California Advancing and Innovating Medi-Cal
All Plan Letter (APL) Attachment 2
Major Organ Transplants (MOT) Requirements

Effective January 1, 2022, all Medi-Cal managed care health plans (MCPs) are required to cover the MOT benefit for adult and pediatric transplant recipients and donors, including related services such as organ procurement and living donor care.

For individuals under 21 years of age, MCPs that do not participate in the Whole Child Model (WCM) program are not required to cover MOTs performed to treat conditions that are medically eligible for the California Children's Services (CCS) Program.

MCPs must authorize, refer, and coordinate 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 not otherwise covered by the MCP contract, and care coordination for transplants that the MCP is responsible for.[1, 2, 3] MCPs *are* not required to pay for costs associated with *MOT for medical conditions* that qualify as a CCS-*eligible* condition if the MCP does not participate in the WCM program. MCPs must also cover all medically necessary services for both living donors and cadaver organ transplants.

MCPs may only authorize MOTs to be performed in approved transplant programs located within a hospital that meets the Department of Health Care Services' (DHCS) criteria. This Attachment provides further details on covered benefits, current enrollment and care coordination requirements, and transplant programs that meet DHCS criteria.

I. Covered Benefits

1. MCPs are required to cover all medically necessary adult and pediatric major organ transplants as outlined in the Medi-Cal Provider Manual,[4] including all updates and amendments to the Provider Manual.[5]

[1] Billing Examples for Inpatient Services for transplants is available here.

[2] Further information about transplants is available here.

[3] Donor protocol for transplants is available here.

[4] The Transplant section of the Medi-Cal Provider Manual is available here.

[5] The Transplant section of the Medi-Cal Provider Manual is available here.

MCPs are 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. Physician Certification Statement forms are not required for MOT donors requesting NEMT services to ensure the donor can get to the hospital for the MOT transplant.*

MCPs must refer to APL *22-008*, Non-Emergency Medical and Non-Medical Transportation Services *and Related Travel Expenses*, or any superseding APL. APL *22-008 includes* guidance for *transportation* related travel expenses, including *meals and* lodging.

2. *Lodging* and transportation services are available to CCS-eligible beneficiaries as covered under the Maintenance and Transportation (M&T) benefit and *continued* after January 1, 2022. Only MCPs participating in the WCM program are required to authorize the M&T benefit for CCS-eligible beneficiaries. Refer to the CCS *Numbered* Letter for more information on the M&T benefit: https://www.dhcs.ca.gov/services/ccs/Documents/ccsnl030810.pdf.

3. Medi-Cal Rx *must* pay pharmacy claims for prescription drugs, including those related to MOT, unless a beneficiary has other primary health insurance or Medicare. The MCP or other health coverage/Medicare *is* responsible for the cost of *the* facility *or physician-administered* drugs, depending on the case history.

II. Current Enrollment and Care Coordination Requirements

1. All MCP beneficiaries in non-COHS counties*,* approved for a MOT and disenrolled from the MCP prior to January 1, 2022, remain disenrolled from the MCP and enrolled in Fee-For-Service (FFS) Medi-Cal. The *Medical Exemption Request (*MER*)* and *Emergency Disenrollment Exemption Request (*EDER*)* process allows beneficiaries to be disenrolled from an MCP. The enrollment process into Medi-Cal *Managed Care* for mandatory enrollees will begin after the expiration of their MER or EDER. MCPs may refer to APL 17-007 *or any superseding APL* for guidance on notifications provided to beneficiaries 45 days prior to the expiration of a MER.

2. MCPs must ensure care management for all covered services and coordination of care for beneficiaries between all *Providers*, organ donation entities, and transplant programs to ensure the MOT is completed as expeditiously as possible. The MCP or other health coverage *is* responsible for providing care management and care coordination services to the transplant recipients as well as the living donors.

In order to ensure critical timely care and avoid unnecessary delays, when a beneficiary is transitioning from managed care to FFS or when a potential CCS eligibility determination is pending, the MCPs must proactively communicate and coordinate with DHCS.

III. Transplant Program Requirements

1. MCPs are required to ensure all MOT procedures are performed in a Medi-Cal approved Center of Excellence (COE) transplant program which operates within a hospital setting, is certified and licensed through the Centers for Medicare and Medicaid Services (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).[6] Additionally, MCPs 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).[7]

3. MCPs must authorize MOTs to be performed in a transplant program that meets DHCS' criteria. See #4 through #6 below for further details.

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

4. Most *medical* conditions requiring organ transplants qualify as 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 beneficiaries. MOTs for CCS-eligible beneficiaries must be performed in an SCC that has been approved for the specific organ and age group. If the CCS program determines that the beneficiary is not eligible for the CCS *Program*, but the MOT is medically necessary, the MCP *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] Section 1138 of the SSA is available at: https://www.ssa.gov/OP_Home/ssact/title11/1138.htm
[7] 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

5. The criteria described in III. 4. and III. 5. 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 listed in Section III. 4. in this Attachment. 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, MCPs may email their Managed Care Operations Division Contract Manager to obtain the most current list of COEs to build its MOT network.

6. MCPs 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 beneficiary (i.e., the facility is closer to where the beneficiary resides or the beneficiary is able to obtain the transplant sooner than the in-state facility). In addition, the beneficiary must consent to receiving the MOT out-of-state. In such cases, the MCP must ensure that the process for directly referring, authorizing referrals and coordinating transplants for beneficiaries 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. MCPs must also ensure that out-of-state transplant programs meet the criteria outlined in III. 4. and III. 6. of this Attachment, and that the out-of-state transplant program is enrolled as a Medi-Cal *Provider*.

7. The transplant program is responsible for placing beneficiaries on the National Waitlist maintained by OPTN, administered by HRSA, once it has determined that the beneficiary is a suitable transplant candidate. The MCP must refer beneficiaries or authorize referrals to the appropriate transplant program for an evaluation when the beneficiary's primary care physician (PCP) or specialist communicates to the MCP that the beneficiary has been identified as a potential transplant candidate.

8. 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 for a certain period of time depending on the type of MOT as outlined 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

9. MCPs are responsible for monitoring the status of contracted hospitals with approved transplant programs to ensure they do not refer beneficiaries 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. MCPs should require the necessary documentation from contracted hospitals in which transplant programs are located to validate that requirements are met no less than annually.

10. Under circumstances in which the transplant program cannot perform the MOT surgery and an organ is available, the MCP may arrange for the surgery to be performed at a different transplant program outside of its network. The MCP 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; and
    - CCS-approved SCC within a tertiary hospital.

IV. Referral and Authorization Process and Requirements

1. MCPs must directly refer adult beneficiaries or authorize referrals to a transplant program that meets DHCS criteria for an evaluation within 72 hours of a beneficiary's PCP or specialist identifying the beneficiary as a potential candidate for the MOT and receiving all of the necessary information to make a referral or authorization.[8] MCPs *can then* authorize the request for the MOT after the transplant program confirms the MOT candidacy of the beneficiary. *MCPs 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.*

2. MCPs 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 beneficiary's Primary Care Provider or specialist

[8] Note that 72 hours means standard hours, not 72 business hours.

identifying the beneficiary as a potential candidate for the MOT and receiving all of the necessary information to make a referral or authorization. WCM MCPs *can then* authorize the request for the MOT after the transplant program confirms the MOT candidacy for the beneficiary. *WCM MCPs 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 CMO must review the request and determine the appropriateness of the denial.*

Non-WCM MCPs must refer beneficiaries *less than 21 years of age* to the *county* CCS *Program* for eligibility determination within 72 hours of the beneficiary's PCP or specialist identifying the beneficiary as potential candidate for *transplantation*. *CCS Program staff must determine or confirm medical eligibility for all transplant candidates. The county CCS Program is* responsible for referring the CCS-eligible beneficiary to the *Transplant* SCC. *For MOT, a* DHCS Medical Consultant or designee within the Integrated Systems of Care Division *is* responsible for determination of medical *eligibility and* necessity and adjudication of the request. If the CCS *Program* determines that the beneficiary is not eligible for CCS *services*, but the MOT is medically necessary, the MCP must refer the beneficiary to a transplant program within 72 hours of receipt of the eligibility determination and *is* responsible for authorizing the MOT, *as appropriate*.

Once the *Transplant SCC* confirms that the beneficiary is a suitable transplant candidate, the MCP (*WCM MCPs)* or DHCS Medical Consultant or designee *(non- WCM MCPs) can then* authorize the request for the *transplant. MCPs or a DHCS Medical Consultant or designee can apply appropriate utilization management protocols that do not establish unreasonable or arbitrary barriers for accessing coverage. However, if an authorization request is denied by an MCP, the MCP's CMO must review the claim and determine the appropriateness of the denial*. Expedited authorizations are required if the organ that the beneficiary 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 beneficiary's condition. The expedited authorizations are required to be completed *in* no later than 72 hours *following receipt of appropriate medical necessity documentation*.

V. 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, the MCPs must contract with hospitals that have approval for a transplant program that meets the criteria described in III. 4. through III. 6. above for the organs listed below. Transplant 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*. MCPs 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 MCP 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 MCP's beneficiaries.

MCPs *must* have a contract with as many COEs as needed to cover the following organs for adult beneficiaries:

- 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

2. *DHCS will allow for Provider enrollment requirements to be waived for single case agreements/letters of agreement with out-of-state transplant programs.*

3. Each MCP is responsible for oversight and monitoring of its MOT network. If a MCP 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 MCP must notify any beneficiary who has an active referral to the transplant program no later than 30 days prior to the planned inactivation date. MCPs must coordinate the referral and transfer of beneficiaries to a different approved transplant program.

VI. Oversight Requirements

1. MCPs are required to develop and implement policies and procedures on the inclusion of the MOT benefit. MCPs must submit the policies and procedures to DHCS for review and approval. A deliverables matrix was provided to MCPs in August 2021.

2. 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. Additionally, MCPs' transplant programs *are* subject to grievances and appeals reporting, as well as the quarterly monitoring process. 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.

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