



Guidelines for Medical Necessity Determination for Organ Transplant Procedures

This edition of the Guidelines for Medical Necessity Determination (Guidelines) identifies the clinical information MassHealth needs to determine medical necessity for the transplant procedures identified in Section I of these Guidelines. These Guidelines are based on generally accepted standards of practice, review of the medical literature, and federal and state policies and laws applicable to Medicaid programs.

Providers should consult MassHealth regulations at [130 CMR 433.000: *Physician Services*](#) and [130 CMR 450.000: *Administrative and Billing Regulations*](#) and [Subchapter 6 of the *Physician Manual*](#) for information about coverage, limitations, service conditions, and other prior-authorization (PA) requirements.

Providers serving members enrolled in a MassHealth-contracted accountable care partnership plan (ACPP), Managed Care Organization (MCO), One Care organization, Senior Care Organization (SCO), or Program of All-inclusive Care for the Elderly (PACE) should refer to the ACPP's, MCO's, One Care Organization's, SCO's, or PACE's medical policies, respectively, for covered services.

MassHealth reviews requests for PA on the basis of medical necessity. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including member eligibility, other insurance, out-of-state services, and other program restrictions.

SECTION I. GENERAL INFORMATION

1

Transplants are procedures that transfer living tissue or organs from one area of the body to another area of the same body, or from a donor to a recipient, for the purpose of maintaining functional integrity of tissue or organs in the recipient. Such procedures are used to treat life-threatening complications resulting from end-stage organ diseases and malignant or non-malignant conditions. These Guidelines apply to the following single- or double-organ transplants: liver, heart, lung, pancreas, and small bowel.

SECTION II. CLINICAL GUIDELINES

2

A. CLINICAL COVERAGE

MassHealth bases its determination of medical necessity for these organ transplant procedures on a combination of clinical data and the presence of indicators that would complicate surgery, affect postoperative recovery, and otherwise affect the relative risks and benefits of the surgery for the patient. 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 MassHealth-enrolled facility that is certified by the United Network of Organ Sharing (UNOS) for adult transplants, and, for pediatric transplants, is in compliance with pediatric component qualification standards set forth by the Organ Procurement and Transplantation Network (OPTN).

The member must meet the transplanting institution's selection criteria. Transplant center criteria must 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). Criteria and scoring systems involving estimated glomerular filtration rate must be race neutral.

Transplants may be medically necessary to treat end-stage organ failure caused by a variety of conditions, including, but not limited to:

- congenital maldevelopment;
- failure of a vital organ function;
- trauma or toxic insult;
- viral or other infection; or
- primary malignancy.

Submissions from a qualified transplant center will be reviewed for medical necessity. Follow the link to locate a qualified transplant center: <https://optn.transplant.hrsa.gov/about/search-membership/>.

B. NONCOVERAGE

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. The member has an uncontrolled HIV infection, defined as:
 - a. CD4 count greater than 200 cells/mm³ at any time during the past 6 months; or
 - b. has not been on stable anti-viral therapy for at least 3 months; or
 - c. presently has other complications from AIDS, such as opportunistic infections (e.g., aspergillus, tuberculosis, coccidioidomycosis, resistant fungal infections) or neoplasms (e.g., Kaposi's sarcoma, non-Hodgkin's lymphoma).
4. 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.
5. The member has irreversible disease that significantly impairs or limits quality or duration of life.

3

SECTION III. SUBMITTING CLINICAL DOCUMENTATION

- A. Requests for PA of these organ transplants must be submitted by a surgeon who is a MassHealth provider practicing at one of the qualified transplant centers. Requests for PA must include the following:
1. documentation of the qualified transplant center's selection criteria; and
 2. the clinical rationale for why the member meets such selection criteria, including any supporting documentation.
- B. For out-of-state requests, the PA submission must include the following:
1. documentation of the transplant centers' selection criteria;
 2. the clinical rationale for why the member meets such selection criteria;
 3. the reason that the transplant cannot be performed in-state; and
 4. information identifying which in-state facility will assume postoperative and ongoing medical care of the patient when the patient is determined to be stable by both the in-state transplant specialist and the out-of-state facility.
- C. Clinical information must be submitted by the surgeon who will be performing the transplant.
- D. Providers must electronically submit PA requests and all supporting documentation using the Provider Online Service Center (POSC), unless the provider has a currently approved electronic claims waiver (hereinafter, "waiver"). Please see [All Provider Bulletin 369](#) for further waiver information. Questions about POSC access should be directed to the MassHealth Customer Service Center at (800) 841-2900, TDD/TTY: 711.

For PA requests that are not submitted using the POSC, providers with currently approved waivers must include the MassHealth Prior Authorization Request (PA-1 Form) and all supporting documentation. The PA-1 Form can be found at mass.gov/prior-authorization-for-masshealth-providers.

Select References

1. American Society of Transplantation Guidelines and Opinions accessed on April 2019 at <https://www.myast.org/education/guidelines-and-opinions>.
2. Bramis K, Gordon-Weeks AN, Friend PJ, et al. [Systematic review of total pancreatectomy and islet autotransplantation for chronic pancreatitis](#). Br J Surg. 2012;99(6):761-766.
3. Dong M, Parsaik AK, Erwin PJ, et al. [Systematic review and meta-analysis: Islet autotransplantation after pancreatectomy for minimizing diabetes](#). Clin Endocrinol. 2011;75(6):771-779.
4. Harper SJE, Jamieson NV. Intestinal and multivisceral transplantation. Surgery (Oxford). 2014;32(7):377-382.
5. Martin P, DiMartini A, Feng S, et al. [Evaluation for liver transplantation in adults: 2013 practice guideline by the American Association for the Study of Liver Diseases and the American Society of Transplantation](#). Hepatology 2014;59:1144.

6. 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. *Journal of Heart Lung Transplant*. 2016 Jan;35(1):1-23. doi: 10.1016/j.healun.2015.10.023. Available at http://www.jhltonline.org/pb/assets/raw/Health%20Advance/journals/healun/ISHLT_GUIDELINE.pdf.
7. Organ Procurement and Transplantation Network Policies. Available at <https://optn.transplant.hrsa.gov/>. Accessed April 2019.
8. United Network for Organ Sharing (UNOS): Organ Allocation Policies. Available at <https://unos.org/policy/>. Accessed April 2019.
9. Weill D, Benden C, Corris PA, Dark JH, Davis RD, Keshavjee S, Lederer DJ, Mulligan MJ, Patterson GA, Singer LG, Snell GI, Verleden GM, Zamora MR, Glanville AR. [A consensus document for the selection of lung transplant candidates: 2014—an update from the Pulmonary Transplantation Council of the International Society for Heart and Lung Transplantation](#). *J Heart Lung Transplant*. 2015 Jan;34(1):1-15. doi: 10.1016/j.healun.2014.06.014.

These Guidelines are based on review of the medical literature and current practice in organ transplant surgery. MassHealth reserves the right to review and update the contents of these Guidelines and cited references as new clinical evidence and medical technology emerge.

This document was prepared for medical professionals to assist them in submitting documentation supporting the medical necessity of the proposed treatment, products, or services. Some language used in this communication may be unfamiliar to other readers; in this case, they should contact their health care provider for guidance or explanation.

Policy Revision Effective Date: October 3, 2023

Approved by: _____



Jatin K. Dave, MD, MPH
Chief Medical Officer, MassHealth

Policy Effective Date: July 3, 2019