



KERN HEALTH SYSTEMS

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POLICY AND PROCEDURES					
SUBJECT: Major Organ Transplant			POLICY #: 3.02-P		
DEPARTMENT: Utilization Management					
Effective Date: 08/1997	Review/Revised Date: 8/21/2023	DMHC		PAC	
		DHCS	X	QI/UM COMMITTEE	
		BOD		FINANCE COMMITTEE	

Emily Duran
Chief Executive Officer

Date _____

Chief Medical Officer

Date _____

Director of Member Services

Date _____

Director of Population Health Management

Date _____

Director of Utilization Management

Date _____

PURPOSE¹:

Effective January 1, 2022, all Medi-Cal managed care plans (KHS) are 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.

SCOPE:

This policy applies to all employees, contractors, consultants, temporary, and other workers at KHS who interact directly with our members.

POLICY STATEMENT:

Kern Health Systems (KHS), KHS participating providers, and/or KHS delegates must refer, coordinate, and authorize the delivery of the MOT benefit and all medically necessary services associated with MOTs, including, but not limited to, pre-transplantation assessments and appointments, organ procurement costs, hospitalization, surgery, discharge planning, readmissions from complications, post-operative services, medications, and care coordination. KHS must also cover all medically necessary services for both living donors and cadaver organ transplants.

KHS must only authorize MOTs to be performed in approved transplant programs located within a hospital that meets the Department of Health Care Services' (DHCS) criteria.

ENFORCEMENT:

KHS verifies compliance to this policy through various methods, including but not limited to review of identification and enrollment reporting, business tool reporting, training, and case documentation audits.

PROCEDURE:

Covered Benefits

1. KHS is required to cover all medically necessary major organ transplants as outlined in the Medi-Cal Provider Manual², including all updates and amendments to the Provider Manual.

KHS is required to ensure adult members receive covered benefits at a facility designated as a Medi-Cal approved Center of Excellence (COE) for transplants related to the following major organs:

- Bone marrow transplants (BMT)
- Heart transplants (HT)
- Heart/lung transplants (HT/LUT)
- Kidney transplants (KT)
- Liver transplants (LT)
- Small Bowel Transplants (SBT)
- Combined liver and small bowel transplants (LT/SBT)
- Lung transplants (LUT)
- Simultaneous Kidney-Pancreas (KT/PT)
- Pancreas (PT)

Kidney, corneal, and autologous islet cell transplants are not required to be performed in a COE or Special Care Center (SCC). For these organs, the KHS must ensure that they 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. KHS is required to authorize appropriate non-emergency medical transportation (NEMT), non-medical transportation (NMT) services and related travel expenses related to MOT for transplant recipients and living donors to obtain medically necessary services upon the request

of the MOT donor or the MOT recipient. For more information see *KHS Policy and Procedure 5.15-P Member Transportation Assistance*.

3. Lodging and transportation services are available to eligible members as covered under the Maintenance and Transportation (M&T) benefit and continued after January 1, 2022. Only KHSs participating in the program are required to authorize the M&T benefit for CCS-eligible members. Refer to the CCS Numbered Letter for more information on the M&T benefit: <https://www.dhcs.ca.gov/services/ccs/Documents/ccsnl030810.pdf>. Transplants qualifying as a CCS eligible condition are referred to and provided by the CCS Program. For more information see *KHS Policy and Procedure 3.16-P California Children's Services*.
4. Medi-Cal Rx must pay pharmacy claims for MOT-related prescription drugs unless a member has other primary insurance or Medicare. KHS or other primary insurer/Medicare is responsible for the cost of facility physician administered drugs, that are submitted on a medical claim, depending on the case history.

Current Enrollment and Care Coordination Requirements

1. All Kern Health System members approved for a MOT and disenrolled from the Kern Health Systems prior to January 1, 2022, remain disenrolled from the KHS and enrolled in Fee-For-Service (FFS) Medi-Cal. The Medical Exemption Request (MER) and Emergency Disenrollment Exemption Request (EDER) process allows members to be disenrolled from a KHS. The enrollment process into Medi-Cal Managed Care for mandatory enrollees will begin after the expiration of their MER or EDER. KHSs may refer to Implementation of Monthly Medical Exemption Review Denial Reporting, for guidance on notifications provided to beneficiaries 45 days prior to the expiration of a MER.
2. KHS will ensure coordination of care between all providers, organ donation entities, and transplant programs to ensure the MOT is completed as expeditiously as possible. Care coordination must be provided to the transplant recipients as well as the living donors.
3. In order to ensure timely care and avoid unnecessary delays, when a beneficiary is transition from managed care to FFS or when a potential CCS eligibility determines is pending, KHS must proactively communicate and coordinate with DHCs.

Transplant Program Requirements

1. KHS is required to ensure all MOT procedures are performed in an approved 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)³. Additionally, KHS must ensure that all contracted hospitals within which transplant programs are located, meet DHCS' criteria and the hospital is 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 Organ

Procurement and Transplantation Network (OPTN), which is administered by the United Network for Organ Sharing (UNOS).⁴

3. KHS must authorize MOTs to be performed in a transplant program that meets DHCS' criteria.
4. Solid organ transplant programs must meet the CMS Conditions of Participation for the specific organ type and must maintain an active membership with OPTN administered by UNOS.

Bone marrow transplant programs must have current accreditation by the Foundation for the Accreditation of Cellular Therapy.

5. Most medical conditions requiring organ transplants qualify as a CCS-eligible. Conditions MOTs for beneficiaries less than 21 years of age are required to be performed only in a CCS-approved Special Care Center (SCC). SCCs are within CCS-approved hospitals that provide comprehensive, coordinated health care to CCS-eligible members. MOTs for CCS-eligible members must be performed in an SCC that has been approved for the specific organ and age group. If the CCS program determines that the member is not eligible for the CCS Program, but the MOT is medically necessary, the KHS is responsible for authorizing the MOT, as appropriate.

A list of approved SCCs can be found on the DHCS website here:
<https://www.dhcs.ca.gov/services/ccs/scc/Pages/SCCType.aspx>

6. The criteria described in the Transplant Program Requirements section of this policy are the standards for all transplant programs in the United States and are overseen by CMS. However, DHCS also reviews and approves the transplant programs by applying the same criteria described in the Transplant Program Requirements section of this policy. Upon approval, DHCS designates the transplant program as a Medi-Cal approved COE. A COE is not a physical location, rather, it is a designation assigned by DHCS upon confirmation that the transplant unit within the hospital meets DHCS' criteria for a transplant program.

DHCS does not publish the COE list on its website; however, Kern Health Systems may email their Managed Care Operations Division Contract Manager to obtain the most current list of COEs to build its MOT network.

Members requiring major organ transplants are identified by their KHS provider. Organ transplant services require prior authorization. Providers should submit referrals to KHS as outlined in *KHS Policy and Procedure #3.22-P: Referral and Authorization Process*. KHS UM staff assist the provider in making the referral to an appropriate transplant Center of Excellence and act as an initial liaison between transplant center staff and the provider.

7. KHS 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.e., the facility is closer to where the member resides, or the member is able to obtain the transplant sooner than the in-state facility). In addition, the member must consent to receiving the MOT out-of-state. In such cases, KHS 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. KHS must also ensure that out-of-state transplant programs meet the criteria as described in the Transplant Program Requirements section of this policy. and that the out-of-state transplant program is enrolled as a Medi-Cal Provider.

8. The transplant program is responsible for placing members on the National Waitlist maintained by OPTN, administered by HRSA, once it has determined that the member is a suitable transplant candidate. The KHS 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.
9. CCS MOT Service Authorization Requests (SARs) are typically authorized to the end of the period of Program eligibility for up to 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

10. KHS 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. KHS should require the necessary documentation from contracted hospitals in which transplant programs are located to validate that requirements are met no less than annually.
11. Under circumstances in which the transplant program cannot perform the MOT surgery and an organ is available, KHS may arrange for the surgery to be performed at a different transplant program outside of its network. Kern Health Systems must ensure that the transplant program meets DHCS’ COE requirements that are based on the following criteria
 - CMS approval for the appropriate organ; and
 - OPTN membership for solid organs transplants; or
 - Accreditation by the Foundation for the Accreditation of Cellular Therapy for bone marrow transplants; or

- CCS-approved SCC within a tertiary hospital.

Referral and Authorization Process and Requirements

1. KHS must directly refer adult members or authorize 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. KHSs can then authorize the request for the MOT after the transplant program confirms the MOT candidacy of the member.
2. KHS participating in the WCM program must directly refer beneficiaries less than 21 years of age or authorize referrals to a transplant program for an evaluation within 72 hours of the member's Primary Care Provider or specialist identifying the member as a potential candidate for the MOT. WCM KHSs must authorize the request for the MOT after the transplant program confirms the MOT candidacy for the member.

Non-WCM (KHS)s must refer beneficiaries less than 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 transplantation. The County CCS program is responsible for referring the CCS-eligible member to the Transplant SCC. An Integrated Systems of Care (ISCD) Medical Consultant or designee will be responsible for determination of medical necessity and adjudication of the request for the MOT upon the SCC's confirmation that the member is a suitable candidate for the MOT. If the CCS Program determines that the member is not eligible for the CCS services, but the MOT is medically necessary, KHS is responsible for authorizing the MOT within 72 hours of receipt of the eligibility determination.

3. Once the transplant program confirms that the member is a suitable transplant candidate, the KHS or ISCD Medical Consultant or designee will be required to authorize the request for the MOT. 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 has the ability to provide immediate transplant services that would benefit the member's condition. The expedited authorizations are required to be completed in no later than 72 hours following receipt of appropriate medical necessity documentation.
4. KHS can apply appropriate utilization management protocols that do not establish unreasonable or arbitrary barriers for accessing coverage. However, if an authorization request for MOT is denied, the MCP's Chief Medical Officer (CMO) must review the request and determine the appropriateness of the denial.

Network Requirements and Submission Guidelines and Requirements

1. Due to the fact that transplant programs are located as a unit within a hospital, for purposes of network certification, KHS must contract with hospitals that have approval for a transplant program that meets the criteria as defined in the Transplant Program Requirements section of this policy.
2. Programs that perform corneal, autologous islet cell or kidney transplants are not required to be a Medi-Cal approved COE as they are not considered MOT. KHS must have as many active

contracts with hospitals as necessary to ensure that an approved transplant program for each organ listed below is within its network. A hospital that has approval for multiple transplant programs will be counted for each organ type, therefore if a KHS contracts with one hospital that has approval for all organs below, the network would be deemed sufficient for certification purposes, presuming that hospital has the capacity to provide all medically necessary transplant services to the KHS members.

Kern Health Systems must have a contract with as many COEs as needed to cover the following organs for adult members:

- Bone marrow
- Heart
- Intestine
- Liver
- Lung
- Simultaneous kidney-pancreas

Non-WCM MCPs are not required to contract with SCCs or pediatric transplant programs. MCPs participating in WCM are required to contract with hospitals that have approved transplant programs to serve its adult beneficiaries aged 21 years and older, as well as with SCCs to serve beneficiaries under 21 years of age:

- Bone marrow
- Heart-lung
- Heart
- Liver

3. DHCS will allow for Provider enrollment requirements to be waived for single case agreements/letters of agreement with out-of-state transplant programs.
4. KHS is responsible for oversight and monitoring of its MOT network. If a KHS becomes aware that a contracted transplant program is no longer active, has lost its Medi-Cal approved COE status, or is no longer on DHCS' COE or SCC list, the KHS must notify any member who has an active referral to the transplant program no later than 30 days prior to the planned inactivation date. KHS must coordinate the referral and transfer of members to a different approved transplant program.

Oversight Requirements

1. KHS is required to develop and implement policies and procedures on the inclusion of the MOT benefit. KHS must submit the policies and procedures to DHCS for review and approval. More detailed information on required deliverables is forthcoming. A deliverables matrix was provided to KHS in August 2021.
2. KHS 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. Additionally, KHS transplant programs will be subject to grievances and appeals reporting, as well as the quarterly monitoring process. DHCS reserves the right to request

additional information from the KHS to confirm their obligation to oversee and ensure the selected hospital meets the transplant program criteria outlined above.

3. Guidance on transitional reporting and monitoring was released to KHS in December 2021.

REFERENCE:

Revised 2023-04: Policy revised by Director of Population Management to comply with DHCS All Plan letter 21-015 revised, DHCS approval received on 5/18/2023. ¹**Revised 2022-06:** Policy revised to include a reference to 5.15-P to comply with APL 22-008. **Revised 2021-11:** Policy approved on 11/24/2022 by DHCS for MOT 3 and 4 deliverables. Revision based on APL 21-015 MOT deliverables. **Revision 2019-01:** Policy reviewed as part of Internal Compliance Review of APL 17-006. No revision to policy, Attachment replaced with DHCS link to approved transplant centers. **Revision 2015-01:** “Attachment A” the Medi-Cal approved transplant list updated. **Revision 2013-12:** Minor revisions provided by Director of Health Services to remove references to Health Families. **Revision 2010-05:** Reviewed by KHS Chief Health Services Officer. Attachment updated. **Revision 2006-02:** Routine review. Policy reviewed against DHS Contract 03-76165 (Effective 5/1/2004). **Revision 2001-05:** Routine review. Added Attachments A-D per DHS Comment Letter (4/30/01).

² The Transplant section of the Medi-Cal Provider Manual is available at: <https://files.medi-cal.ca.gov/pubsdoco/publications/masters-mtp/part2/transplant.pdf>

³ Section 1138 of the SSA is available at: https://www.ssa.gov/OP_Home/ssact/title11/1138.htm

⁴ Title 42 Code of Federal Regulations (CFR) parts 405, 482, 488, and 498. Title 42 of the CFR is searchable at: https://www.ecfr.gov/cgi-bin/text-idx?gp=&SID=e356c5978e7e6c490f3e8cee1b7e34e6&mc=true&tpl=/ecfrbrowse/Title42/42tab_02.tpl