies aim to use donated organs efficiently (OPTN, 2024).

The United Network for Organ Sharing (UNOS) is a non-profit charitable organization managing OPTN operations under the federal contract. UNOS is the organization responsible for the procurement and distribution of organs for transplantation in the United States. A national database of transplant candidates, donors, recipients, and donor-recipient matching and histocompatibility is maintained by UNOS. When a transplant hospital accepts a person as a transplant candidate, it enters medical data, information such as the person’s blood type and medical urgency and the location of the transplant hospital, about that candidate into UNOS' computerized network. When an organ procurement organization (OPO) gets notification of a potential organ donor and consent for an organ donation, it also enters medical data, information such as the donor’s blood type and body size and the location of the donor hospital, into UNOS' network. Using the combination of donor and candidate information, the UNOS computer system generates a match run, a rank-order list of candidates to be offered each organ. This match is unique to each donor and each organ. The candidates who will appear highest in the ranking are those who are in most urgent need of the transplant, and/or those most likely to have the best chance of survival if transplanted (UNOS, 2025).

Statistical and analytical support for the solid organ transplant community is provided by the Scientific Registry of Transplant Recipients (SRTR), an entity operating under contract with the US Department of Health and Human Services. SRTR collects information from various sources and provides information upon request to CMS, private insurance providers, OPTN committees, external investigators, and the public in order to fulfill its mission of providing advanced statistical and epidemiological analyses related to solid organ allocation and transplantation. The SRTR website also helps to find and compare transplant programs and offers free public information on each transplant program's performance (SRTR, 2022).

Centers for Medicare and Medicaid (CMS) in 2007 has published the Medicare Conditions of Participation (CoPs), a set of requirements for acceptable quality in the operation of health care entities and transplant programs. In order to be granted approval from the CMS to provide transplant services, a transplant center must be located within a hospital that has a Medicare provider agreement and must be a member of and abide by the approved rules and requirements of the OPTN. Medicare CoPs requirements cover all aspects of the organ transplant process, including pre-transplant evaluation, transplant waiting period, transplant surgery, post-transplant care provided by the transplant center, as well as the requirements for transplant center and transplant providers (CMS, 2007).

TRICARE has its own requirements for transplant programs for liver, heart, combined heart-kidney (CHKT), combination liver-kidney (CLKT), lung, heart-lung, and small intestine (SI) within its region (Medicare is the approving authority for kidney transplant centers). To obtain TRICARE certification as an organ transplant center, the center must have an active solid organ transplant program, be a member of OPTN, have a trained interdisciplinary transplant team available at all times for transplant patients, and meet certain transplant volume and survival rate requirements. The centers that meet TRICARE certification requirements are monitored for compliance at least every 2 years (TRICARE, 2021).

Transplant programs in the United States evaluate the suitability of potential transplant candidates using eligibility criteria developed by the transplant programs in alignment with the OPTN organ allocation policies. The criteria are both medical and non-medical in nature. The medical criteria may include detailed diagnosis, age, lab values, BMI calculation, functional status, supplemental oxygen requirements, ventilation status, mechanical support, interventions/therapies attempted. The use of non-medical criteria in evaluating patients for transplantation can affect the decision of the transplant team to list a potential transplant candidate for transplantation. These criteria include, but not limited to, an estimate of life expectancy, potentially injurious behaviors, adherence, social and financial support, and intellectual disability (UNOS, 2025).

Although organ allocation is centralized, the suitability criteria and contraindications to listing for some organ transplantation are often transplant center-specific. One of the examples is a liver transplant for severe alcoholic hepatitis. Some transplant centers have a strict 6-month of sobriety rule for patients to be listed for alcohol-related liver disease. However, since a landmark publication in the New England Journal of Medicine (NEJM), (Mathurin, 2011), there has been a trend towards more programs willing to forgo the "6-month" rule. To rephrase, a recipient might not be an acceptable candidate at one transplant center but meet eligibility requirements at another.

Given the scarcity of available donated organs, UNOS/OPTN adjust the organ specific match run algorithms to maximize the lives saved (e.g. MELD score for liver transplant and priority points for highly sensitized patients with renal failure) and organ longevity (i.e., low Kidney Donor Profile Index (KPDI) organs for patients with the best Estimated Post Transplant Survival score (EPTS). Many factors are used to match organs with potential recipients. These factors are not the same for all organs and are assessed periodically. How broadly organs are shared is in part determined by the organ specific tolerance for cold ischemia time. Kidneys can be allocated nationally whereas the heart is not. This may change as systems for organ preservation increase our ability to transport organs over a great distance.

VII. CODING DISCLAIMER

Note: The following CPT/HCPCS codes are included below for informational purposes and may not be all inclusive. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member's specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee of payment. Other policies and coverage determination guidelines may apply.

Note: All inpatient admissions require pre-authorization.

Adherence to the provision in this policy may be monitored and addressed through post payment data analysis and/or medical review audits
Advantage MD: Regulatory guidance supersedes JHHP Medical Policies. If there are no statutes, regulations, NCDs, LCDs, or LCAs, or other CMS guidelines, apply the Medical Policy criteria.
Employer Health Programs (EHP): Specific Summary Plan Descriptions (SPDs) supersedes JHHP Medical Policy. If there are no criteria in the SPD, apply the Medical Policy criteria.
Johns Hopkins Health Plan of Virginia Inc. (JHHPVA): Regulatory guidance supersedes JHHP Medical Policies. If there are no statutes, regulations, NCDs, LCDs, or LCAs, or other CMS guidelines, apply the Medical Policy criteria.
Priority Partners (PPMCO): Regulatory guidance supersedes JHHP Medical Policy. If there are no criteria in COMAR regulations, or other State guidelines, apply the Medical Policy criteria.
US Family Health Plan (USFHP): Regulatory guidance supersedes JHHP Medical Policy. If there are no TRICARE policies, or other regulatory guidelines, apply the Medical Policy criteria.

VIII. CODING INFORMATION

CPT® CODES ARE FOR INFORMATIONAL PURPOSES ONLY	
CPT® CODES	**DESCRIPTION**
32850	Donor pneumonectomy(s) (including cold preservation), from cadaver donor
32851	Lung transplant, single; without cardiopulmonary bypass
32852	Lung transplant, single; with cardiopulmonary bypass
32853	Lung transplant, double (bilateral sequential or en bloc); without cardiopulmonary bypass
32854	Lung transplant, double (bilateral sequential or en bloc); with cardiopulmonary bypass
33927	Implantation of a total replacement heart system (artificial heart) with recipient cardiectomy
33928	Removal and replacement of total replacement heart system (artificial heart)
33930	Donor cardiectomy-pneumonectomy (including cold preservation)
33935	Heart-lung transplant with recipient cardiectomy-pneumonectomy
33940	Donor cardiectomy (including cold preservation)
33945	Heart transplant, with or without recipient cardiectomy
44132	Donor enterectomy (including cold preservation), open; from cadaver donor
44133	Donor enterectomy (including cold preservation), open; partial, from living donor
44135	Intestinal allotransplantation; from cadaver donor
44136	Intestinal allotransplantation; from living donor
44137	Removal of transplanted intestinal allograft, complete
47133	Donor hepatectomy (including cold preservation), from cadaver donor

47135	Liver allotransplantation, orthotopic, partial or whole, from cadaver or living donor, any age
47140	Donor hepatectomy (including cold preservation), from living donor; left lateral segment only (segments II and III)
47141	Donor hepatectomy (including cold preservation), from living donor; total left lobectomy (segments II, III and IV)
47142	Donor hepatectomy (including cold preservation), from living donor; total right lobectomy (segments V, VI, VII and VIII)
48160	Pancreatectomy, total or subtotal, with autologous transplantation of pancreas or pancreatic islet cells
48550	Donor pancreatectomy (including cold preservation), with or without duodenal segment for transplantation
48554	Transplantation of pancreatic allograft
48556	Removal of transplanted pancreatic allograft
50300	Donor nephrectomy (including cold preservation); from cadaver donor, unilateral or bilateral
50320	Donor nephrectomy (including cold preservation); open, from living donor
50340	Recipient nephrectomy (separate procedure)
50360	Renal allotransplantation, implantation of graft; without recipient nephrectomy
50365	Renal allotransplantation, implantation of graft; with recipient nephrectomy
50370	Removal of transplanted renal allograft
50380	Renal autotransplantation, reimplantation of kidney
50547	Laproscopy, surgical; donor nephrectomy (including cold preservation), from living donor

HCPCS CODES ARE FOR INFORMATIONAL PURPOSES ONLY	
HCPCS CODES	**DESCRIPTION**
S2053	Transplantation of small intestine and liver allografts
S2054	Transplantation of multivisceral organs
S2055	Harvesting of donor multivisceral organs, with preparation and maintenance of allografts; from cadaver donor
S2060	Lobar lung transplantation
S2061	Donor lobectomy (lung) for transplantation, living donor
S2065	Simultaneous pancreas kidney transplantation
S2152	Solid organ(s), complete or segmental, single organ or combination of organs; deceased or living donor(s), procurement, transplantation, and related complications; including: drugs; supplies; hospitalization with outpatient follow-up; medical/surgical, diagnostic, emergency, and rehabilitative services, and the number of days of pre- and posttransplant care in the global definition

IX. REFERENCE STATEMENT

Analyses of the scientific and clinical references cited below were conducted and utilized by the Johns Hopkins Health Plans (JHHP) Medical Policy Team during the development and implementation of this medical policy. The Medical Policy Team will continue to monitor and review any newly published clinical evidence and revise the policy and adjust the references below accordingly if deemed necessary.

X. REFERENCES

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XI. APPROVALS

Historical Effective Dates: 03/2003, 10/22/2004, 10/21/2005, 10/19/2006, 06/25/2008, 06/04/2009, 06/04/2010, 01/07/2011, 08/20/2013, 12/06/2013, 09/04/2015, 09/01/2017, 08/03/2020, 05/02/2022, 05/01/2023, 04/01/2024, 04/01/2025