



# Guidelines for Medical Necessity Determination for Organ Transplant Procedures

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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), integrated care organization (ICO), senior care organization (SCO), or program of all-inclusive care for the elderly (PACE) should refer to the ACPP's, MCO's, ICO's, SCO's, or PACE's medical policies 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.

## 1

### SECTION I. GENERAL INFORMATION

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.

## 2

### SECTION II. CLINICAL GUIDELINES

#### 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 should 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.)

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.

## **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. 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.
4. The member has an active substance use disorder, or uses substances that are illicit or contraindicated.
5. The member has irreversible disease that significantly impairs or limits quality or duration of life.
6. The member has psychological or social conditions that make the member unable or unlikely to be able to actively participate in the disciplined medical regimens required by transplantation.
7. Current non-adherence to medical therapy or a history of repeated or prolonged episodes of non-adherence to medical therapy that are perceived to increase the risk of non-adherence after transplantation.

# 3

## SECTION III. SUBMITTING CLINICAL DOCUMENTATION

Requests for PA of these organ transplants must be submitted by a surgeon who is a MassHealth provider, and accompanied by clinical documentation that supports the medical necessity for the procedure being requested. Providers are strongly encouraged to submit PA requests electronically. Providers must submit a package of information that includes the PA request and all of the following.

- A. Clinical note(s) or letter that documents the medical necessity of the procedure from the relevant transplant surgeon, team, or specialist (for example, cardiothoracic surgeon for heart) describing the need for the transplant procedure being requested.
- B. A summary of the member's medical history that includes
  1. the primary diagnosis name and ICD-CM code specific to the condition requiring the transplant;
  2. the date the member was diagnosed with the medical condition requiring the transplant;
  3. the past treatment course and current plan of care; and
  4. the listing date and UNOS status assigned (only if urgent/priority assignment) for the organ to be transplanted.
- C. Documentation of recent clinical evaluations that include all of the following.
  1. **DIAGNOSTIC STUDIES AND LABORATORY TESTS**—results of studies and tests deemed relevant to the type of transplant being requested that have been conducted in the last year;
  2. **MEDICATION REGIMEN**—the type and name of prescription and over-the-counter drugs the member has received within the last three to six months;
  3. **RISK FACTORS**—description of all current medical or comorbid conditions (e.g., neurologic disease, obesity, cardiovascular disease, diabetes, HIV), surgeries or procedures, functional status, or cognitive function that may contraindicate the proposed transplant procedure or may impact postoperative recovery. Documentation of risk factors must also include
    - a. **PAST AND PRESENT SUBSTANCE MISUSE** (e.g., alcohol, tobacco, marijuana, opiates, cocaine), including date or period of time since last use. Serial blood and urine testing can be used to verify abstinence from substances that are of concern;
    - b. **ACTIVE TOBACCO USE** is an absolute contraindication for some transplants (e.g. heart, lung [ISLD, 2016]) and has been shown to be related to increased post-operative complications. Poorer clinical outcomes in smokers have made it a relative contraindication in many organ transplant guidelines. The transplant team must address and document tobacco-cessation efforts, including testing for abstinence, if clinically indicated; and
    - c. any other non-coverage circumstances listed in **SECTION II.B.** above;
  4. **PSYCHIATRIC ASSESSMENT**—a statement from the transplant team's psychiatric clinician (psychiatrist or psychologist) that includes information on the member's mental status, history and screening of alcohol or drug use with a statement attesting to a period of abstinence, the psychiatric clinician's expectation that the member will adhere to a disciplined medical regimen, and other issues that may affect postoperative recovery;

5. **PSYCHOSOCIAL EVALUATION**—a statement from the transplant team’s coordinator or social worker that includes information on the member’s social support system, household living status, work history, and list of caregivers available to assist with care plan requirements; and
  6. **CARE PLAN**—a summary of the follow-up care plan to manage and monitor postoperative recovery for medical complications, pharmacological therapy, nutritional support, social support, and other pertinent information, including a list of providers (individuals and facilities) responsible for providing and monitoring the care plan.
- D. A list of the transplant team members (e.g., transplant specialist and psychiatrist/psychologist) involved in determining whether the member is eligible for the proposed transplant procedure(s), including the names and contact information for in-state and out-of-state providers; and
  - E. For out-of-state requests, the PA submission must include the reason that the transplant cannot be performed in-state, and 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.
  - F. Clinical information must be submitted by the surgeon who will be performing the transplant. *Providers are strongly encouraged to submit requests electronically.* Providers must submit the request for PA and all supporting documentation using the [Provider Online Service Center \(POSC\)](#), or by completing a MassHealth Prior Authorization Request form (using the PA-1 paper form found at [www.mass.gov/masshealth](http://www.mass.gov/masshealth)) and attaching all supporting documentation. The PA-1 form and documentation should be mailed to the address on the back of the form. Questions about the POSC access should be directed to the MassHealth Customer Service Center at (800) 841-2900.

## Select References

1. American Society of Transplantation Guidelines accessed on April 2019 at <https://www.myast.org/education/guidelines-and-opinions>.
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8. United Network for Organ Sharing (UNOS): Organ Allocation Policies. Available at [www.unos.org](http://www.unos.org). 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.

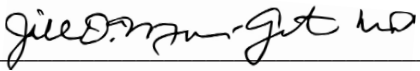
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These Guidelines are based on review of the medical literature and current practice in organ transplant surgery. MassHealth reserves the right to review and update the contents of these Guidelines and cited references as new clinical evidence and medical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

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Approved by:

  
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