

MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES

NOTICE OF PROPOSED POLICY

Public Act 280 of 1939, as amended, and consultation guidelines for Medicaid policy provide an opportunity to review proposed changes in Medicaid policies and procedures.

Please review the policy summary and the attached materials that describe the specific changes being proposed. Let us know why you support the change or oppose the change.

Submit your comments to the analyst by the due date specified. Your comments must be received by the due date to be considered for the final policy bulletin.

Thank you for participating in the consultation process.



Director, Program Policy Division  
Bureau of Medicaid Policy, Operations, and Actuarial Services

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|--------------------------------------|---------------------------------------|--|
| <b>Project Number:</b> 2227-Hospital | <b>Comments Due:</b> October 24, 2022 | <b>Proposed Effective Date:</b> December 1, 2022 |
|--------------------------------------|---------------------------------------|--|

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**Policy Subject:** Organ and Tissue Transplant Services

**Affected Programs:** Medicaid, Healthy Michigan Plan, Children's Special Health Care Services, MI Health Link

**Distribution:** All Providers

**Policy Summary:** This bulletin provides updated policy for organ and tissue transplant services. The policy includes general requirements, coverages, organ-specific requirements, prior authorization, donors, and transportation and lodging.

**Purpose:** Policy for organ transplants was not consistent with current and evolving practices in this field. Associated State Plan language was out-of-date and has been reduced and revised. The majority of policy that existed in the State Plan is being transitioned to the Medicaid Provider Manual.

# Proposed Policy Draft

Michigan Department of Health and Human Services  
Behavioral and Physical Health and Aging Services Administration

**Distribution:** All Providers

**Issued:** November 1, 2022 (proposed)

**Subject:** Organ and Tissue Transplant Services

**Effective:** December 1, 2022 (proposed)

**Programs Affected:** Medicaid, Healthy Michigan Plan, Children's Special Health Care Services, MI Health Link

The purpose of this bulletin is to update Medicaid policy for the coverage of medically-necessary organ and tissue transplant services. Organ and tissue transplant services are covered when the transplant is likely to prolong life and restore a range of physical and social function to activities of daily living. All other medical and surgical therapies expected to affect short- and long-term survival must have been tried or considered.

## **Coverage Criteria**

For purposes of this coverage, the term 'organ' is defined as kidney, liver, heart, lung, pancreas, intestine (including the esophagus, stomach, small and/or large intestine, or any portion of the gastrointestinal tract), any vascularized composite allograft, or other organ defined in the National Organ Transplant Act of 1984, as amended, and hematopoietic stem/poietic stem/progenitor cells, cornea, bone and skin. The following criteria must be satisfied for the coverage of organ transplant services:

- Transplant services meet the requirements of Section 1138(B) of the Social Security Act, hospital protocols for organ procurement, Food and Drug Administration regulations, and standards for organ procurement agencies and transplant services as defined under State law where applicable.
- In making the selection of beneficiaries undergoing the transplant procedure, similarly-situated individuals are treated alike.
- Transplant services must be reasonable in their amount, duration, and scope to achieve their purpose.

Organ and tissue transplant services, including inpatient and outpatient, pre- and post-operative medical, surgical, hospital, physician, behavioral health, and related transportation services, are covered for eligible beneficiaries when medically necessary.

Covered services include:

- Pre-operative care, including required dental services to facilitate appropriate perioral health and hygiene
- Transplant care, including facility and professional fees
- Organ procurement fees, including donor fees
- Post-transplant care, including immunosuppressant drugs
- Psychological assessment
- Living donor expenses provided throughout the procurement process.

### **General Requirements for Transplant Programs**

Transplant services for organs defined in the National Organ Transplant Act of 1984, as amended, must be provided in a facility:

- That is a member of the Organ Procurement and Transplantation Network (OPTN) where applicable to the transplanted organ.
- For heart, lung, liver, and bone marrow transplants, has a current and approved Michigan Certificate of Need.

### **Organ Specific Criteria**

The following organ-specific criteria lists program and prior authorization requirements. Other organ transplants may be covered with prior authorization on an individual basis when the services performed are evidence-based and provided within generally accepted standards of medical practice. Combination of multiple organ transplantations will be considered on an individual basis and requires prior authorization.

NOTE: Medicaid Health Plans and Integrated Care Organizations may develop prior authorization requirements, utilization management, and review criteria that differ from Medicaid requirements. Beneficiaries who are enrolled in a Medicaid Health Plan or Integrated Care Organization must follow the plan’s prior authorization (PA) procedures to obtain approval for organ transplants.

| <b>Organ</b>   | <b>Medical Necessity Criteria</b>   | <b>Approval Duration</b>  | <b>Required Documentation</b>  |
|--|---|---|--|
| Heart<br><br>(May be done in combination with lung transplant) | End-stage heart disease not remediable by more conservative measures and amenable to surgical intervention, and diagnoses for which transplant provides best therapeutic potential. | <ul style="list-style-type: none"> <li>• Initial authorization: 1 year</li> <li>• Continuation of Authorization: as needed</li> </ul> | <ul style="list-style-type: none"> <li>• Completed, signed, and dated Practitioner Special Services Prior Approval – Request/Authorization (<a href="#">MSA-6544-B</a>) form. If submitting electronically via direct data entry in the Community Health Automated Medicaid Processing System</li> </ul> |

| Organ   | Medical Necessity Criteria   | Approval Duration   | Required Documentation   |
|---|--|---|--|
|   |  |   | <p>(CHAMPS), this PA request form is not required.</p> <ul style="list-style-type: none"> <li>• Medical documentation with ejection fraction and recommendation for transplant completed by a cardiologist, transplant surgeon/team</li> <li>• Psychosocial assessment</li> <li>• Approval letter from transplant team/committee</li> </ul>  |
| <p>Lung<br/><br/>(May be done in combination with heart transplant)</p> | <p>Pulmonary disease not remediable by more conservative measures and amenable to surgical intervention, for which transplant provides best therapeutic potential.</p>                     | <ul style="list-style-type: none"> <li>• Initial authorization: 1 year</li> <li>• Continuation of Authorization: as needed</li> </ul> | <ul style="list-style-type: none"> <li>• Completed, signed, and dated <a href="#">MSA-6544-B</a> form. If submitting electronically via direct data entry in CHAMPS, this PA request form is not required.</li> <li>• Medical documentation, including recommendation for transplant completed by a pulmonologist, transplant surgeon/team</li> <li>• Psychosocial assessment</li> <li>• Approval letter from transplant team/committee</li> </ul> |
| <p>Kidney</p>   | <p>End-stage renal disease not remediable by more conservative measures and amenable to surgical intervention, and diagnoses for which transplant provides best therapeutic potential.</p> | <p>Does not require prior authorization</p>   | <p>Documentation to be maintained in the beneficiary's medical record:</p> <ul style="list-style-type: none"> <li>• Assessment and recommendations of suitability for transplantation completed by a nephrologist, transplant surgeon/team</li> <li>• Psychosocial assessment</li> </ul>   |

| Organ    | Medical Necessity Criteria   | Approval Duration  | Required Documentation  |
|----------|--|--|---|
| Liver    | <p>Liver disease not remediable by more conservative measures and amenable to surgical intervention, for which transplant provides best therapeutic potential.</p> <p>Split-liver living donor transplant will be considered in appropriate circumstances.</p> | <ul style="list-style-type: none"> <li>• Initial authorization: 1 year</li> <li>• Continuation of Authorization: as needed</li> </ul>  | <ul style="list-style-type: none"> <li>• Completed, signed, and dated <a href="#">MSA 6544-B form</a>. If submitting electronically via direct data entry in CHAMPS, this PA request form is not required.</li> <li>• Medical documentation including Model for End-Stage Liver Disease (MELD) score (&gt;12 years of age); Pediatric End-Stage Liver Disease (PELD) score (for &lt;12 years of age) and recommendation for transplant completed by a hepatologist, transplant surgeon/team</li> <li>• Psychosocial assessment</li> <li>• Approval letter from transplant team/committee</li> </ul> |
| Pancreas | <p>Pancreatic disease/failure not remediable by more conservative measures and amenable to surgical intervention for which transplant provides the best therapeutic potential.</p>   | <ul style="list-style-type: none"> <li>• Initial authorization: 1 year</li> <li>• Continuation of authorization: Request extended prior authorization as needed, and submitted with: <ul style="list-style-type: none"> <li>○ Updated medical documentation</li> <li>○ Updated psychological/social work assessment</li> </ul> </li> </ul> | <ul style="list-style-type: none"> <li>• Completed, signed, and dated <a href="#">MSA-6544-B form</a>. If submitting electronically via direct data entry in CHAMPS, this PA request form is not required.</li> <li>• Medical documentation, including recommendation for transplant completed by an endocrinologist, gastroenterologist, transplant surgeon/team</li> <li>• Psychosocial assessment</li> <li>• Approval letter from transplant team/committee</li> </ul>   |

| Organ                               | Medical Necessity Criteria  | Approval Duration  | Required Documentation  |
|-------------------------------------|---|--|---|
| Bone Marrow/Hematopoietic Stem Cell | Hematopoietic, bone marrow proliferative, or other diseases not remediable by more conservative measures and amenable to transplant intervention, and diagnoses for which transplant provides best therapeutic potential. | <ul style="list-style-type: none"> <li>• Initial authorization: 1 year</li> <li>• Continuation of authorization: Request extended prior authorization as needed, and submitted with:               <ul style="list-style-type: none"> <li>○ Updated medical documentation</li> <li>○ Updated psychological/social work assessment</li> </ul> </li> </ul> | <ul style="list-style-type: none"> <li>• Completed, signed, and dated <a href="#">MSA-6544-B</a> form. If submitting electronically via direct data entry in CHAMPS, this PA request form is not required.</li> <li>• Medical documentation, including recommendation for transplant completed by a hematologist, metabolic geneticist, oncologist, transplant surgeon/team</li> <li>• Psychosocial assessment</li> <li>• Approval letter from transplant team/committee</li> </ul> |
| Cornea                              | Corneal disease or trauma not remediable by more conservative measures and amenable to surgical intervention, and diagnoses for which transplant provides best therapeutic potential.                                     | Does not require prior authorization   | <p>Documentation to be maintained in the beneficiary's medical record:</p> <ul style="list-style-type: none"> <li>• Assessment and recommendations of suitability for transplantation completed by an ophthalmologist, transplant surgeon/team</li> <li>• Psychosocial assessment</li> </ul>  |

| Organ     | Medical Necessity Criteria   | Approval Duration  | Required Documentation   |
|-----------|--|--|--|
| Intestine | Intestinal disease not remediable by more conservative measures and amenable to surgical intervention, and diagnoses for which transplant provides the best therapeutic potential. | <ul style="list-style-type: none"> <li>• Initial authorization: 1 year</li> <li>• Continuation of authorization: Request extended prior authorization as needed, and submitted with:               <ul style="list-style-type: none"> <li>○ Updated medical documentation</li> <li>○ Updated psychological/social work assessment</li> </ul> </li> </ul> | <ul style="list-style-type: none"> <li>• Completed, signed, and dated <a href="#">MSA-6544-B</a> form. If submitting electronically via direct data entry in CHAMPS, this PA request form is not required.</li> <li>• Medical documentation, including recommendation for transplant completed by a gastroenterologist, intestinal transplant surgeon/team</li> <li>• Psychosocial assessment</li> <li>• Approval letter from transplant team/committee</li> </ul> |

**Prior Authorization**

Prior authorization (PA) is required for beneficiary, donor, and potential donor services related to all organ transplants except cornea and kidney transplants. If transplantation of additional organ(s) is to occur during the same operative session as a cornea or kidney transplant, PA is required.

PA for transplant services, where applicable, is reviewed on a case-by-case basis. Approval is based on critical medical need for transplantation and a maximum likelihood of successful clinical outcomes with consideration for the following:

- All other medical and surgical therapies that might be expected to affect short- and long-term survival must have been tried or considered.
- The beneficiary is not in an irreversible terminal state and the transplant is likely to prolong life and or restore a range of physical and social function to activities of daily living.

If the transplant occurs at a Medicaid-enrolled, in-state hospital, only the transplant services require PA. If the transplant is to be performed at an out-of-state hospital, both the psychosocial assessment and the transplant must be separately prior authorized. In the event the organ transplantation is unable to be secured within the prior authorized timeframe, a request for continued authorization may be submitted and must include updated documentation. A Prior Authorization Certification Evaluation Review (PACER) for the hospital admission is still required per current policy. (Refer to the Hospital chapter of the [MDHHS Medicaid Provider Manual](#) for more information.)

## **A. Psychosocial Assessment**

For those transplants requiring PA, prior to the organ transplant, the beneficiary must have a psychosocial assessment at a qualified transplant center. The assessment is conducted to assist in determining a beneficiary's psychological and social readiness for the demands and stresses associated with transplant surgery, recovery, and rehabilitation. When the psychosocial assessment indicates the beneficiary may require additional supports to overcome perceived or identified challenges during the transplant process, MDHHS will require additional information to determine the beneficiary's ability to successfully achieve the necessary treatment and healthcare requirements pre-/post-transplant.

If the center determines the beneficiary is a transplant candidate, the attending physician must submit the results from the psychosocial assessment and medical evaluation with the PA request to the MDHHS Program Review Division for evaluation by the Office of Medical Affairs (OMA). Requests for beneficiaries with Children's Special Health Care Services (CSHCS)-only coverage must also be submitted to the Program Review Division.

(Refer to the General Information for Providers Chapter, Children's Special Health Care Services Chapter, and the Directory Appendix of the Medicaid Provider Manual for additional language and webpage location of Fee-for-Service Medicaid Prior Authorization Organ Transplant Criteria.)

## **B. Third Party Liability (or Coordination of Benefits)**

PA is not required if Medicare makes payment and Medicaid liability is limited to coinsurance and deductible. If a Medicare application is pending, the provider must indicate that on the PA request and notify MDHHS when the determination is made. All other insurance resources must be exhausted before Medicaid is billed. The denial notice(s) must be submitted with the claim. (Refer to the Coordination of Benefits chapter of the Medicaid Provider Manual for additional policy on other insurance.)

## **Donor and Donor Search**

Medically necessary expenses incurred by a Medicaid-eligible or non-eligible living donor that are directly associated with a Medicaid-covered transplant may be covered. The donor must exhaust all possible insurance sources before Medicaid is billed for the services.

Covered services include:

- Evaluation to determine if the person is a candidate for living donation
- Donation surgery
- Post-operative care through the procurement process
- Transportation and lodging for related medical services
- Paired organ donation



Expenses incurred for complications that arise with respect to the donor are covered only if they are directly and immediately attributed to the organ transplant surgery. Should the Medicaid-covered beneficiary expire or loses Medicaid eligibility, donor services will continue to be covered.

When the donor search does not result in an organ acquisition and transplant, MDHHS reimburses for a donor search and related charges when billed as an outpatient service. Providers are required to submit a copy of the PA letter for the transplant with the claim and include a comment on the claim that the donor search was unsuccessful.

### **Medicaid Organ Donor for Non-Medicaid Recipient**

When a Medicaid beneficiary is an organ donor for a non-Medicaid enrolled recipient, the acquisition of the organ is the responsibility of the recipient's health insurance. (Refer to the Billing & Reimbursement chapters of the Medicaid Provider Manual for additional billing information.)

### **Transportation and Lodging**

MDHHS reimburses for transportation and lodging expenses associated with the evaluation and transplant for the qualified organ recipient and one accompanying individual (e.g., spouse, parent, guardian).

(Refer to the Non-Emergency Medical Transportation [NEMT] chapter of the Medicaid Provider Manual for further information.)