



Policy:	GG.1105
Title:	<b>Coverage of Organ and Tissue Transplants</b>
Department:	Medical Management
Section:	Utilization Management
CEO Approval:	/s/ Michael Hunn 05/09/2024
Effective Date:	07/01/1995
Revised Date:	04/01/2024
Applicable to:	<input checked="" type="checkbox"/> Medi-Cal <input type="checkbox"/> OneCare <input type="checkbox"/> PACE <input type="checkbox"/> Administrative

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## I. PURPOSE

This policy defines Transplant coverage for CalOptima Health Members under the Medi-Cal program.

## II. POLICY

A. CalOptima Health or a Health Network delegated for Transplant services shall cover all Medically Necessary major organ transplants as outlined in this Policy and the Medi-Cal Provider Manual, including all updates and amendments to the Medi-Cal Provider Manual. The following Transplants are covered benefits under Medi-Cal:

1. Heart;
2. Heart and lung;
3. Lung;
4. Bone marrow;
5. Liver;
6. Small bowel;
7. Kidney;
8. Pancreas;
9. Autologous islet cell;
10. Combined liver and kidney;
11. Combined liver and small bowel;
12. Combined kidney and pancreas; and/or
13. Cornea, skin, tendon and sclera transplants.

- B. A Transplant shall be a Covered Service if a Member meets the patient selection criteria as defined in Section III.A. of this Policy and the Transplant is performed by a Medi-Cal approved Center of Excellence (COE) except as provided in this Policy.
  - 1. Transplant Programs that perform cornea, autologous islet cell or kidney Transplants are not required to be a Medi-Cal approved COE.
  - 2. Pediatric organ Transplants that qualify as a California Children's Services (CCS)-Eligible Condition are required to be performed only in a CCS-approved Special Care Center as specified in Section III.C. of this Policy.
- C. CalOptima Health or a Health Networks shall provide case management or complex case management for Covered Services directly related to the Transplant referral and evaluation, in accordance with CalOptima Health Policies GG.1301: Comprehensive Care Management Process and GG.1313: Coordination of Care for Transplant Members.

### **III. PROCEDURE**

#### **A. Selection Criteria**

- 1. A Transplant shall be a Covered Service upon CalOptima Health's or a Health Network's determination that the Member is a candidate for a Transplant, is compliant with all requirements, and does not have significant contraindications for the Transplant as follows:
  - a. Except for Members enrolled in a Health Maintenance Organization (HMO) that is responsible for all Covered Services for its assigned Members under its contract with CalOptima Health. CalOptima Health shall be responsible for the provision and payment of Medically Necessary Covered Services related to the Transplant, including but not limited to evaluation of potential Donors and procurement from living or deceased Donors, and care coordination in accordance with this Policy and CalOptima Health Policies GG.1313: Coordination of Care for Transplant Members, FF.1005a Special Payments – Bone Marrow Transplant and Solid Organ Transplant and FF.2001: Claims Processing for Covered Services for which CalOptima Health is Financially Responsible.
- 2. A Transplant and related services, including pre-transplantation assessments and appointments, hospitalization, surgery, discharge planning, readmissions due to complications, post-operative services, and Medically Necessary medications not otherwise covered, shall be Covered Services if:
  - a. A provider or practitioner obtains authorization for these services from CalOptima Health in accordance with CalOptima Health Policies GG.1500: Authorization Instructions for CalOptima Direct and CalOptima Community Network Providers, GG.1508: Authorization and Processing of Referrals and GG.1313: Coordination of Care for Transplant Members and GG.1535: Utilization Review Criteria and Guidelines;
  - b. The Transplant is performed in an approved facility as set forth in this Policy; and
  - c. The Member is accepted at the approved facility for the Transplant.
  - d. Effective January 1, 2022, pharmacy claims and payment for Transplant-related prescription drugs shall be the responsibility of Medi-Cal Rx. CalOptima Health shall be responsible for Medically Necessary physician administered drugs and facility-based medications billed on a medical claim related to a Transplant.

### 3. Renal Transplants

- a. A renal Transplant and related services are Covered Services if the Transplant is performed at a DHCS-approved Transplant Center.
- b. A renal Transplant and related services are Covered Services for Members with a California Children's Services (CCS)-Eligible Condition if the Transplant is performed at a DHCS-approved Special Care Renal Dialysis and Transplant Center.
- c. CalOptima Health shall consider the selection criteria for a renal Transplant as met if CalOptima Health determines that the Transplant is Medically Necessary, in accordance with Title 22, California Code of Regulations (CCR.), Sections 51003 and 51218.
- d. CalOptima Health or a Health Network delegated for Transplant services is responsible for the provision of all services related to a renal Transplant including, but not limited to, evaluation of potential Donors and nephrectomy from living, or deceased, Donors.

### 4. Cornea, Skin, Tendon, and Sclera Transplants

- a. A Transplant and related services for cornea, skin, tendon, and sclera are Covered Services if the Transplant is performed at a Medi-Cal facility or at a designated Special Care Center for Members with a CCS-Eligible Condition.
- b. CalOptima Health shall consider the selection criteria for such Transplants as met if CalOptima Health determines that the Transplant is Medically Necessary, in accordance with Title 22, California Code of Regulations (CCR), Section 51003.

## B. DHCS-approved Transplant Centers

1. Except for kidney transplants, all Medi-Cal covered transplants must be performed at a Medi-Cal-approved COE. A Medi-Cal approved COE Transplant Program is program that operates within a hospital setting, is certified and licensed through the Centers for Medicare & Medicaid Services (CMS) and meets Medi-Cal state and federal regulations consistent with Title 42, Code of Federal Regulations parts 405, 482, 488, 498, and section 1138 of the Social Security Act (Attachment A).
  - a. Solid Organ Transplant Programs must meet the CMS Conditions of Participation for a specific organ type and must maintain an active membership with the Organ Procurement and Transplantation Network (OPTN) administered by the United Network for Organ Sharing (UNOS).
  - b. Bone marrow Transplant Programs shall have current accreditation by the Foundation for the Accreditation of Cellular Therapy (FACT).
2. DHCS-approved Transplant Center for a renal Transplant is a facility that:
  - a. Is certified for, and participates in, the Medicare program;
  - b. Meets standards established by CMS or DHCS; and
  - c. Is certified by DHCS, to participate in the Medi-Cal program.

3. CalOptima Health's Chief Medical Officer (CMO) or Designee shall have the authority to determine CalOptima Health coverage of a Transplant performed at a DHCS-approved Transplant Center, whose certification by DHCS is probationary.
4. If a CMS- or DHCS-approved Transplant Center loses its certification by DHCS or CMS, CalOptima Health shall transfer any Members who are awaiting Transplants at such facility and shall notify a Member with an active referral to the Transplant Center no later than thirty (30) calendar days prior to the planned inactivation date.
5. Contracted hospitals within which Transplant Programs are located, shall meet DHCS' criteria, be enrolled to participate in the Medi-Cal program, and be evaluated in accordance with CalOptima Health Policy GG.1651: Assessment and Re-Assessment of Organizational Providers.

C. CCS-approved Transplant Special Care Centers

1. For Transplants made necessary by a CCS-Eligible Condition, the Transplant is 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. Transplants for CCS-eligible beneficiaries must be performed in a SCC that has been approved for the specific organ and age group (Attachment B). Special Care Centers shall meet the following criteria:
  - a. Have both a CCS program approved center for the specific organ and appropriate pediatric subspecialists on the hospital staff;
  - b. Include participation of the CCS-paneled pediatric subspecialists with the appropriate specialty for the specific organ, for the care of all patients under the age of eighteen (18) years; and
  - c. Admit all patients under the age of fourteen (14) years to a pediatric unit or floor.
2. CalOptima Health or a Health Network shall identify a DHCS CCS-approved Transplant Special Care Center based upon information, documentation and representation received from DHCS and CCS.
3. CalOptima Health or a Health Network shall refer the CCS-eligible Member for an evaluation within seventy-two (72) hours of the Member's Primary Care Provider (PCP) or specialist identifying the CCS-eligible Member as a potential candidate for a Transplant and shall authorize the request after the SCC confirms that the Member is a suitable candidate.
4. CalOptima Health Chief Medical Officer (CMO) or Designee shall have the authority to determine CalOptima Health coverage of a Transplant performed at a DHCS- and CCS-approved Transplant Special Care Center, whose certification by DHCS CCS is probationary.
5. If a DHCS CCS-approved Transplant Special Care Center loses its certification by DHCS CCS, CalOptima Health shall transfer any Members who are awaiting Transplants at such facility and shall notify a Member with an active referral to the Transplant Center no later than thirty (30) calendar days prior to the planned inactivation date.

D. CalOptima Health shall process and pay claims for Transplants and related services in accordance with CalOptima Health Policies FF.1005a: Special Payments – Bone Marrow Transplant and Solid Organ Transplant, and FF.2001: Claims Processing for Covered Services Rendered to CalOptima

Direct-Administrative Members, CalOptima Community Network Members, or Members Enrolled in a Shared Risk Group.

- E. CalOptima Health shall authorize appropriate Non-emergency Medical Transportation and Non-Medical Transportation services for Transplant recipients and living Donors in accordance with CalOptima Health Policy GG.1505: Transportation: Emergency, Non-Emergency, and Non-Medical.
- F. Out-of-Network Transplants
  - 1. If a Transplant Program cannot perform the major organ transplant surgery and an organ is available, CalOptima Health may arrange for the surgery to be performed at a different Transplant Program outside its network in accordance with CalOptima Health Policy GG.1539: Authorization for Out-of-Network and Out-of-Area Services. CalOptima Health shall ensure that the Transplant Program meets DHCS' COE requirements based on the following criteria:
    - a. CMS approval for the appropriate organ; and
      - i. OPTN membership for solid organ Transplants; or
      - ii. Accreditation by the FACT for bone marrow Transplants.
    - b. CCS-approved Special Care Center within a tertiary hospital.
  - 2. CalOptima Health may authorize a major organ Transplants to be performed outside of California if the reason for the major organ Transplant to be provided out-of-state is advantageous to the Member and the Member agrees to receiving the major organ Transplant out-of-state.
    - a. CalOptima Health shall ensure the process for referring, authorizing referrals and coordinating Transplants is not more restrictive than for in-state Transplants and the facility is designated by CMS to perform Transplants for a specific type of organ, is a current beneficiary of the OPTN, and is enrolled as a Medi-Cal provider.

#### **IV. ATTACHMENT(S)**

- A. Medi-Cal approved Centers of Excellence
- B. California Children's Services (CCS)-approved Special Care Centers for Transplants

#### **V. REFERENCE(S)**

- A. CalOptima Health Contract with the Department of Health Care Services (DHCS) for Medi-Cal
- B. CalOptima Health Policy FF.1005a: Special Payments – Bone Marrow Transplant and Solid Organ Transplant
- C. CalOptima Health Policy FF.2001: Claims Processing for Covered Services for which CalOptima Health is Financially Responsible
- D. CalOptima Health Policy GG.1301: Comprehensive Care Management Process
- E. CalOptima Health Policy GG.1313: Coordination of Care for Transplant Members
- F. CalOptima Health Policy GG.1101: California Children's Services (CCS)/Whole Child Model – Coordination with County CCS Program
- G. CalOptima Health Policy GG.1505: Emergency, Non-Emergency, and Non-Medical
- H. CalOptima Health Policy GG.1539: Authorization for Out-of-Network and Out-of-Area Services
- I. CalOptima Health Policy GG.1651: Assessment and Re-Assessment of Organizational Providers

- J. CalOptima Health Memorandum of Understanding with California Children's Services
- K. CalOptima Health Utilization Management Program
- L. Department of Health Care Services All Plan Letter 21-015: Benefit Standardization and MMCE Provisions of CalAIM
- M. Department of Health Care Services All Plan Letter 23-034 California's Childrens Services Whole Child Model Program (supersedes APL 21-005)
- N. Department of Health Care Services Operating Instruction Letter 139-06, Pancreas Transplants
- O. Medi-Cal Provider Manual (Transplants)
- P. Social Security Act, §1138
- Q. Title 42, Code of Federal Regulations, Parts 405, 482, 488 and 498
- R. Title 22, California Code of Regulations (CCR), §§51003 and 51218
- S. Welfare and Institutions Code, §§14132.69, 14132.70, 14132.71, and 14133.8

## VI. REGULATORY AGENCY APPROVAL(S)

Date	Regulatory Agency	Response
02/24/2016	Department of Health Care Services (DHCS)	Approved as Submitted
10/21/2021	Department of Health Care Services (DHCS)	Approved as Submitted
11/29/2021	Department of Health Care Services (DHCS)	Approved as Submitted
01/03/2022	Department of Health Care Services (DHCS)	Approved as Submitted
03/23/2022	Department of Health Care Services (DHCS)	File and Use
06/30/2023	Department of Health Care Services (DHCS)	Approved as Submitted
05/02/2024	Department of Health Care Services (DHCS)	Approved as Submitted

## VII. BOARD ACTION(S)

Date	Meeting
12/05/2019	Regular Meeting of the CalOptima Board of Directors
03/03/2022	Regular Meeting of the CalOptima Board of Directors

## VIII. REVISION HISTORY

Action	Date	Policy	Policy Title	Program(s)
Effective	07/01/1995	GG.1105	Coverage of Organ and Tissue Transplants	Medi-Cal
Revised	01/01/2007	GG.1105	Coverage of Organ and Tissue Transplants	Medi-Cal
Revised	11/01/2015	GG.1105	Coverage of Organ and Tissue Transplants	Medi-Cal OneCare OneCare Connect
Revised	10/01/2016	GG.1105	Coverage of Organ and Tissue Transplants	Medi-Cal OneCare OneCare Connect
Revised	08/01/2017	GG.1105	Coverage of Organ and Tissue Transplants	Medi-Cal OneCare OneCare Connect
Revised	12/05/2019	GG.1105	Coverage of Organ and Tissue Transplants	Medi-Cal
Revised	10/01/2020	GG.1105	Coverage of Organ and Tissue Transplants	Medi-Cal
Revised	04/01/2021	GG.1105	Coverage of Organ and Tissue Transplants	Medi-Cal
Revised	03/03/2022	GG.1105	Coverage of Organ and Tissue Transplants	Medi-Cal
Revised	06/01/2023	GG.1105	Coverage of Organ and Tissue Transplants	Medi-Cal
Revised	04/01/2024	GG.1105	Coverage of Organ and Tissue Transplants	Medi-Cal

## IX. GLOSSARY

Term	Definition
Bone Marrow Transplant	A procedure in which a patient's bone marrow is destroyed by chemotherapy or radiotherapy and replaced with new bone marrow from a Donor. The Donor may be the patient (autologous), a sibling with human histocompatibility antigens (HL-A) identical to the patient's, or a matched unrelated donor (MUD) with human histocompatibility antigens (HL-A) that meet the Department of Health Care Services (DHCS) standards.
California Children's Services (CCS)-Eligible Conditions	A medical condition that qualifies a Child to receive medical services under the CCS Program, as specified in 22 CCR section 41515.1 et seq.
California Children's Services (CCS) Program	A State and county program providing Medically Necessary services to treat CCS-Eligible Conditions.
Covered Services	<p>Those health care services, set forth in W&amp;I sections 14000 et seq. and 14131 et seq., 22 CCR section 51301 et seq., 17 CCR section 6800 et seq., the Medi-Cal Provider Manual, the California Medicaid State Plan, the California Section 1115 Medicaid Demonstration Project, this Contract, and APLs that are made the responsibility of CalOptima Health pursuant to the California Section 1915(b) Medicaid Waiver authorizing the Medi-Cal managed care program or other federally approved managed care authorities maintained by DHCS.</p> <p>Covered Services do not include:</p> <ol style="list-style-type: none"> <li>1. Home and Community-Based Services (HCBS) program as specified in Exhibit A, Attachment III, Subsections 4.3.15 (Services for Persons with Developmental Disabilities), 4.3.20 (Home and Community-Based Services Programs) regarding waiver programs, 4.3.21 (In-Home Supportive Services), and Department of Developmental Services (DDS) Administered Medicaid Home and Community-Based Services Waiver. HCBS programs do not include services that are available as an Early and Periodic Screening, Diagnosis and Treatment (EPSDT) service, as described in 22 CCR sections 51184, 51340 and 51340.1. EPSDT services are covered under this Contract, as specified in Exhibit A, Attachment III, Subsection 4.3.11 (Targeted Case Management Services), Subsection F4 regarding services for Members less than 21 years of age. CalOptima Health is financially responsible for the payment of all EPSDT services;</li> <li>2. California Children's Services (CCS) as specified in Exhibit A, Attachment III, Subsection 4.3.14 (California Children's Services), except for Contractors providing Whole Child Model (WCM) services;</li> <li>3. Specialty Mental Health Services as specified in Exhibit A, Attachment III, Subsection 4.3.12 (Mental Health Services);</li> <li>4. Alcohol and SUD treatment services, and outpatient heroin and other opioid detoxification, except for medications for addiction treatment as specified in Exhibit A, Attachment III, Subsection 4.3.13 (Alcohol and Substance Use Disorder Treatment Services);</li> <li>5. Fabrication of optical lenses except as specified in Exhibit A, Attachment III, Subsection 5.3.7 (Services for All Members);</li> </ol>

Term	Definition
	<ol style="list-style-type: none"> <li>6. Direct Observed Therapy for Treatment of Tuberculosis (TB) as specified in Exhibit A, Attachment III, Subsection 4.3.18 (Direct Observed Therapy for Treatment of Tuberculosis);</li> <li>7. Dental services as specified in W&amp;I sections 14131.10, 14132(h), 14132.22, 14132.23, and 14132.88, and EPSDT dental services as described in 22 CCR section 51340.1(b). However, CalOptima Health is responsible for all Covered Services as specified in Exhibit A, Attachment III, Subsection 4.3.17 (Dental) regarding dental services;</li> <li>8. Prayer or spiritual healing as specified in 22 CCR section 51312;</li> <li>9. Educationally Necessary Behavioral Health Services that are covered by a Local Education Agency (LEA) and provided pursuant to a Member's Individualized Education Plan (IEP) as set forth in Education Code section 56340 et seq., Individualized Family Service Plan (IFSP) as set forth in California Government Code (GC) section 95020, or Individualized Health and Support Plan (IHSP). However, CalOptima Health is responsible for all Medically Necessary Behavioral Health Services as specified in Exhibit A, Attachment III Subsection 4.3.16 (School-Based Services);</li> <li>10. Laboratory services provided under the State serum alpha-feto-protein-testing program administered by the Genetic Disease Branch of California Department of Public Health (CDPH);</li> <li>11. Pediatric Day Health Care, except for Contractors providing Whole Child Model (WCM) services;</li> <li>12. State Supported Services;</li> <li>13. Targeted Case Management (TCM) services as set forth in 42 USC section 1396n(g), W&amp;I sections 14132.48 and 14021.3, 22 CCR sections 51185 and 51351, and as described in Exhibit A, Attachment III, Subsection 4.3.11 (Targeted Case Management Services). However, if Members less than 21 years of age are not eligible for or accepted by a Regional Center (RC) or a local government health program for TCM services, CalOptima Health must ensure access to comparable services under the EPSDT benefit in accordance with APL 23-005;</li> <li>14. Childhood lead poisoning case management provided by county health departments;</li> <li>15. Non-medical services provided by Regional Centers (RC) to individuals with Developmental Disabilities, including but not limited to respite, out-of-home placement, and supportive living;</li> <li>16. End of life services as stated in Health and Safety Code (H&amp;S) section 443 et seq., and APL 16-006; and</li> <li>17. Prescribed and covered outpatient drugs, medical supplies, and enteral nutritional products when appropriately billed by a pharmacy on a pharmacy claim, in accordance with APL 22-012.</li> </ol>
Department of Health Care Services (DHCS)-approved Transplant Center	<p>Facilities that are approved by the Department of Health Care Services (DHCS) to provide specific Transplant services. For renal transplants, a DHCS-approved Transplant Center is a facility that:</p> <ol style="list-style-type: none"> <li>1. Is certified for, and participates in, the Medicare program; and</li> <li>2. Meets standards established by DHCS and is certified by DHCS to participate in the Medi-Cal program.</li> </ol>



<b>Term</b>	<b>Definition</b>
Designee	A person selected or designated to carry out a duty or role. The assigned designee is required to be in management or hold the appropriate qualifications or certifications related to the duty or role.
Donor	For the purposes of this policy, refers to an individual who undergoes a surgical operation for the purpose of donating a body organ or human tissue or cells for Transplant.
Medically Necessary or Medical Necessity	Reasonable and necessary Covered Services to protect life, to prevent significant illness or significant disability, or alleviate severe pain through the diagnosis or treatment of disease, illness, or injury, as required under W&I Code 14059.5(a) and Title 22 CCR Section 51303(a). Medically Necessary services shall include Covered Services necessary to achieve age-appropriate growth and development, and attain, maintain, or regain functional capacity. For Members under 21 years of age, a service is Medically Necessary if it meets the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) standard of medical necessity set forth in Section 1396dI(5) of Title 42 of the United States Code, as required by W&I Code 14059.5(b) and W&I Code Section 14132(v). Without limitation, Medically Necessary services for Members under 21 years of age include Covered Services necessary to achieve or maintain age-appropriate growth and development, attain, regain or maintain functional capacity, or improve, support or maintain the Member's current health condition. CalOptima Health shall determine Medical Necessity on a case-by-case basis, taking into account the individual needs of the child.
Member	A Medi-Cal eligible beneficiary as determined by the County of Orange Social Services Agency, the California Department of Health Care Services (DHCS) Medi-Cal Program, or the United States Social Security Administration, who is enrolled in the CalOptima Health program.
Non-Emergency Medical Transportation (NEMT)	Ambulance, litter van and wheelchair van medical transportation services 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, per Title 22, CCR, Sections 51231.1 and 51231.2, rendered by licensed Providers.
Non-Medical Transportation (NMT)	Transportation of Members to medical services by passenger car, taxicabs, or other forms of public or private conveyances provided by persons not registered as Medi-Cal providers. 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.
Solid Organ Transplant	A Transplant for: <ol style="list-style-type: none"> <li>1. Heart;</li> <li>2. Heart and lung;</li> <li>3. Lung;</li> <li>4. Liver;</li> <li>5. Small bowel;</li> <li>6. Kidney;</li> <li>7. Combined liver and kidney;</li> <li>8. Combine liver and small bowel; or</li> <li>9. Combined kidney and pancreas</li> </ol>
Transplant	A Non-Experimental procedure for human tissue, blood or organ Transplant.

Term	Definition
Transplant Program	A unit within a hospital that has received approval from the Centers for Medicare & Medicaid Services (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).