

Contra Costa Health Plan

Utilization Management

Title: Major Organ Transplant

Policy #: UM15.067

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Applies to:

Medi-Cal

LIHP

Medicare

State Sponsored

Commercial

All

N/A

Regulatory/Accreditation:

DHCS:

Other Reg. References:

CMS:

NCQA: UM 7, 9, 12

DMHC:

N/A

Units:

Administration

Compliance

Marketing

Provider Affairs

Advice Nurses

Case Management

Member Services

Quality Management

All Staff

Health Ed/Cultural Ling.

Auth/Utilization Management.

POLICY

Medically necessary Major Organ Transplant is covered by CCHP as of January 1, 2022. Please see DHCS APL 21-015

(<https://www.dhcs.ca.gov/formsandpubs/Documents/MMCDAPLsandPolicyLetters/APL2021/APL21-015.pdf>) and APL 21-015 Attachment 2

(<https://www.dhcs.ca.gov/formsandpubs/Documents/MMCDAPLsandPolicyLetters/APL2021/APL21-015-Attachment-2-MOT.pdf>) for further details. The below is a repeat of these two documents.

As of January 1, 2022, CCHP 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.

CCHP must authorize, refer and coordinate the delivery of the MOT benefit and all medically necessary covered services associated with MOTs, including, but not limited to, pre-transplantation assessments and appointments, organ procurement costs, hospitalization, surgery, discharge planning, readmissions from complications, postoperative services, medications not otherwise covered by CCHP's contract, and care coordination for transplants that CCHP is responsible for. CCHP will not be required to pay for costs associated with transplants that qualify as a California Children's Services (CCS) condition. CCHP must also cover all medically necessary covered services for both living donors and cadaver organ transplants.

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

CCHP will refer pediatric beneficiaries that are identified as MOT candidates by their Primary Care Provider or specialist to the CCS County program to determine the beneficiary's eligibility for the CCS program. If the CCS County program determines that the beneficiary is CCS-eligible, the CCS County program will be required to refer the beneficiary to the appropriate CCS-approved Special Care Center (SCC). The DHCS Integrated Systems of Care Division will be responsible for determination of medical necessity and adjudication of the request for the MOT upon the SCC's confirmation that the beneficiary is

a suitable candidate for the MOT. If the CCS County program determines that the beneficiary is not eligible for the CCS program, CCHP will be responsible for referring the beneficiary to an appropriate transplant program that meets DHCS' criteria. CCHP will be responsible for authorizing the request and covering the transplant once the transplant program determines that the beneficiary is a suitable candidate for the MOT.

PROCEDURE

Details on covered benefits, current enrollment and care coordination requirements, and transplant programs that meet DHCS criteria are provided below.

Covered Benefits

CCHP is required to cover all medically necessary adult and pediatric major organ transplants as outlined in the Medi-Cal Provider Manual, including all updates and amendments to the Provider Manual. CCHP will not be required to cover pediatric MOTs that qualify as a CCS-eligible condition. CCHP must authorize and cover costs for organ donors, including living donors and cadavers, regardless of a living donor's Medi-Cal eligibility. CCHP must cover transplant-related costs such as evaluation, hospitalization for the living donor, organ removal and all Medically Necessary services related to organ removal including complications, and transportation. CCHP must cover all readmissions and costs related to any complications the Member or the living donor experiences from the organ transplant.

- Billing Examples for Inpatient Services for transplants is available at:
<https://files.medical.ca.gov/pubsdoco/publications/masters-mtp/part2/transplantexip.pdf>
- Further information about transplants is available at:
<https://files.medical.ca.gov/pubsdoco/publications/masters-mtp/part2/transplant.pdf>
- Donor protocol for transplants is available here:
<https://files.medical.ca.gov/pubsdoco/publications/masters-mtp/part2/transplantproto.pdf>
- The Transplant section of the Medi-Cal Provider Manual is available at:
<https://files.medical.ca.gov/pubsdoco/publications/masters-mtp/part2/transplant.pdf>.
- The Transplant section of the Medi-Cal Provider Manual is available at:
<https://files.medical.ca.gov/pubsdoco/publications/masters-mtp/part2/transplant.pdf>.

Transportation, Travel Related Expenses, and Lodging

CCHP 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 MOT recipient. Physician Certification forms are not required for MOT donors requesting NEMT services to ensure the donor can get to the hospital for the MOT transplant. CCHP must refer to APL 22-008, Non-Emergency Medical and Non-Medical Transportation Services, last revised May 18, 2022, or any superseding APL. APL 22-008 includes guidance for related travel expenses, including meals and lodging for the non-CCS population. CCHP must allow for an attendant for the donor if CCHP determines that an attendant to accompany the donor is necessary.

Lodging and transportation services are available to California Children's Services (CCS)-eligible beneficiaries as covered under the Maintenance and Transportation (M&T) benefit and will continue to be

the responsibility of CCS in Contra Costa County. Refer to the CCS Number Letter for more information on the M&T benefit: <https://www.dhcs.ca.gov/services/ccs/Documents/ccsnl030810.pdf>.

Pharmacy Coverage for Prescription Drugs

Medi-Cal Rx pays pharmacy claims for prescription drugs, including those related to MOT, unless a beneficiary has other primary health insurance or Medicare. CCHP or other health coverage/Medicare will be responsible for the cost of the facility or physician administrated drugs, depending on the case history.

Enrollment and Care Coordination Requirements

CCHP beneficiaries approved for a MOT and disenrolled from the CCHP prior to January 1, 2022, remain disenrolled from CCHP 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 managed care Medi-Cal for mandatory enrollees will begin after the expiration of their MER or EDER. CCHP will refer to APL 17-007 or any superseding APL for guidance on notifications provided to beneficiaries 45 days prior to the expiration of the MER.

CCHP will 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. CCHP or other health coverage will be 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, CCHP will proactively communicate and coordinate with DHCS.

Transplant Program Requirements

CCHP is 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).

Additionally, CCHP 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. 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 beneficiary of the OPTN, which is administered by the United Network for Organ Sharing (UNOS).

CCHP must authorize MOTs to be performed in a transplant program that meets DHCS' criteria. Bone marrow transplant programs must have current accreditation by the Foundation for the Accreditation of Cellular Therapy.

Most pediatric conditions requiring organ transplants qualify as a CCS-eligible condition. As such, MOTs for pediatric beneficiaries 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 will be 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>

The standards for all transplant programs in the United States are overseen by CMS. However, DHCS also reviews and approves the transplant programs. Upon approval, DHCS designates the transplant program as a Medi-Cal approved Center of Excellence (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, CCHP may email its Managed Care Operations Division Contract Manager to obtain the most current list of COEs to build its MOT network.

CCHP 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, CCHP 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 beneficiary of the OPTN. CCHP must also ensure that out-of-state transplant programs meet the criteria outlined in APL 20-015 Attachment 2 and that the out-of-state transplant program is enrolled as a Medi-Cal provider.

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. CCHP 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 CCHP that the beneficiary has been identified as a potential transplant candidate.

CCS MOT Service Authorization Requests (SARs) are typically authorized for one year. Non-CCS Treatment Authorization Requests (TARs) are authorized for a certain period of time depending on to 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

CCHP is 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. CCHP should require the necessary documentation from contracted hospitals in which transplant programs are located to validate that requirements are met no less than annually.

Under circumstances in which the transplant program cannot perform the MOT surgery and an organ is available, CCHP may arrange for the surgery to be performed at a different transplant program outside of its network. CCHP 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.

Referral and Authorization Process and Requirements

CCHP 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.

CCHP must then authorize the request for the MOT after the transplant program confirms the MOT candidacy of the beneficiary. CCHP can apply appropriate utilization management protocols that do not establish unreasonable or arbitrary barriers for assessing coverage. However, if an authorization request for MOT is denied, CCHP's Chief Medical Officer (CMO) will review the request and determine the appropriateness of the denial. Note that 72 hours means standard hours, not 72 business hours.

CCHP must refer pediatric beneficiaries (less than 21 years of age) to the County CCS program for CCS eligibility determination within 72-hours of the beneficiary's PCP or specialist identifying the beneficiary as potential candidate for the MOT. CCS Program staff must determine or confirm medical eligibility for all transplant candidates. The County CCS program will be 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 will be 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, CCHP must refer the beneficiary to a transplant program within 72 hours of receipt of the eligibility determination and will be responsible for authorizing the MOT, as appropriate.

Once the Transplant SCC confirms that the beneficiary is a suitable transplant candidate, the DHCS Medical Consultant or designee can then authorize the request for the transplant. The DHCS Medical Consultant or designee can apply appropriate utilization management protocols that do not establish unreasonable or arbitrary barriers for accessing coverage.

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

Network Requirements

Network requirements are monitored by CCHP Provider Relations but summarized here:

Due to the fact that transplant programs are located as a unit within a hospital, for purposes of network certification CCHP must contract with hospitals that have approval for a transplant program as described above. Transplant programs that perform corneal, autologous islet cell or kidney transplants are not required to be a Medi-Cal approved COE. CCHP 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 CCHP 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 CCHP's beneficiaries.

CCHP will be required to 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

CCHP will not be required to contract with SCCs or pediatric transplant programs. MCPs participating in Whole Child Model 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

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

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