

PARTNERSHIP HEALTHPLAN OF CALIFORNIA

POLICY/ PROCEDURE

Policy/Procedure Number: MCUP3104			Lead Department: Health Services	
Policy/Procedure Title: Transplant Authorization Process			<input checked="" type="checkbox"/> External Policy <input type="checkbox"/> Internal Policy	
Original Date: 04/21/2010		Next Review Date: 02/14/2025 Last Review Date: 02/14/2024		
Applies to:	<input checked="" type="checkbox"/> Medi-Cal		<input type="checkbox"/> Employees	
Reviewing Entities:	<input checked="" type="checkbox"/> IQI		<input type="checkbox"/> P & T	
	<input type="checkbox"/> OPERATIONS		<input type="checkbox"/> EXECUTIVE	
Approving Entities:	<input type="checkbox"/> BOARD		<input type="checkbox"/> COMPLIANCE	
	<input type="checkbox"/> CEO <input type="checkbox"/> COO		<input type="checkbox"/> CREDENTIALING	
			<input type="checkbox"/> COMPLIANCE <input type="checkbox"/> DEPARTMENT	
			<input type="checkbox"/> FINANCE <input checked="" type="checkbox"/> PAC	
			<input type="checkbox"/> DEPT. DIRECTOR/OFFICER	
Approval Signature: Robert Moore, MD, MPH, MBA			Approval Date: 02/14/2024	

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. Center of Excellence (COE): 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. Direct Member: 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. Organ Procurement and Transplantation Network (OPTN): 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.

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- D. Transplant Program: 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 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 (PHC) 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⁺
12. Corneal transplant⁺
13. Autologous islet cell⁺
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.

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

VI. POLICY / PROCEDURE:

- A. PHC 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, medications¹, 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: https://mcweb.apps.prd.cammiis.medi-cal.ca.gov/assets/8B313A4A-3B84-49DB-B98B-6A51BECCF01C/transplant.pdf?access_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).

¹ 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 [APL 22-012 Revised](#) "Governor's [Executive Order N-01-19](#) 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 State Medi-Cal/Magellan instead of PHC. Please refer to the State Medi-Cal Rx Education & Outreach page at this website: <https://medi-calrx.dhcs.ca.gov/home/education/>

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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: <https://www.dhcs.ca.gov/services/ccs/scc/Pages/SCCType.aspx>
 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 [Transplants section](#) 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 [Transplants section](#) 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 PHC-contracted Medi-Cal approved Transplant Center for evaluation as described in VI.A. Consistent with PHC 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 PHC. The request may be submitted electronically through PHC'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. PHC 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 PHC'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, PHC assigns the member to a Direct Member status, Health Plan 5, for an initial period of 12 months to ensure continuity of care. Re-evaluation of the continued need for Direct Member status will be reviewed at the end of the 12-month period.
- 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 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, PHC 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, PHC 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

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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 PHC Direct Member status called “Whole Child Model” (WCM)² 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 PHC’s Referral Authorization Form (RAF) process. (See policy MCCP2024 Whole Child Model for California Children’s Services and MCUP3039 Direct Members).
 5. PHC 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 PHC. In the event that a WCM member moves outside of PHC’s services area, PHC will collaborate with the receiving county CCS staff to facilitate continuity of care.
- D. Donors
1. Per DHCS policy, PHC 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-D policy](#)
- G. Medi-Cal Provider Manual/ Guidelines: [Chemotherapy: Drugs E-O policy](#)
- H. Medi-Cal Provider Manual/ Guidelines: [Chemotherapy: Drugs P-Z policy](#)
- I. Title 42 Code of Federal Regulations (CFR) parts 405, 482, 488, 498
- J. Section 1138 of the Social Security Act (SSA).
- K. DHCS [APL 21-015](#) Benefit Standardization and Mandatory Managed Care Enrollment Provisions of the California Advancing and Innovating Medi-Cal Initiative (10/18/2021) [Attachment 2 Major Organ Transplant Requirements](#). (Revised 10/14/2022)
- L. DHCS [APL 22-012](#) Governor’s Executive Order N-01-19 Regarding Transitioning Medi-Cal Pharmacy Benefits from Managed Care to Medi-Cal Rx (Revised 12/30/2022)
- M. DHCS [APL 22-008](#) Non-Emergency Medical and Non-Medical Transportation Services and Related Travel Expenses (05/18/2022)

VIII. DISTRIBUTION:

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

² In PHC’s service area, 14 counties participate in the Whole Child Model program (Del Norte, Humboldt, Lake, Lassen, Marin, Modoc, Mendocino, Napa, Shasta, Siskiyou, Solano, Sonoma, Trinity, Yolo). As of January 1, 2024, the following 10 counties in PHC’s service area are participants in the State’s CCS program and are not participants in PHC’s Whole Child Model program: Butte, Colusa, Glenn, Nevada, Placer, Plumas, Sierra, Sutter, Tehama, and Yuba.

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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

*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

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 PHC 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 PHC.

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