

Medicare Medical Policy

Organ Transplantation

MEDICARE MEDICAL POLICY NUMBER: 279

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INSTRUCTIONS FOR USE: Company Medicare Medical Policies serve as guidance for the administration of plan benefits and do not constitute medical advice nor a guarantee of coverage. Company Medicare Medical Policies are reviewed annually to guide the coverage or non-coverage decision-making process for services or procedures in accordance with member benefit contracts (otherwise known as Evidence of Coverage or EOCs) and Centers of Medicare and Medicaid Services (CMS) policies, manuals, and other CMS rules and regulations. In the absence of a CMS coverage determination or specific regulation for a requested service, item or procedure, Company policy criteria or applicable utilization management vendor criteria may be applied. These are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

The Company reserves the right to determine the application of Medicare Medical Policies and make revisions to these policies at any time. Any conflict or variance between the EOC and Company Medical Policy will be resolved in favor of the EOC.

SCOPE: Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

PRODUCT AND BENEFIT APPLICATION

Medicare Only

MEDICARE COVERAGE CRITERIA

IMPORTANT NOTE: More than one Centers for Medicare and Medicaid Services (CMS) reference may apply to the same health care service, such as when more than one coverage policy is available (e.g., both an NCD and LCD exist). All references listed should be considered for coverage decision-making. The Company uses the most current version of a Medicare reference available at the time of publication; however, these websites are not maintained by the Company, so Medicare references and their corresponding hyperlinks may change at any time. If there is a conflict between the Company Medicare Medical Policy and CMS guidance, the CMS guidance will govern.

Notes: See Policy Guidelines below for information regarding Medicare’s approach to organ transplant coverage.

Service	Medicare Guidelines
<i>All organ transplants</i>	<p>Medicare has national coverage determinations (NCDs) related to specific transplant types, with detailed coverage criteria requirements, which are applied when relevant.</p> <p>Organ transplantation services without an NCD may still be Medicare-covered services. Medicare coverage for these transplant procedures is granted at the facility level.</p> <p>For all organ transplant types, Medicare requires services to be performed in facility with a Medicare-approved transplant program specific to the type of transplant being performed (e.g., liver transplants must be performed in a facility with a Medicare-approved liver transplant program, lung transplants must be performed in a facility with an approved lung transplant program, etc.). This requirement applies to all organ transplant services, with the exception of corneal and stem cell transplants (rendering these services in a Medicare-approved facility is sufficient, it doesn’t have to be a transplant-specific center).</p> <p>CMS-Approved Organ Transplant Programs can be found on the Quality, Certification and Oversight Reports (QCOR) web site. (Select “Resources,” found at the top of the main QCOR page and the list is a downloadable Excel spreadsheet.)</p>
<i>Liver Transplantation</i>	<ul style="list-style-type: none"> • NCD for Adult Liver Transplantation (260.1) • NCD for Pediatric Liver Transplantation (260.2)
<i>Heart Transplants</i>	NCD for Heart Transplants (260.9)
<i>Intestinal and Multivisceral Transplantation</i>	NCD for Intestinal and Multi-Visceral Transplantation (260.5)

	According to the NCD, multi-visceral transplantation includes organs in the digestive system (stomach, duodenum, pancreas, liver and intestine). Therefore, a combined transplant of these organs for intestinal failure would be subject to this NCD.
<i>Pancreas Transplant Alone</i>	NCD for Pancreas Transplants (260.3)
<i>Combined Pancreas/Kidney Transplantation</i>	
<i>Pancreas Transplant Following Kidney Transplants</i>	
<i>Pancreatic Islet Cell Transplantation</i>	NCD for Islet Cell Transplantation in the Context of a Clinical Trial (260.3.1)
<i>Kidney (Renal) Only Transplantation</i>	<p>These organ transplant services do not have specific coverage criteria; however, Medicare has some references which note clinical indications that may warrant these organ transplants:</p> <ul style="list-style-type: none"> • <u>Kidney:</u> Medicare Benefit Policy Manual, Chapter 11 - End Stage Renal Disease (ESRD), §140 - Transplantation <ul style="list-style-type: none"> ○ Medicare states kidney transplants are covered benefits, particularly for ESRD. • <u>Lung and Combined Heart/Lung:</u> Federal Register / Vol. 60, No. 22 / Thursday, February 2, 1995 Medicare Program; Criteria for Medicare Coverage of Lung Transplants (Page 6538 [or page 2 of the pdf], middle of second column) <ul style="list-style-type: none"> ○ Medicare will cover lung transplants when it is expected that transplant of the lung will result in improved cardiac function for beneficiaries with: <ul style="list-style-type: none"> ○ progressive end-stage pulmonary disease or ○ for end-stage cardiopulmonary disease. ○ Medicare will also 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 <i>both heart and lung</i> transplantation. • <u>Cornea:</u> No specific Medicare criteria, but it is a covered Medicare service, with noted billing guidance.^{10,11}
<i>Lung Only Transplantation</i>	
<i>Heart/Lung Transplantation</i>	
<i>Corneal Transplants</i>	

IMPORTANT NOTICE: While some services or items may appear medically indicated for an individual, they may also be a direct exclusion of Medicare or the member’s benefit plan. Such excluded services or items by Medicare and member EOCs include, but are not limited to, services or procedures considered to be cosmetic, not medical in nature, or those considered not medically reasonable or necessary under *Title XVIII of the Social Security Act, §1862(a)(1)(A)*. If there is uncertainty regarding coverage of a service or item, please review the member EOC or submit a pre-service organization determination request. Note that the Medicare Advance Beneficiary Notice of Noncoverage (ABN) form **cannot** be used for Medicare Advantage members. (*Medicare Advance Written Notices of Non-coverage. MLN006266 May 2021*)

- [Stem Cell Transplantation](#), MP283

The full Company portfolio of Medicare Medical Policies is available online and can be [accessed here](#).

POLICY GUIDELINES

Medicare has specific coverage criteria for some organ transplantation services which can be found in NCDs noted in the criteria table above.

However, there is not an NCD for all types of transplants, specifically for kidney (renal) transplants, lung transplants, combined heart/lung transplants, or corneal transplants. For these services, Medicare does not manage coverage criteria for these organ transplant services. Instead, coverage is approved at the facility or transplant program level. In other words, if a facility is Medicare-approved for a specific type of organ transplant, their transplant program for that same service is approved, making transplant services performed in those settings considered medically necessary. This is because established protocols developed and implemented by that Medicare-approved program would have been used for patient selection. Medicare requirements to approve a transplant program includes having adequate written patient selection criteria and an implementation plan.¹

Medicare's requirement for transplantation services to be performed in a Medicare-approved transplant program applies to all organ transplant procedures, whether they are addressed in this medical policy or not (exceptions are corneal and stem cell transplants).

NOTE: Individual transplant facilities are required by Medicare to have protocols or selection criteria which must be met in order for the member to be eligible for a transplant in their facility. Approval by the Plan does not guarantee acceptance into any specific transplant program or facility.

REGULATORY STATUS

U.S. FOOD & DRUG ADMINISTRATION (FDA)

While clearance by the Food and Drug Administration (FDA) is a prerequisite for Medicare coverage, the 510(k) premarket clearance process does not in itself establish medical necessity. Medicare payment policy is determined by the interaction of numerous requirements, including but not limited to, the availability of a Medicare benefit category and other statutory requirements, coding and pricing guidelines, as well as national and local coverage determinations and clinical evidence.

BILLING GUIDELINES AND CODING

According to Medicare, HCPCS code V2785 (*Processing, preserving and transporting corneal tissue*) should only be reported when corneal tissue is used in a corneal transplant procedure. It should not be reported in any other circumstances.¹¹

Like all S-codes, the *National Physician Fee Schedule Relative Value File (NPF SRVF)*, which is published by Medicare¹³, indicates HCPCS codes S2053-S2055 and S2152 have been assigned a Status Indicator of "I."

This is defined as “Not valid for Medicare purposes.” In addition, all HCPCS codes, including these S-codes, are not recognized as valid codes for claim submission as indicated in the relevant Company Coding Policy (*HCPCS S-Codes and H-Codes*, 22.0). Providers need to use alternate available CPT or HCPCS codes to report for the service. If no specific CPT or HCPCS code is available, then an unlisted code may be used. Note that unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. Thus, if an unlisted code is billed related to a non-covered service addressed in this policy, it will be denied as not covered

CODES*		
CPT	0494T	Surgical preparation and cannulation of marginal (extended) cadaver donor lung(s) to ex vivo organ perfusion system, including decannulation, separation from the perfusion system, and cold preservation of the allograft prior to implantation, when performed
	0495T	Initiation and monitoring marginal (extended) cadaver donor lung(s) organ perfusion system by physician or qualified health care professional, including physiological and laboratory assessment (eg, pulmonary artery flow, pulmonary artery pressure, left atrial pressure, pulmonary vascular resistance, mean/peak and plateau airway pressure, dynamic compliance and perfusate gas analysis), including bronchoscopy and X ray when performed; first two hours in sterile field
	0496T	Initiation and monitoring marginal (extended) cadaver donor lung(s) organ perfusion system by physician or qualified health care professional, including physiological and laboratory assessment (eg, pulmonary artery flow, pulmonary artery pressure, left atrial pressure, pulmonary vascular resistance, mean/peak and plateau airway pressure, dynamic compliance and perfusate gas analysis), including bronchoscopy and X ray when performed; each additional hour (List separately in addition to code for primary procedure)
	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
	32855	Backbench standard preparation of cadaver donor lung allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to prepare pulmonary venous/atrial cuff, pulmonary artery, and bronchus; unilateral
	32856	Backbench standard preparation of cadaver donor lung allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to prepare pulmonary venous/atrial cuff, pulmonary artery, and bronchus; bilateral
	33929	Removal of a total replacement heart system (artificial heart) for heart transplantation (List separately in addition to code for primary procedure)
	33930	Donor cardiectomy-pneumonectomy (including cold preservation)
	33933	Backbench standard preparation of cadaver donor heart/lung allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to prepare aorta, superior vena cava, inferior vena cava, and trachea for implantation
	33935	Heart-lung transplant with recipient cardiectomy-pneumonectomy
	33940	Donor cardiectomy (including cold preservation)
	33944	Backbench standard preparation of cadaver donor heart allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to

		prepare aorta, superior vena cava, inferior vena cava, pulmonary artery, and left atrium for implantation
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
44715		Backbench standard preparation of cadaver or living donor intestine allograft prior to transplantation, including mobilization and fashioning of the superior mesenteric artery and vein
44720		Backbench reconstruction of cadaver or living donor intestine allograft prior to transplantation; venous anastomosis, each
44721		Backbench reconstruction of cadaver or living donor intestine allograft prior to transplantation; arterial anastomosis, each
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)
47143		Backbench standard preparation of cadaver donor whole liver graft prior to allotransplantation, including cholecystectomy, if necessary, and dissection and removal of surrounding soft tissues to prepare the vena cava, portal vein, hepatic artery, and common bile duct for implantation; without trisegment or lobe split
47144		Backbench standard preparation of cadaver donor whole liver graft prior to allotransplantation, including cholecystectomy, if necessary, and dissection and removal of surrounding soft tissues to prepare the vena cava, portal vein, hepatic artery, and common bile duct for implantation; with trisegment split of whole liver graft into 2 partial liver grafts (ie, left lateral segment [segments II and III] and right trisegment [segments I and IV through VIII])
47145		Backbench standard preparation of cadaver donor whole liver graft prior to allotransplantation, including cholecystectomy, if necessary, and dissection and removal of surrounding soft tissues to prepare the vena cava, portal vein, hepatic artery, and common bile duct for implantation; with lobe split of whole liver graft into 2 partial liver grafts (i.e., left lobe (segments II, III, and IV) and right lobe (segments I, V through VIII))
47146		Backbench reconstruction of cadaver or living donor liver graft prior to allotransplantation; venous anastomosis, each
47147		Backbench reconstruction of cadaver or living donor liver graft prior to allotransplantation; arterial anastomosis, each
48550		Donor pancreatectomy (including cold preservation), with or without duodenal segment for transplantation
48551		Backbench standard preparation of cadaver donor pancreas allograft prior to transplantation, including dissection of allograft from surrounding soft tissues, splenectomy, duodenotomy, ligation of bile duct, ligation of mesenteric vessels, and Y-graft arterial anastomoses from iliac artery to superior mesenteric artery and to splenic artery

	48552	Backbench reconstruction of cadaver donor pancreas allograft prior to transplantation, venous anastomosis, each
	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
	50323	Backbench standard preparation of cadaver donor renal allograft prior to transplantation, including dissection and removal of perinephric fat, diaphragmatic and retroperitoneal attachments, excision of adrenal gland, and preparation of ureter(s), renal vein(s), and renal artery(s), ligating branches, as necessary
	50325	Backbench standard preparation of living donor renal allograft (open or laparoscopic) prior to transplantation, including dissection and removal of perinephric fat and preparation of ureter(s), renal vein(s), and renal artery(s), ligating branches, as necessary
	50327	Backbench reconstruction of cadaver or living donor renal allograft prior to transplantation; venous anastomosis, each
	50328	Backbench reconstruction of cadaver or living donor renal allograft prior to transplantation; arterial anastomosis, each
	50329	Backbench reconstruction of cadaver or living donor renal allograft prior to transplantation; ureteral anastomosis, each
	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
	50547	Laparoscopy, surgical; donor nephrectomy (including cold preservation), from living donor
	65710	Keratoplasty (corneal transplant); anterior lamellar
	65730	Keratoplasty (corneal transplant); penetrating (except in aphakia or pseudophakia)
	65750	Keratoplasty (corneal transplant); penetrating (in aphakia)
	65755	Keratoplasty (corneal transplant); penetrating (in pseudophakia)
	65756	Keratoplasty (corneal transplant); endothelial
	65757	Backbench preparation of corneal endothelial allograft prior to transplantation (List separately in addition to code for primary procedure)
	65767	Epikeratoplasty
HCPCS	S2053	Transplantation of small intestine, and liver allografts <i>(CMS-assigned Status "I" code – See above billing guidelines)</i>
	S2054	Transplantation of multivisceral organs <i>(CMS-assigned Status "I" code – See above billing guidelines)</i>
	S2055	Harvesting of donor multivisceral organs, with preparation and maintenance of allografts; from cadaver donor <i>(CMS-assigned Status "I" code – See above billing guidelines)</i>
	S2152	Solid organs(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 <i>(Not valid for Medicare use)</i>
	V2785	Processing, preserving and transporting corneal tissue

***Coding Notes:**

- The code list above is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit. According to Medicare, “presence of a payment amount in the MPFS and the Medicare physician fee schedule database (MPFSDB) does not imply that CMS has determined that the service may be covered by Medicare.” The issuance of a CPT or HCPCS code or the provision of a payment or fee amount by Medicare does **not** make a procedure medically reasonable or necessary or a covered benefit by Medicare. (*Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, §30 - Services Paid Under the Medicare Physician’s Fee Schedule, A. Physician’s Services*)
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company [Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website](#) for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as “medically unlikely edits” (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCES

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2. Medicare web page for *Transplant*; Last Updated: 12/1/2021; Available at: <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Transplant-Laws-and-Regulations>. Accessed 11/29/2022.
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4. Medicare Claims Processing Manual, Chapter 3 - Inpatient Hospital Billing, § 90.4 - Liver Transplants; Last Updated: 09/2021; Available at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf>. Accessed 11/29/2022.
5. Medicare Claims Processing Manual, Chapter 3 - Inpatient Hospital Billing, §90.2 - Heart Transplants; Last Updated: 09/2014; Available at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf>. Accessed 11/29/2022.
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9. Medicare Claims Processing Manual, Chapter 3 - Inpatient Hospital Billing, §90.1 - Kidney Transplant - General; Last Updated: 10/2007; Available at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf>. Accessed 11/29/2022.
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11. Medicare Change Request (CR) 9484; Dated 12/29/2015; Available at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3430CP.pdf>. Accessed 11/29/2022
12. Medicare *Transplant* web page. Last Updated: 12/1/2021. <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandCompliance/Transplant>. Accessed 11/29/2022
13. Medicare Physician Fee Schedule (PFS) Relative Value Files; Available at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Relative-Value-Files>

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
2/2023	Annual review, no changes. Converted to new policy template.