# PARTNERSHIP HEALTHPLAN OF CALIFORNIA

# **POLICY/ PROCEDURE**

Policy/Procedure Number: MCUP3104			Lead Department: Health Services Business Unit: Utilization Management		
Policy/Procedure Title: Transplant Authori			zation Process	⊠External Policy □ Internal Policy	
<b>Original Date</b> : 04/21/2010		Next Review Date: 02/12/2026 Last Review Date: 02/12/2025			
Applies to:	🛛 Medi-Cal			Employees	
Reviewing	⊠IQI		□ P & T	⊠ QUAC	
Entities:	□ OPERATIONS		<b>EXECUTIVE</b>	<b>COMPLIANCE</b>	DEPARTMENT
Approving Entities:	□ BOARD		□ COMPLIANCE	□ FINANCE	⊠ PAC
			CREDENTIALING	DEPT. DIRECTOR/OFFICER	
Approval Signature: Robert Moore, MD, MPH, MBA			Approval Date: 02/12	2/2025	

## I. RELATED POLICIES:

- A. MCUP3124 Referral to Specialists (RAF) Policy
- B. MCUP3041 Treatment Authorization Request (TAR) Review Process
- C. MCUP3137 Palliative Care: Intensive Program (Adult)
- D. MCUP3140 Palliative Care: Pediatric Program for Members Under the Age of 21
- E. MCUP3039 Direct Members
- F. MCUP3138 External Independent Medical Review
- G. MCCP2024 Whole Child Model for California Children's Services (CCS)
- H. MCCP2016 Transportation Policy for Non-Emergency Medical (NEMT) and Non-Medical Transportation (NMT)
- I. MCCP2030 Transportation-Related Travel Expenses: Lodging, Meals, Attendants, Parking and Tolls
- J. MPCR700 Assessment of Organizational Providers
- K. MPPR200 Provider Contracts

## II. IMPACTED DEPTS:

- A. Health Services
- B. Claims
- C. Member Services
- D. Provider Relations

## **III. DEFINITIONS**:

- A. <u>Center of Excellence (COE)</u>: A Medi-Cal-approved 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).
- B. <u>Direct Member</u>: Direct Members are those whose service needs are such that Primary Care Provider (PCP) assignment would be inappropriate. Assignment to Direct Member status may be based on the member's medical condition, prime insurance, demographics or administrative eligibility status. Direct Members do not require a Referral Authorization Form (RAF) to see a specialist.
- C. <u>Organ Procurement and Transplantation Network (OPTN)</u>: The OPTN is operated under contract with the Health Resources & Services Administration (HRSA) of the U.S. Department of Health and Human Services by the United Network for Organ Sharing (UNOS). OPTN maintains the National Waitlist but only a Transplant Program can register patients on the National Wait list or remove them from the list.
- D. <u>Transplant Program</u>: 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 Organ Procurement and

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

#### IV. ATTACHMENTS:

A. N/A

#### V. PURPOSE:

- A. The purpose of this policy is to describe the Partnership HealthPlan of California treatment authorization process for transplants including the following:
  - 1. Bone Marrow (stem cell)\*
  - 2. Heart\*
  - 3. Lung\*
  - 4. Heart/lung\*
  - 5. Liver\*
  - 6. Combined liver/kidney\*
  - 7. Simultaneous Pancreas/Kidney (SPK)\*
  - 8. Pancreas After Kidney (PAK)\*
  - 9. Small Bowel (Intestinal) Transplant\*
  - 10. Combined liver/small bowel(intestinal)\*
  - 11. Kidney<sup>+</sup>
  - 12. Corneal transplant<sup>+</sup>
  - 13. Autologous islet cell<sup>+</sup>
  - 14. Chimeric Antigen Receptor T-Cell (CAR T-cell) therapy

\* These transplants can only be approved when performed by a Medi-Cal approved Center of Excellence (COE) as defined in III.A.

<sup>+</sup> Programs that perform corneal, autologous islet cell or kidney transplants are not required to be a Medi-Cal approved COE.

#### VI. POLICY / PROCEDURE:

- A. Partnership authorizes, refers, and coordinates the delivery of the Medi-Cal Major Organ Transplant (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<sup>1</sup>, and care coordination for transplants. All medically necessary adult and pediatric major organ transplants are covered as outlined in the Medi-Cal Provider Manual, including all updates and amendments to the Provider Manual. The Transplant section of the Medi-Cal Provider Manual is available at: <a href="https://mcweb.apps.prd.cammis.medi-cal.ca.gov/assets/8B313A4A-3B84-49DB-B98B-6A51BECCF01C/transplant.pdf?access">https://mcweb.apps.prd.cammis.medi-cal.ca.gov/assets/8B313A4A-3B84-49DB-B98B-6A51BECCF01C/transplant.pdf?access</a> token=6UyVkRRfByXTZEWIh8j8QaYyIPyP5ULO.
  - 1. Transplants will only be authorized to be performed in an approved transplant program located within a hospital that meets the Department of Health Care Services' (DHCS) criteria.
  - 2. As noted in V.A. above, certain transplants are only covered when performed by Medi-Cal approved Centers of Excellence (COE).

<sup>&</sup>lt;sup>1</sup> Effective January 1, 2022 with the implementation of Medi-Cal Rx, the pharmacy benefit is carved-out to Medi-Cal Fee-for-Service as described in <u>APL 22-012 Revised</u> "Governor's <u>Executive Order N-01-19</u> regarding Transitioning Medi-Cal Pharmacy Benefits from Managed Care to Medi-Cal Rx" and all medications (Rx and OTC) which are provided by a pharmacy must be billed to the State Medi-Cal/DHCS contracted pharmacy administrator instead of Partnership. Please refer to the State Medi-Cal Rx Education & Outreach page at this website: <u>https://medi-calrx.dhcs.ca.gov/home/education/</u>

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- 3. Bone marrow transplant programs must have current accreditation by the Foundation for the Accreditation of Cellular Therapy.
- 4. Major organ transplants for pediatric beneficiaries are required to be performed only in a Special Care Center (SCC) as approved by California Children's Services (CCS). A directory of SCCs can be found here: <u>https://www.dhcs.ca.gov/services/ccs/scc/Pages/SCCType.aspx</u>
- 5. Total pancreatectomy with autologous islet cell transplantation (TPIAT) is reimbursable by Medi-Cal when the patient has chronic pancreatitis or relapsing acute pancreatitis and meets medical necessity criteria as stated in the <u>Transplants section</u> of the Medi-Cal Provider Manual.
- 6. Kidney transplants must be performed by transplant programs approved by the Centers for Medicare & Medicaid (CMS) and the program must have current membership in the Organ Procurement and Transplantation Network (OPTN). Patients must meet medical necessity criteria as stated in the <u>Transplants section</u> of the Medi-Cal Provider Manual.
- 7. CAR T-cell therapy must meet drug-specific Risk Evaluation and Mitigation Strategy (REMS) requirements. For more information, refer to Medi-Cal Provider Manual Guidelines for chemotherapy drugs as Referenced in VII.F.-H. below.
- B. Members Age 21 and Over
  - 1. When a Member is identified as a potential candidate for a transplant, the Member should be referred to a Partnership-contracted Medi-Cal approved Transplant Center for evaluation as described in VI.A. Consistent with Partnership policy MCUP3124 Referral to Specialists (RAF) Policy, referrals to contracted specialists are auto-adjudicated and written approval is generated to the requesting primary care provider (PCP) and the specialist within one working day of the receipt of the request (not to exceed 72 hours).
  - 2. Members remain assigned to their primary care provider (PCP) during the evaluation process.
  - 3. Upon completion of the evaluation, if the Transplant Center Team confirms the Member is appropriate for transplant, the transplant program is responsible for placing the beneficiary on the National Waitlist maintained by The Organ Procurement and Transplantation Network OPTN. A Treatment Authorization Request (TAR) must then be submitted to Partnership. The request may be submitted electronically through Partnership's online Provider Portal, or by fax to 707-863-4118. The complete medical record including the member's medical and treatment history (including, starting in January 2020, either a palliative care consultation or equivalent documentation of discussion of options, prognosis, goals of care, and completion of advance care planning documents) pertinent lab studies, current condition and treatment, and requested procedure must accompany the TAR.
  - 4. Partnership will review the transplant request for medical necessity using the most up-to-date InterQual® criteria and DHCS medical and procedural guidelines. Transplant requests are reviewed by Partnership's Chief Medical Officer (CMO) or Physician designee and may be sent for external independent medical review as appropriate.
  - 5. Once the TAR is approved, the member, physician and facility are notified in writing.
  - 6. When the TAR for a transplant is approved, Partnership assigns the Member to a Direct Member status, Health Plan 5, to ensure continuity of care. Re-evaluation of the continued need for Direct Member status will be reviewed at the end of 12 months or as follows:
    - a. Heart transplant recipients are granted H5 for plan lifetime.
    - b. Bone Marrow transplant Members (including CAR T-cell therapy and gene therapy) become eligible for assignment to a PCP two years after receiving the transplant, but may qualify for continued H5 based on continuity of care criteria as detailed in policy MCUP3039 Direct Members.
- C. Members Under Age 21
  - 1. For members under age 21, the procedures noted in sections VI.B.1 through VI.B.4 remain the same. However, these members will also be evaluated for eligibility under the California Children's

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Services (CCS) program (see VI.C.3 for additional authorization criteria).

- 2. If the Member has not already been determined eligible under the CCS program, Partnership will work with the member's physician, parents/legal guardians and refer the case to the designated County CCS office for a financial and residential eligibility determination.
- 3. If the Member is determined eligible for CCS, Partnership will review the transplant request for medical necessity using a combination of the most up-to-date InterQual® criteria as well as the medical and procedural guidelines as directed in the DHCS "Numbered Letters" for CCS (some of which have not been updated for current standards of medical care). Medical Directors may obtain outside expert advice for complex cases or those where the Numbered Letters seem to conflict with current standards of care.
- 4. Members under age 21 with coverage under CCS are assigned to a Partnership Direct Member status called "Whole Child Model" (WCM) and will remain in that status until they reach their 21st birthday, as long as they retain residential, financial and medical eligibility with CCS. This status allows for direct referral to a specialist, without being subject to Partnership's Referral Authorization Form (RAF) process. (See policy MCCP2024 Whole Child Model for California Children's Services and MCUP3039 Direct Members).
- 5. Partnership will provide ongoing case management services and continue to coordinate care and transition of services for these members regardless of age, for as long as they remain eligible for coverage under Partnership. In the event that a WCM Member moves outside of Partnership's services area, Partnership will collaborate with the receiving county CCS staff to facilitate continuity of care.
- D. Donors
  - Per DHCS policy, Partnership will cover designated donor related hospital services associated with the transplant, including organ procurement for cadaver organ transplants or living donor care and related transportation expenses, if not covered by other insurance. (see also policy MCCP2016 – Transportation Policy for Non-Emergency Medical (NEMT) and Non-Medical Transportation (NMT) as well as policy MCCP2030 Ancillary Transportation Services: Lodging, Meals, Attendants, Parking and Tolls).

## VII. REFERENCES:

- A. In compliance with the California Department of Health Care Services (DHCS) contract
- B. In compliance with DHCS "Numbered Letters" for California Children's Services (CCS)
- C. InterQual® Criteria
- D. Medi-Cal Provider Manual/ Guidelines: Transplants
- E. Medi-Cal Provider Manual/ Guidelines: Surgery: Eye and Ocular Adnexa
- F. Medi-Cal Provider Manual/ Guidelines: Chemotherapy: Drugs A Policy
- G. Medi-Cal Provider Manual/ Guidelines: Chemotherapy: Drugs B Policy
- H. Medi-Cal Provider Manual/ Guidelines: Chemotherapy: Drugs C Policy
- I. Medi-Cal Provider Manual/ Guidelines: Chemotherapy: Drugs D Policy
- J. Medi-Cal Provider Manual/ Guidelines: Chemotherapy: Drugs E-H Policy
- K. Medi-Cal Provider Manual/ Guidelines: Chemotherapy: Drugs I-L Policy
- L. Medi-Cal Provider Manual/ Guidelines: Chemotherapy: Drugs M Policy
- M. Medi-Cal Provider Manual/ Guidelines: Chemotherapy: Drugs N-O Policy
- N. Medi-Cal Provider Manual/ Guidelines: Chemotherapy: Drugs P-Q Policy
- O. Medi-Cal Provider Manual/ Guidelines: Chemotherapy: Drugs R-S Policy
- P. Medi-Cal Provider Manual/ Guidelines: Chemotherapy: Drugs T-Z Policy
- Q. <u>Title 42</u> Code of Federal Regulations (CFR) parts 405, 482, 488, 498
- R. <u>Section 1138</u> of the Social Security Act (SSA).
- S. DHCS <u>APL 21-015</u> Benefit Standardization and Mandatory Managed Care Enrollment Provisions of the

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California Advancing and Innovating Medi-Cal Initiative (10/18/2021) <u>Attachment 2 Major Organ</u> <u>Transplant Requirements</u>. (*Revised* 10/14/2022)

- T. DHCS <u>APL 22-012</u> Governor's Executive Order N-01-19 Regarding Transitioning Medi-Cal Pharmacy Benefits from Managed Care to Medi-Cal Rx (*Revised* 12/30/2022)
- U. DHCS <u>APL 22-008</u> Non-Emergency Medical and Non-Medical Transportation Services and Related Travel Expenses (05/18/2022)

#### VIII. DISTRIBUTION:

- A. Partnership Department Directors
- B. Partnership Provider Manual

#### IX. POSITION RESPONSIBLE FOR IMPLEMENTING PROCEDURE: Chief Health Services Officer

#### X. **REVISION DATES:**

01/18/12; 02/18/15; 02/17/16; 02/15/17; \*03/14/18; 09/11/19; 09/09/20; 02/10/21; 02/09/22; 02/08/23: 02/14/24; 02/12/25

\*Through 2017, Approval Date reflective of the Quality/Utilization Advisory Committee meeting date. Effective January 2018, Approval Date reflects that of the Physician Advisory Committee's meeting date.

# PREVIOUSLY APPLIED TO:

N/A

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In accordance with the California Health and Safety Code, Section 1363.5, this policy was developed with involvement from actively practicing health care providers and meets these provisions:

- Consistent with sound clinical principles and processes
- Evaluated and updated at least annually
- If used as the basis of a decision to modify, delay or deny services in a specific case, the criteria will be disclosed to the provider and/or enrollee upon request

The materials provided are guidelines used by Partnership to authorize, modify or deny services for persons with similar illnesses or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under Partnership.

Partnership's authorization requirements comply with the requirements for parity in mental health and substance use disorder benefits in 42 CFR 438.910.