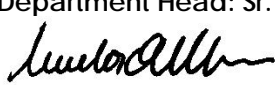
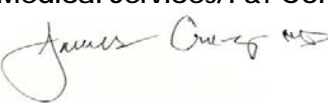


Policy Title: Major Organ Transplant		POLICY #: 10.2.14	
		Line of business: Medi-Cal	
Department Name: Utilization Management	Original Date 11/97	Effective Date 5/19, 9/21, 1/22	Revision Date 12/18, 8/21/ 11/21
Department Head: Sr. Director, UM 			Date: 12/21
Medical Services/P&T Committee: (If Applicable) 			Date: 12/21

PURPOSE

Effective January 1, 2022, Blue Shield of California Promise (Blue Shield Promise) is required to cover the Major Organ Transplant (MOT) benefit for adult and pediatric transplant recipients and donors, including related services such as organ procurement and living donor care.

Blue Shield Promise will refer, coordinate, and authorize the delivery of the MOT benefit and all medically necessary services associated with MOTs for both living donors and cadaver organ transplants, including but not limited to:

- Pre-transplantation assessments and appointments
- Organ procurement costs
- Hospitalization
- Surgery
- Discharge planning
- Readmissions from complications
- Post-operative services
- Medications
- Care coordination

POLICY

Blue Shield Promise will cover all medically necessary services for both living donors and cadaver organ transplants as outlined in the Medi-Cal Provider Manual, including all updates and amendments to the Provider Manual.

Blue Shield will only authorize MOTs to be performed in approved transplant programs located within a Medi-Cal approved Center of Excellence (COE) or hospital that meets the Department of Health Care Services' (DHCS) criteria.

All covered benefits related to the following major organs will be provided for at a Medi-Cal approved COE:

- Bone marrow
- Heart
- Heart-lung
- Kidney
- Liver
- Pancreas

- Small bowel
 - Combined liver and small bowel
 - Lung
 - Simultaneous kidney-pancreas
1. Kidney, corneal, and autologous islet cell transplants are not required to be performed in a COE or a Special Care Center (SCC). For these organs, Blue Shield Promise will refer members to a transplant program that is approved by Centers for Medicare and Medicaid Services (CMS) to perform transplants for the respective organ and is a current Organ Procurement and Transplantation Network (OPTN) member.
 2. Blue Shield Promise will authorize appropriate non-emergency medical transportation, non-medical transportation services and related travel expenses related to MOT for transplant recipients and living donors to obtain medically necessary services.
 - a. For additional information on non-emergency medical transportation reference internal P&P 10.2.44 Non-Emergency Medical Transportation Services

Current Enrollment and Care Coordination Requirements:

1. All Blue Shield Promise members approved for MOT and disenrolled from Blue Shield Promise prior to January 1, 2022, will remain disenrolled from Blue Shield Promise and enrolled in Fee-For-Service (FFS) Medi-Cal.
 - a. The Medical Exemption Request (MER) and Emergency Disenrollment Exemption Request (EDER) process allows members to be disenrolled from Blue Shield Promise. The enrollment process into managed care Medi-Cal for mandatory enrollees will begin after the expiration of their MER or EDER.
2. Blue Shield Promise must ensure coordination of care between all providers, organ donation entities, and transplant programs to ensure the MOT is completed as expeditiously as possible.
 - a. Care coordination must be provided to the transplant recipients as well as the living donors.
 - b. Reference internal P&P 70.4.3 Complex Case Management Process for administering and monitoring the provision of complex case management to members

Transplant Program Requirements:

1. Blue Shield Promise is required to ensure all MOT procedures are performed in an approved transplant program which operates within a hospital or COE, is certified, and licensed through CMS, and meets Medi-Cal state and federal regulations consistent with 42 CFR, parts 405, 482, 488, 498 and Section 1138 of the Social Security Act (SSA). All hospitals or COEs contracted with for transplant programs must meet DHCS criteria and enrolled to participate in the Medi-Cal program.
2. A Transplant program is a unit within a hospital that has received approval from CMS to perform transplants for a specific type of organ and is a current member of the OPTN, which administered by the United Network for Organ Sharing (UNOS).

3. Solid organ transplant programs must meet the CMS Conditions of Participation (CoP) for the specific organ type and must maintain an active membership with OPTN administered by UNOS.
 - a. Bone marrow transplant programs must have current accreditation by the Foundation for the Accreditation of Cellular Therapy.
4. Most pediatric conditions requiring organ transplants qualify as a CCS-eligible condition. As such, MOTs for pediatric members are required to be performed only in a CCS-approved SCC.
 - a. MOTs for CCS-eligible members must be performed in an SCC that has been approved for the specific organ and age group.
 - b. If the CCS program determines that the member is not eligible for the CCS program, but the MOT is medically necessary, Blue Shield Promise is responsible for authorizing the MOT.
 - c. CCS MOT Service Authorization Requests (SARs) are typically authorized for one year. Non-CCS Treatment Authorization Requests (TARs) are authorized according to the type of MOT in the table below
 - d. For additional information regarding CCS, reference internal P&P 10.2.17 California Children’s Services

Transplant	Duration of TAR Authorization
Liver with Hepatocellular Carcinoma	4 Months
Cirrhosis	6 Months
Bone Marrow	6 Months
Heart	6 Months
Lungs	6 Months
All else	1 Year

5. Blue Shield Promise may authorize MOTs to be performed in a transplant program located outside of California if the reason for the MOT to be provided out-of-state is advantageous to the member.
 - a. The member must consent
 - b. Blue Shield Promise must ensure that the process for directly referring, authorizing referrals and coordinating transplants for members to out-of-state transplant programs is not more restrictive than for in-state transplant programs and the facility is designated by CMS to perform transplants for a specific type of organ and is a current member of the OPTN.
6. The transplant program is responsible for placing members on the National Waitlist by OPTN, administered by Health Resources and Services Administration, once it has determined that the member is a suitable transplant candidate.
 - a. Blue Shield Promise must refer members or authorize referrals to the appropriate transplant program for an evaluation if the member’s primary care physician (PCP) or specialist identifies the member as a potential transplant candidate.
7. Blue Shield Promise is responsible for monitoring the status of contracted hospitals with approved transplant programs to ensure they do not refer members or authorize referrals to a transplant program that no longer meets DHCS requirements or is no longer approved by CMS for the appropriate transplant type.

- a. Blue Shield Promise may require the necessary documentation from contracted hospitals in which transplant programs are located to validate those requirements are met no less than annually.
8. If the transplant program cannot perform the MOT surgery and an organ is available, Blue Shield Promise may arrange for the surgery to be performed at a different transplant program outside of its network. Blue Shield Promise must ensure that the transplant program meets Medi-Cal approved Center of Excellence (COE) COE requirements that are based on the following criteria:
- a. CMS approval for the appropriate organ; and
 - i. OPTN membership for solid organ transplants; or
 - ii. Accreditation by the Foundation for the Accreditation of Cellular Therapy for bone marrow transplants; or
 - b. CCS approved SCC within a tertiary hospital

PROCEDURE

Referral and Authorization Process and Requirements

1. Blue Shield Promise must directly refer adult members or authorize referrals to a transplant program that meets Medi-Cal for an evaluation within 72 hours of a member's PCP or specialist identifying the member as a potential candidate for the MOT.
 - a. Blue Shield Promise must authorize the request for the MOT after the transplant program confirms the MOT candidacy of the member.
2. For Prior Authorization review process, reference internal P&P 70.2.50
3. Reference internal P&P 10.2.43 Utilization Management Decision Making Time Frame for Medi-Cal
4. Blue Shield Promise must refer pediatric members to the County CCS program for CCS eligibility determination within 72 hours of the member's PCP or specialist identifying the member as potential candidate for the MOT.
 - a. The County CCS program will be responsible for referring the CCS-eligible member to the transplant SCC.
 - b. If the CCS program determines that the member is not eligible for the CCS program, but the MOT is medically necessary, Blue Shield Promise will be responsible for authorizing the MOT.
5. Once the transplant program confirms that the member is a suitable transplant candidate, Blue Shield Promise, or Integrated Systems of Care (ISCD) Medical Consultant or designee will be required to authorize the request for the MOT.
 - a. Expedited authorizations, no later than 72 hours, are required if the organ that the member will receive is at risk of being unusable due to any delay in obtaining prior authorization or if the transplant program can provide immediate transplant services that would benefit the member's condition.
6. DHCS Major Organ Transplant Program Audits
 - a. Blue Shield Promise is subject to medical audits conducted by DHCS' Audit and Investigations Division in which all activities related to MOTs will be audited, including, but not limited to, service authorizations, referral processes, and general oversight and monitoring of the transplant programs

- b. Blue Shield Promise's transplant programs will be subject to grievances and appeals reporting
- c. DHCS reserves the right to request additional information from the MCP to confirm their obligation to oversee and ensure the selected hospital meets the transplant program criteria outlined above.

Evidence Based Criteria for Major Organ Transplants

- A. For additional information on the medical decision making for MOT services please reference Blue Shield Promise UM Criteria Hierarchy

REFERENCES

Medi-Cal Provider Manual
Health & Safety Code Section 53887
42 CFR, parts 405, 482, 488, 498
Section 1138 of the Social Security Act
APL 21-015