



Policy: MA.6044
Title: **Coverage of Solid Organ and Stem Cell Transplants**
Department: Medical Management
Section: Utilization Management

CEO Approval: /s/ Michael Hunn 12/20/2024

Effective Date: 12/05/2019

Revised Date: 12/01/2024

Applicable to: ☐ Medi-Cal
☒ OneCare
☐ PACE
☐ Administrative

I. PURPOSE

This policy defines the coverage of Solid Organ and Stem Cell Transplants and related care and services for CalOptima Health Members in the OneCare Program.

II. POLICY

- A. A Solid Organ or Stem Cell 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.
- B. CalOptima Health or a Health Network shall be responsible for the provision and payment of Covered Services related to a Transplant including the following:
 - 1. Pre-transplant evaluation, including physician, psychological and social work consultations, necessary lab work and imaging;
 - 2. Evaluation of potential Donors and organ/stem cell procurement fees, excluding procurement fees for kidney transplants which shall be the responsibility of Original Medicare Fee for Service program;
 - 3. Transplant care, including inpatient facility and professional fees;
 - 4. Post-transplant care, including Medically Necessary immunosuppressant drugs.
- C. A Solid Organ or Stem Cell Transplant and related services shall be Covered Services if:
 - 1. A Provider or Practitioner obtains prior authorization for these services from CalOptima Health or a Health Network in accordance with CalOptima Health Policy GG.1508: Authorization and Processing of Referrals. The Transplant meets Medically Necessity and utilization review criteria and guidelines for coverage of the Solid Organ or Stem Cell Transplant and related services as described in CalOptima Health Policy GG.1535: Utilization Review Criteria and Guidelines.
 - 2. The Transplant is performed at an approved facility, as set forth in Section III.A. of this Policy; and

3. The Member is accepted at the approved facility for the following Transplants:

- a. Heart;
- b. Lung;
- c. Heart/Lung;
- d. Kidney;
- e. Pancreas;
- f. Kidney/Pancreas;
- g. Liver;
- h. Intestine;
- i. Liver/Intestine; and
- j. Stem Cell.

D. CalOptima Health or a Health Network shall not approve the following Transplants:

- 1. Transplants that are experimental/investigational in nature, unless in a qualified Medicare-approved clinical trial;
- 2. Combined kidney and liver Transplant;
- 3. Pancreas Transplant for diabetic Members who have not experienced end stage renal failure secondary to diabetes;
- 4. Partial pancreatic tissue transplantation;
- 5. Adult liver transplantation for malignancies (excluding hepatocellular carcinoma); and
- 6. Nationally non-covered indications in the respective National Coverage Determinations.

E. Routine costs for Investigational Services associated with a Clinical Trial may be covered by CalOptima Health or a Health Network in accordance with CalOptima Health Policy GG.1102: Experimental and Investigational Service Coverage.

F. CalOptima Health or a Health Network shall provide notification on decisions for services requiring prior authorization in accordance with CalOptima Health Policy GG.1507: Notification Requirements for Covered Services Requiring Prior Authorization.

G. When CalOptima Health or a Health Network authorizes a Member to receive a Transplant outside of CalOptima Health's Service Area, CalOptima Health or a Health Network shall cover reasonable expenses for transportation to and lodging at the distant location for the Member and a companion.

H. Transplants not covered under the OneCare program, may be covered under the CalOptima Health Medi-Cal program as set forth in CalOptima Health Policy GG.1105: Coverage of Organ and Tissue Transplants.

III. PROCEDURE

A. Centers for Medicare & Medicaid Services (CMS)-approved Transplant Centers

1. A Transplant must be performed in a CMS-approved Transplant Center for that specific Transplant type; as required by CMS and the decision based on Medicare coverage criteria, including national and local coverage determinations (NCDs and LCDs)
2. CalOptima Health or a Health Network shall identify a CMS-approved Transplant Center, based upon information, documentation, and representation received from CMS.
3. CalOptima Health or a Health Networks' Chief Medical Officer (CMO) or Designee shall have the authority to determine coverage of a Transplant performed at a CMS-approved Transplant Center, whose certification by CMS is probationary.
4. If a CMS-approved Transplant Center loses its certification by CMS, CalOptima Health shall have the right to transfer any Members who are awaiting Transplants at such facility.

IV. ATTACHMENT(S)

Not Applicable

V. REFERENCE(S)

- A. CalOptima Health Contract with the Centers for Medicare & Medicaid Services (CMS) for Medicare Advantage
- B. Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee for Service, and Medicaid Managed Care Programs FY2024 (Final Rule CMS-4190-F1)
- C. CalOptima Health Policy GG.1102: Experimental and Investigational Service Coverage
- D. CalOptima Health Policy GG.1105: Coverage of Organ and Tissue Transplants
- E. CalOptima Health Policy GG.1507: Notification Requirements for Covered Services Requiring Prior Authorization
- F. CalOptima Health Policy GG.1508: Authorization and Processing of Referrals
- G. CalOptima Health Policy GG.1535: Utilization Review Criteria and Guidelines
- H. CalOptima Health Utilization Management Program

VI. REGULATORY AGENCY APPROVAL(S)

None to Date

VII. BOARD ACTION(S)

Date	Meeting
12/05/2019	Regular Meeting of the CalOptima Board of Directors
11/05/2020	Regular Meeting of the CalOptima Board of Directors

VIII. REVISION HISTORY

Action	Date	Policy	Policy Title	Program(s)
Effective	12/05/2019	MA.6044	Coverage of Solid Organ and Stem Cell Transplants	OneCare OneCare Connect

Action	Date	Policy	Policy Title	Program(s)
Revised	01/01/2021	MA.6044	Coverage of Solid Organ and Stem Cell Transplants	OneCare OneCare Connect
Revised	06/01/2021	MA.6044	Coverage of Solid Organ and Stem Cell Transplants	OneCare OneCare Connect
Revised	12/31/2022	MA.6044	Coverage of Solid Organ and Stem Cell Transplants	OneCare
Revised	12/31/2023	MA.6044	Coverage of Solid Organ and Stem Cell Transplants	OneCare
Revised	12/01/2024	MA.6044	Coverage of Solid Organ and Stem Cell Transplants	OneCare

IX. GLOSSARY

Term	Definition
Centers for Medicare & Medicaid Services (CMS)	The federal agency under the United States Department of Health and Human Services responsible for administering the Medicare and Medicaid programs.
Covered Services	Those medical services, equipment, or supplies that CalOptima Health is obligated to provide to Members under the Centers for Medicare & Medicaid Services (CMS) Contract.
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 solid organ or stem cells for Transplant.
Medically Necessary or Medical Necessity	Reasonable and necessary medical 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 includes Medi-Cal Services necessary to achieve age-appropriate growth and development, and attain, maintain, or regain functional capacity.
Member	A beneficiary enrolled in a CalOptima Health program.
Practitioner	A licensed independent Practitioner including but not limited to a Doctor of Medicine (MD), Doctor of Osteopathy (DO), Doctor of Podiatric Medicine (DPM), Doctor of Chiropractic Medicine (DC), Doctor of Dental Surgery (DDS), Doctor of Psychology (PhD or PsyD), Licensed Clinical Social Worker (LCSW), Marriage and Family Therapist (MFT or MFCC), Nurse Practitioner (NP), Nurse Midwife, Physician Assistant (PA), Optometrist (OD), Registered Physical Therapist (RPT), Occupational Therapist (OT), Speech and Language Therapist furnishing Covered Services.
Provider	Any Medicare provider (e.g., hospital, skilled nursing facility, home health agency, outpatient physical therapy, comprehensive outpatient rehabilitation facility, end-stage renal disease facility, hospice, physician, non-physician provider, laboratory, supplier) providing Covered Services under Medicare Part B. Any organization, institution, or individual that provides Covered Services to Medicare members. Physicians, ambulatory surgical centers, and outpatient clinics are some of the providers of Covered Services under Medicare Part B.
Service Area	The county or counties that CalOptima Health is approved to operate under the terms of CalOptima Health's contracts with DHCS and CMS.
Stem Cell Transplant	A process which includes mobilization, harvesting, and transplant of peripheral blood stem cells and the administration of high dose chemotherapy or radiotherapy prior to the actual Transplant.
Transplant	A non-experimental procedure for Solid Organ or Stem Cell Transplant.
Transplant Center	For the purposes of this policy, refers to facilities that are approved by the Centers for Medicare & Medicaid (CMS) to provide specific Transplant services.