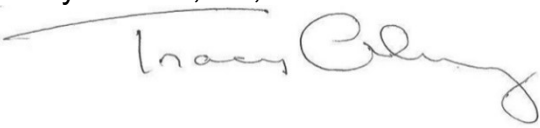
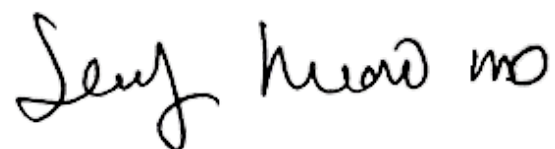


Policy Title: Major Organ Transplant (MOT)		POLICY #: 10.02.09	
		Line of business: Medi-Cal	
Department Name: Utilization Management	Original Date 11/97	Effective Date 11/22	Revision Date 12/18, 8/21, 1/22, 3/22, 10/22, 2/23, 3/24
VP Approval: Tracy Alvarez, VP, Medical Care Solutions 			Date of Approval: 3/12/2024
Medical Services/P&T Committee: (If Applicable) Jennifer Nuovo, MD 			Date of Committee Review: 3/12/2024

A. PURPOSE

To provide guidance on how Blue Shield of California Promise Health Plan (Blue Shield Promise) will process the Major Organ Transplant (MOT) benefit for adult and non-California Children’s Services (CCS) eligible pediatric transplant recipients and donors as outlined in the Medi-Cal Provider Manual, including related services such as organ procurement and living donor care per the Department of Health Care Services (DHCS) All Plan Letter (APL) 21-015 and Attachment 2.

Blue Shield Promise shall refer, coordinate, and authorize the delivery of the MOT benefit and all medically necessary services associated with MOTs, including but not limited to:

1. Pre-transplantation assessments and appointments
2. Organ procurement
3. Hospitalization
4. Surgery
5. Discharge planning
6. Readmissions from complications
7. Post-operative services
8. Medications
9. Care coordination

B. DEFINITIONS

1. “Center of Excellence (COE)” - an organ transplant center with a proven ability to perform successful transplants and deliver quality patient care as evidenced by outcomes and sound policies and procedures.

2. “Special Care Center (SCC)” – a center within a CCS-approved hospital that provides comprehensive, coordinated health care to CCS-eligible beneficiaries.
3. “Transplant program” – a unit within a hospital that has received approval from the Centers for Medicare and Medicaid Services (CMS) to perform transplants for a specific type of organ and is a current member of the Organ Procurement and Transplantation Network (OPTN), which is administered by the United Network for Organ Sharing (UNOS).

C. POLICY

- I. Blue Shield Promise will cover all medically necessary services for both living donors, regardless of Medi-Cal eligibility, and cadaver organ transplants.
- II. All covered benefits related to the following major organs will be provided for at a Medi-Cal approved COE (or SCC for members less than 21 years of age):
 - Bone marrow
 - Heart
 - Intestine
 - Liver
 - Lung
 - Simultaneous kidney-pancreas
- III. Kidney, corneal, and autologous islet cell transplants are not required to be performed in a COE or a SCC. For these organs, Blue Shield Promise Utilization Management Team will refer members to a transplant program that is approved by the 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.
- IV. 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 10.31.1 Non-Emergency Medical Transportation (NEMT) and Non-Medical Transportation (NMT) Services and Related Travel Expenses
- V. Current Enrollment and Care Coordination Requirements:
 - a. 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.
 - i. 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.
 - b. Blue Shield Promise will ensure coordination of care between all providers, organ donation entities, and transplant programs to ensure the MOT is completed as expeditiously as possible.
 - i. Care coordination must be provided to the transplant recipients as well as the living donors.
 - ii. Reference 10.4.6 Complex Case Management Process for

administering and monitoring the provision of complex case management to members

VI. Transplant Program Requirements:

- a. Blue Shield Promise ensures all MOT procedures are performed in a Medi-Cal approved COE transplant program which operates within a hospital setting, 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 for transplant programs must meet DHCS criteria and be enrolled to participate in the Medi-Cal program.
- b. Blue Shield Promise will authorize MOTs to be performed in a transplant program that meets DHCS' criteria.
 - i. Bone marrow transplant programs must have current accreditation by the Foundation for the Accreditation of Cellular Therapy.
- c. Most medical conditions requiring organ transplants qualify as CCS-eligible conditions. As such, MOTs for pediatric members less than 21 years of age are required to be performed only in a CCS-approved SCC.
 - i. MOTs for CCS-eligible members must be performed in an SCC that has been approved for the specific organ and age group.
 - ii. 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.
 - iii. For additional information regarding CCS, reference 10.2.11 California Children's Services (CCS)
 - iv. 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:

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

- d. 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.
 - i. The member must consent
 - ii. 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 to perform transplants for a specific type of organ and is a current member of the OPTN.

- e. 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.
 - i. Blue Shield Promise will 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.

- f. 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.
 - i. 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.

- g. 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 will ensure that the transplant program meets DHCS' COE requirements that are based on the following criteria:
 - i. CMS approval for the appropriate organ; and
 - 1. OPTN membership for solid organ transplants; or
 - 2. Accreditation by the Foundation for the Accreditation of Cellular Therapy for bone marrow transplants; or
 - ii. CCS approved SCC within a tertiary hospital

D. PROCEDURE

- I. Referral and Authorization Process and Requirements
 - i. Blue Shield Promise directly refers adult members or authorizes referrals to a transplant program that meets DHCS criteria for an evaluation within 72 hours of a member's PCP or specialist identifying the member as a potential candidate for the MOT and receiving all of the necessary information to make a referral or authorization.

- ii. Blue Shield Promise will authorize the request for the MOT after the transplant program confirms the MOT candidacy of the member.
 - iii. For Prior Authorization review process, reference 10.02.38 Prior Authorization Review. For turnaround times, reference 10.2.22 Utilization Management Decision Making & Timeframes
- b. Blue Shield Promise will refer members under 21 years of age 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.
- i. Blue Shield Promise will be responsible for referring and coordinating the delivery of the MOT benefit and all medically necessary services associated with MOT.
 - ii. The County CCS program will be responsible for referring the CCS-eligible member to the transplant SCC.
 - iii. Blue Shield Promise will provide case management and care coordination as stated in the Promise CHP Nurse Care Coordination and Care Management Process, ID Number 1886.
 - iv. If the CCS program determines that the member is not eligible for CCS services, but the MOT is medically necessary, Blue Shield Promise will be responsible for referring the member to a transplant program within 72 hours of receipt of the eligibility determination and authorizing the MOT as appropriate.
- c. 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.
- i. Expedited authorizations 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. Expedited authorizations will be completed no later than 72 hours following receipt of appropriate medical necessity documentation.

E. MONITORING

- I. DHCS Major Organ Transplant Program Audits
 - a. Managed Care Plans (MCPs) are 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. MCPs' 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.

F. REPORTING

N/A

G. REFERENCES & ATTACHMENTS

1. 42 CFR, parts 405, 482, 488, 498
2. APL 21-015 and Attachment 2
3. Health & Safety Code Section 53887
4. Medi-Cal Provider Manual
5. Promise CHP Nurse Care Coordination and Care Management Process, ID Number 1886
6. Section 1138 of the Social Security Act
7. 10.02.38 Prior Authorization Review
8. 10.2.22 Utilization Management Decision Making & Timeframes
9. 10.2.11 California Children's Services (CCS)
10. 10.2.38 Prior Authorization
11. 10.2.43 Utilization Management Decision Making Time Frame
12. 10.31.1 Non-Emergency Medical Transportation (NEMT) and Non-Medical Transportation (NMT) Services and Related Travel Expenses
13. 10.4.6 Complex Case Management Process

H. REVISION HISTORY

Date	Modification (Reviewed and/or revised)	E-Filing Number
3/2024	2024 Annual Review <ul style="list-style-type: none">• Formatting updates• Added references	
08/2023	Updated due to AIR R.0208 Requirements	
2/2023	Updated Regulatory Requirements DHCS	