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Purpose:

To define PHC California's (the Health Plan) utilization and coordination of care for major organ transplantation (MOT) for enrollees who are potential organ recipients and donors.

Policy:

1. The Health Plan shall refer, coordinate, and authorize the delivery of the major organ transplant benefit and all medically necessary services associated with major 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, and care coordination. Plan shall also cover all medically necessary services for both living donors and cadaver organ transplants.

2. The Health Plan shall only authorize major organ transplants to be performed in approved transplant programs located within a hospital that meets the Department of Health Care Services' (DHCS) criteria. This Policy and Procedure provides further details on covered benefits, current enrollment and care coordination requirements, and transplant programs that meet Department of Health Care Services (DHCS) criteria.

Covered Benefits:

1. The Health Plan covers all medically necessary major organ transplants as outlined in the Medi-Cal Provider Manual, including all updates and amendments to the Provider Manual.

2. The Health Plan shall ensure adult enrollees receive covered benefits at a facility designated as a Medi-Cal approved Center of Excellence (COE) for transplants related to the following major organs:

   a. Bone marrow

   b. Heart

   c. Heart-lung

   d. Kidney

   e. Liver

   f. Small bowel

g. Combined liver and small bowel

h. Lung

i. Simultaneous kidney-pancreas

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 Health Plan shall ensure that it refers 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.

3. The Health Plan's Care Coordination Department shall authorize appropriate non-emergency medical transportation, non-medical transportation services and related travel expenses related to major organ transplant for transplant recipients and living donors to obtain medically necessary services.

4. Medi-Cal Rx must pay pharmacy claims for major organ transplant related prescription drugs unless a member has other primary insurance or Medicare prescription drug coverage. The Health Plan or other primary insurer/Medicare shall be responsible for the cost of facility-administrated drugs, depending on the case history.

Current Enrollment and Care Coordination:

1. Enrollees approved for a major organ transplant and disenrolled from the Health Plan prior to January 1, 2022, shall remain disenrolled from the Health Plan and enrolled in a Fee-For-Service (FFS) Medi-Cal. The Medical Exemption Request (MER) and Emergency Disenrollment Exemption Request (EDER) process allows enrollees to be disenrolled from the Health Plan. The enrollment process into managed care Medi-Cal for mandatory enrollees will begin after the expiration of their MER or EDER. The Health Plan may refer to Implementation of Monthly Medical Exemption Review Denial Reporting, for guidance on notifications provided to beneficiaries forty-five (45) days prior to the expiration of an MER.

2. The Health Plan shall ensure coordination of care between all providers, organ donation entities, and transplant programs to ensure the major organ transplant is completed as expeditiously as possible. The Health Plan shall provide care coordination and care management services to transplant recipients.

Transplant Program Requirements:

1. The Health Plan shall ensure all major organ transplant 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, the Health Plan shall 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 OPTN, which is administered by the United Network for Organ Sharing (UNOS)[4].

3. The Health Plan shall authorize major organ transplants to be performed in a transplant program that meets DHCS' criteria. See below for further details.

    a. 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.

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

4. The criteria described above 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 above. 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.

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

5. The Health Plan shall authorize major organ transplants to be performed in a transplant program located outside of California if the reason for the major organ transplant 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 beneficiary must consent to receiving the major organ transplant out-of-state. In such cases, the Health Plan 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. The Plan must also ensure that out-of-state transplant programs meet the criteria outlined in 4 and 6, and that the out-of-state transplant program is enrolled as a Medi-Cal provider.

6. 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 Health Plan shall refer members or authorize referrals to the appropriate transplant program for an evaluation when the beneficiary's primary care physician (PCP) or specialist communicates to the Plan that the beneficiary has been identified as a potential transplant candidate.

7. Non-California Children's Services (CCS) Treatment Authorization Requests are authorized for a certain period of time depending on the type of major organ transplant as outlined below:

TRANSPLANT	DURATION OF TAR AUTHORIZATION
Liver with Hepatocellular Carcinoma	Four (4) months
Cirrhosis	Six (6) months
Bone Marrow	Six (6) months
Heart	Six (6) months
Lungs	Six (6) months
All others	One (1) year

8. The Plan shall monitor 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. The Plan shall require the necessary documentation from contracted hospitals in which transplant programs are located to validate those requirements are met no less than annually.

9. Under circumstances in which the transplant program cannot perform the major organ transplant surgery and an organ is available, the Health Plan's Utilization Department may arrange for the surgery to be performed at a different transplant program outside of its network. The Health Plan will ensure that the transplant program meets DHCS' COE requirements that are based on the following criteria:

    a. CMS approval for the appropriate organ; and

        i. OPTN membership for solid organs transplants; or

        ii. Accreditation by the Foundation for the Accreditation of Cellular Therapy for bone marrow transplants;

Referral and Authorization:

1. The Health Plan shall do the following:

    a. Directly refer adult beneficiaries or authorize referrals to a transplant program that meets DHCS criteria for an evaluation within seventy-two (72) standard hours of beneficiary's PCP or specialist identifying the beneficiary as a potential candidate for MOT and receiving all of the necessary information to make a referral or authorization.

2. The Health Plan can authorize the request for major organ transplant after the designated transplant program confirms member is a suitable transplant candidate.

3. The Health Plan can apply appropriate utilization management protocols that do not establish unreasonable or arbitrary barriers for accessing coverage. However, if an authorization request for major organ transplant is denied, the Health Plan's Medical Director must review the request and determine the appropriateness of the denial.

4. An expedited authorization is required if the organ 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 no later than seventy-two (72) hours.

5. If not specified above, the Health Plan shall follow policies and procedures for pre-authorization, concurrent review, retrospective review, appeals, timeframes for medical authorization, detection of under-and over-utilization, delegation of activities, and lists of services requiring prior authorization/utilization review criteria (see Policy and Procedures: UM 21, UM 22, UM, 23, UM 24, UM 35, UM 58, UM 59, and/or UM 99).

6. Execute a reinsurer contract to maintain a national major organ transplant COE network. The

Health Plan delegates major organ transplant COE network contracting functions to the reinsurer. The Health Plan's contract with its reinsurer stipulates ongoing major organ transplant COE network maintenance to ensure access needs are met for enrollees. The Health Plan shall retain responsibility for utilization management and care coordination/care management functions for major organ transplant cases.

Network Requirements:

1. The Health Plan shall contract with hospitals directly or through its reinsurer that have approval for a transplant program that meets the criteria provided by DHCS.

    a. 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 a major organ transplant.

2. The Health Plan shall have as many active contracts with hospitals as necessary to ensure that an approval transplant program for each organ listed below is within its network.

3. The Health Plan 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

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

5. The Plan is responsible for oversight and monitoring of its major organ transplant network. If the Plan 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 Plan must notify any beneficiary who has an active referral to the transplant program no later than thirty (30) days prior to the planned inactivation date. The Plan must coordinate the referral and transfer of beneficiaries to a different approved transplant program.

Transportation:

1. The Plan shall cover transportation services as required by the contract and directed in DHCS All Plan Letter 22-008, Non-Emergency Medical and Non-Medical Transportation Services and Related Travel Expenses, to ensure Members and their living transplant donors have access to all medically necessary services.

2. The Health Plan shall cover Emergency Medical Transportation services necessary to provide

access to all Medi-Cal Covered Services as described in Title 22 CCR Section 51323.

3. The Health Plan shall cover appropriate, NMT, NEMT, and related travel expenses to MOT for transplant recipient and living donors to obtain medically necessary services, upon the request of the major organ transplant donor or the major organ transplant recipient. as provided for in Title 22 CCR Section 51323, subject to Plan's Physician Certification Statement Form being completed by the Member's Provider.

    a. Physician Certification Statement (PCS) forms are not required for major organ transplant donors requesting NEMT services to ensure the donor has the ability to get to the hospital for the major organ transplant transplant. The Plan may utilize prior authorization and utilization management controls for the provision of related travel expenses, including protocols for determining whether an attendant is necessary for the member and the donor. The Health Plan will allow for an attendant for the donor if the Medical Director determines that an attendant to accompany the donor is necessary.

    b. The Plan must refer to DHCS All Plan Letter 22-008, Non-Emergency Medical and Non-Medical Transportation Services and Related Travel Expenses, or any superseding APL. DHCS APL 22-008 includes guidance for transportation related travel expenses, including meals and lodging.

4. The Plan shall refer and coordinate NEMT for Medi-Cal services not covered in this Contract.

5. As provided for in Welfare and Institutions Code, Section 14132(ad), the Health Plan shall authorize all NMT for Members to obtain Medically Necessary Covered Services in accordance with the requirements and guidelines set forth in DHCS APL 17-010. Nothing in this Provision should be construed to prohibit the Health Plan from developing policies and procedures which may include Prior Authorization requirements for NMT. The Health Plan must also provide NMT for all Medi-Cal services not covered under this Contract. These services include, but are not limited to, specialty mental health, substance use disorder, dental, and any other benefits delivered through Medi-Cal FFS.

6. If not mentioned above, the Health Plan shall follow policies and procedures for transportation (see Policy and Procedures: CM 43).

Procedure:

A. Major Organ Transplants (MOT) Care Coordination

1. Utilization Management Phase

    a. The attending medical provider shall identify the Member as a potential candidate for major organ transplant.

    b. Provider shall request authorization for Transplant Evaluation Services in accordance with the Health Plan and Medical Treatment Authorization Request Procedures.

    c. The Health Plan Utilization Management (UM) department will authorize request of outpatient referral and inpatient TAR process when it is medically indicated and appropriate. If the major organ transplant request does not meet the evidence-based

criteria for transplant, the referral will be referred to the Health Plan's Medical Director for review and decision.

2. Care Management Phase

   a. The Health Plan Care Manager shall complete an assessment and create a care plan appropriate for the Member.

   b. The Health Plan Care Manager shall update the assessment and care plan as the Member's status changes. In addition, the Care Manager will follow-up with the Member as necessary, based on the severity and complexity of the Member's case, to identify any issues that may prevent the Member from completing the major organ transplant.

3. Center of Excellence (COE) Transplant Center Evaluation Phase

   a. A Medi-Cal approved Center of Excellence (COE) Transplant Center shall request authorization for Transplant evaluation to the Health Plan for the major organ transplant.

   b. The Health Plan shall provide authorization for a Transplant evaluation at a COE for major organ transplant or a CMS approved transplant program for kidney, corneal, and autologous islet cell transplants. Upon completion of a Member's evaluation, the COE shall submit a Transplant Packet to Plan for review and approval for a major organ transplant.

   c. The Health Plan shall notify the COE of the outcome of the Transplant Packet review by Positive Healthcare, including approval or denial of the Transplant within the timeframes set forth in the Plan Utilization Management (UM) Program. The DHCS shall notify the Health Plan and the Transplant Center for other major organ transplant approvals/denials.

   d. The Health Plan Care Manager shall verify Member eligibility on a monthly basis and shall notify the Member's Health Network Care Manager and the COE of any changes in the Member's eligibility for members undergoing a major organ transplant.

4. Post-Authorization and Acceptance Phase

   a. The Health Plan Utilization Department will refer this member to a COE or to a CMS approved transplant program for: kidney, corneal, and/or autologous islet cell transplants.

   b. If a member qualifies as a candidate for a major organ transplant, the Health Plan Utilization Department will provide all Medically Necessary Covered Services as long as this member stays enrolled in the Health Plan.

   c. The Health Plan's Utilization Department will ensure continuity of care by transferring member's medical documentation of the Transplant Provider, as available, to care management team and primary care provider.

   d. The Health Plan will cover the cost of the evaluation performed by the COE.

B. Discharge Planning and Continued Care Coordination

1. The Health Plan Care Coordination Department shall ensure the provision of discharge planning when member is admitted to a hospital or institution and continuation into the post discharge period. Discharge planning shall include ensuring that necessary care, services, and supports are in place in the community for the member once they are discharged from a hospital or institution, including scheduling an outpatient appointment and/or conducting follow-up with the member and/or caregiver. Minimum criteria for a discharge planning checklist include:

    a. Documentation of pre-admission status, including living arrangements, physical and mental function, social support, Durable Medical Equipment (DME), and other services received.

    b. Documentation of pre-discharge factors, including an understanding of the medical condition by the member or a representative of the member as applicable, physical and mental function, financial resources, and social supports.

    c. Services needed after discharge, type of placement preferred by the member/representative of the member and hospital/institution, type of placement agreed to by the member/representative of the member, specific agency/home recommended by the hospital, specific agency/home agreed to by the member/representative of the member, and pre-discharge counseling recommended.

    d. Summary of the nature and outcome member/representative of the member involvement in the discharge planning process, anticipated problems in implementing post-discharge plans, and further action contemplated by the hospital/institution.

C. If not mentioned above, the Health Plan Care Coordination Department will follow policies and procedures for complex care management, care coordination, discharge planning/transitions of care, and transportation (see Policy and Procedures: CM 15, CM 30, UM 2 and UM 22).

Definitions:

1. All Plan Letter (APL) or Policy Letter (PL): means a binding document that has been dated, numbered, and issued by Department of Health Care Services (DHCS) that provides clarification of Health Plan’s contractual obligations, implementation instructions for Health Plan’s contractual obligations due to changes in State and federal law or judicial decisions, and/or guidance with regulatory force and effect when DHCS interprets, implements, or makes specific relevant State statutes under its authority.

2. Network Provider: means any Provider or entity that has a Network Provider Agreement with Health Plan, Health Plan’s Subcontractor, or Health Plan’s Downstream Subcontractor, and receives Medi-Cal funding directly or indirectly to order, refer, or render Covered Services under this Contract. A Network Provider is not a Subcontractor or Downstream Subcontractor by virtue of the Network Provider Agreement.

3. Non-Emergency Medical Transportation (NEMT): means ambulance, litter van, wheelchair van, and air medical transportation services. NEMT is used when the Member's medical and physical condition is such that transport by ordinary means of public or private conveyance is medically

contraindicated, and transportation is required for the purpose of obtaining needed medical care, and pursuant to 22 CCR sections 51323, 51231.1, and 51231.2, is rendered by licensed Providers.

4. Non-Medical Transportation (NMT): means transportation of Members to obtain Covered Services or Excluded Services by passenger car, taxicabs, or other forms of public or private conveyances, and mileage reimbursement when conveyance is in a private vehicle arranged by the Member and not through a transportation broker, bus passes, taxi vouchers, or train tickets. NMT does not include the transportation of sick, injured, invalid, convalescent, infirm, or otherwise incapacitated Members by ambulances, litter vans, or wheelchair vans licensed, operated, and equipped in accordance with State and local statutes, ordinances, or regulations.

Monitoring:

This policy and procedure is reviewed and updated as often as required and approved annually Utilization Management Committee (UMC).

Reference(s):

1. Department of Health Care Services All Plan Letter 21-015 Benefit Standardization and Mandatory Managed Care Enrollment Provisions of the California Advancing and Innovating Medi-Cal Initiative, Attachment 2 published October 18, 2021 (Revised October 14, 2022).

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

3. Monthly Medical Exemption Review Denial Reporting: https://www.dhcs.ca.gov/formsandpubs/Documents/MMCDAPLsandPolicyLetters/APL2017/APL17-007.pdf

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

5. 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

6. CM PHC-CA Care Coordination

7. CM PHC-CA Chronic Care Model

8. CM PHC-CA Transportation Benefit

9. UM PHC-CA Transition of Care

10. UM PHC-CA Access to Self-Referred Covered Services

11. UM PHC-CA Authorization Referral Process

12. UM PHC-CA Over-Under Utilization

13. UM PHC-CA Adverse Benefit Determination Appeal Process

14. UM PHC-CA Clinical Criteria and Guidelines

15. UM PHC-CA Inpatient Concurrent Review

16. UM PHC-CA Independent Medical Review

17. UM PHC-CA UM Vendor Delegation Oversight