



Promise Health Plan

## POLICY & PROCEDURE Medical Services

**Policy Title: Organ Transplantation**

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**Revision No:** 6

**Department Head:**

**Date:**

**Medical Services/P&T Committee:**

**Date:**

**P&P Committee:**

**Date:**

**Department(s):**

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### PURPOSE:

To establish a mechanism for providers and Blue Shield Promise Health Plan to identify members potentially requiring organ transplant and to facilitate diagnosis, work up, referral, and if necessary, disenrollment from the plan.

#### Types of Major Organ Transplantation

- Bone marrow transplants
- Heart transplants
- Lung and Heart-lung transplant
- Liver transplants
- Liver-kidney combined transplant

### POLICY:

#### Overview:

Except for kidney transplants, major organ transplants that are Medi-Cal FFS benefits are not covered under the contract with LA Care. The major organ transplants listed above are excluded services because members age 21 and older who are approved as candidates for an approved procedure listed above will be disenrolled and covered by fee-for-service Medi-Cal. For Blue Shield Promise members under 21 years of age, the responsibility for provision of and payment for major organ transplant procedures is covered by California Children Services (CCS). Kidney & Cornea transplants for members under 21 are also covered by CCS. It is Care1st goal to achieve early identification of potential transplant candidates and carefully coordinate services so that members are evaluated for organ transplants promptly and directed to approved facilities.

#### RENAL TRANSPLANTS

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Renal transplants for members aged 21 years and older are a covered benefit under Blue Shield Promise Health Plan. Upon identification of a members in need of a renal transplant, Blue Shield Promise will refer the member to an approved renal transplant center Blue Shield Promise is responsible for the continuation of all necessary primary care services and the provision of all services related to renal transplantation including (but not limited to) evaluation of potential donors and nephrectomy from living or cadaver donors.

Blue Shield Promise will refer members under 21 years of age in need of evaluation as potential renal transplant candidates to the appropriate CCS program office for referral to an approved CCS Renal Dialysis and Transplant center. All related transplant service requests shall be sent to the local CCS program office authorization. Blue Shield Promise will continue to coordinate services with CCS.

## **PROCEDURE:**

### Identification, Evaluation, Authorization, and Disenrollment

Primary Care Physicians, Specialty Physicians, or Hospitals may identify members as potential transplant candidates.

When a member is identified as a potential transplant candidate, he/she is referred to Case Management. The Case Manager will coordinate referral of the member to a Medi-Cal approved transplant center including facilitating the forwarding of pertinent medical records.

If the transplant center physician considers the member to be a suitable candidate, the Blue Shield Promise Case Manager shall submit a Treatment Authorization Request (TAR) to either the Medi-Cal Field Office (for adults) or CCS (for children) for approval. Blue Shield Promise Health Plan Case Manager will initiate disenrollment of the member when all of the following has occurred:

- Referral of the member to the organ transplant facility
- The facility's evaluation has concurred that the member is a candidate for a major organ transplant
- The major organ transplant is authorized by either DHS Medi-Cal Field Office (for adults) or CCS (for children)

Blue Shield Promise Health Plan will continue to provide all medically necessary covered services until the member has been disenrolled from the plan.

Upon the disenrollment effective date, Blue Shield Promise Health Plan will ensure continuity of care by transferring all of the member's medical documentation to the transplant physician. The effective date of the disenrollment will be retroactive to the beginning of the month in which the member was approved as a major organ transplant candidate. The request of reimbursement for services in the month during which the transplant is approved are to be sent by the provider

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directly to the Medi-Cal FFS fiscal intermediary. The capitation payment for the member will be recovered from the Blue Shield Promise by DHS.

If a member is evaluated and determined not to be a candidate for a major organ transplant, or DHS denies authorization for a transplant, the member will not be disenrolled. Blue Shield Promise is responsible for the cost of the evaluation performed by the Medi-Cal approved transplant center.

### **Clinical Selection Criteria from MMCS Letter 94-11, Major Organ Transplants**

#### **Bone Marrow Transplants (BMT)**

##### *General Criteria*

- Upper age limits:
  - 50 years old ALBMT
  - 65 years old for syngeneic and AUBMT
  - 50 years old for Matched Unrelated Donor BMT
- The BMT is intended to cure the patient of the disease for which BMT is performed
- The patient is one for whom current medical therapy is not as likely as BMT to be curative or to prevent progressive disability or death.
- After the BMT is performed, the patient is expected to have a range of physical and social function consistent with usual activities of daily living
- The patient does not have an additional progressive disorder, which would otherwise seriously jeopardize survival; i.e., another life shortening or seriously disabling condition.
- A Medi-Cal approved BMT center has evaluated the patient and a BMT was recommended.

#### **Heart Transplants**

##### *General Criteria*

- The patient has end stage heart disease for which current medical therapy will not prevent progressive disability and death, and the expectation of survival does not exceed a few months.
- The heart transplantation is likely to prolong life for at least five years (better than 50% five-year survival) and restore a range of physical and social function suited to activities of daily living.
- The patient's psychological assessment, social arrangement and/or support system indicate reasonable expectation that the patient will comply strictly with the difficult long-term medical regimen which will be required to assure survival post transplant.

##### *Absolute Contraindications*

Irreversible terminal state (e.g., incurable cancer or uncontrolled infection).

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#### *Relative Contraindications*

- Other major system disease (e.g., lung, liver, brain, or renal damage) which would preclude surgery or indicate a poor potential for rehabilitation.
- Active infection
- Recent pulmonary infarction
- Elevated and fixed pulmonary vascular resistance
- Complicated insulin dependent diabetes mellitus
- Morbid obesity
- History of substance abuse or mental illness

#### *Criteria for Re-Transplantation:*

- Early graft failure
- End stage heart disease, which meets all of the above criteria for de-novo transplant.

#### Lung and Heart-Lung Transplants

##### *General Criteria*

- The patient must have irreversible, progressively disabling, end-stage pulmonary or cardiopulmonary disease, and limited life expectancy of less than 24 months without transplantation. Prognosis with transplant must be good, for both survival and rehabilitation.
- All other medical and surgical therapies that might be expected to yield both short and long-term survival rates comparable to that of transplantation must have been tried.
- The patient must not have any non-pulmonary condition that would shorten life expectancy or increase the risk of death from rejection or from complication of immunosuppression.
- The patient must be psychologically stable, with a firm commitment to the idea transplantation and the support system and capability of complying with long term disciplined medical regimen.
- The patient must be ambulatory despite oxygen dependency and have adequate nutritional status.

##### *Absolute Contraindication*

- Major medical problem other than lung; (e.g., collagen vascular disease; renal disease (creatinine > 3mg/dl) or hepatic disease (total bilirubin>2.5 mg/ml)
- A diagnosed malignant disease with poor prognosis
- Drug and/or alcohol abuse
- Recent smoking history (6 months or less)
- Morbid Obesity
- For Lung Transplants (single, double) – significant cardiac disease

#### *Relative Contraindications*

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- Age: (the upper age limit for single lung transplant is 60; for double lung 55 years; for heart/lung transplant, 50 years)
- Severe cachexia or malnourishment
- Insulin dependent diabetes mellitus with severe target organ damage
- Ventilator dependency

### Liver Transplant

#### *General Criteria*

- The patient has progressive, potentially fatal liver disorder or suffers from complication directly related to a liver disorder which substantially impairs the quality of life and daily function, and for which all alternative medical and surgical treatments short of liver transplantation have been exhausted.
- The patient is not in an irreversible terminal state (moribund)
- The patient's underlying hepatic disease is not expected to recur; if it does recur, it is not expected to cause substantial disability within a period five years.
- The liver transplant is likely to prolong life for at least five years (better than 50% chance of five-year survival), and the liver transplant will restore the patient to a range of physical and social functions suitable for activities of daily living.
- The patient does not have involvement of a major system (e.g., kidneys, lung, heart, or brain damage) which would preclude surgery or indicate a poor potential for rehabilitation.
- The patient's psychological assessment, social arrangement and family support indicate reasonable expectation that the patient will adhere strictly to the difficult long-term medical regimen which will require post-transplant.
- The patient has a diagnosis appropriate for liver transplant and does not have absolute contra-indications.
- After proper evaluation of the patient by a transplant committee, a Medi-Cal approved facility recommends a liver transplant and is willing to undertake the procedure.

#### *Contraindications*

- Malignancies
- Sepsis unresponsive to treatment
- HIV sero-positivity
- Current Substance abuse
- Disease affecting other organ systems not correctable by liver transplantation
- Coma with evidence of irreversible brain damage
- Severe, uncorrectable major system congenital anomalies
- HBV infection with HbeAG (+)

#### *Combined Liver and Kidney Transplants (LT/KT)*

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Hepatorenal syndrome generally resolves with liver transplantation. Combined liver and kidney transplantation may be authorized for a patient with end-stage liver disease meeting criteria for LT and end-stage renal disease meeting criteria for renal transplant.

#### *Combined Liver and Small Bowel Transplants (LT/SBT)*

LT/SBT is indicated in patients who have intestinal insufficiency requiring chronic TPN for survival and who additionally developed end-stage cholestatic liver dysfunction, meeting criteria for LT.

#### *Living Related Liver Transplants*

- Recipient Selection Criteria:
  - Potential recipient meets the general and specific patient selection criteria stated above.
  - Limited to children (maximum age of 13)
- Donor Selection Criteria
  - Age between 18 and 55 years
  - Genetically related to recipient
  - Normal results of a comprehensive history and physical examination and psychiatric evaluation

#### Kidney Transplants

Medi-Cal does not have official patient selection criteria. The following are established criteria from the kidney transplant program at UCLA, and will be adopted by Blue Shield Promise Health Plan.

#### *General Criteria*

In general, all end-stage renal failure patients, who, after having been informed of the risks of the transplant surgery and the inevitable chronic immunosuppressive therapy, still express a clear desire for the modality of treatment, will be accepted as candidates for transplantation.

The following categories of patients are considered on a case-by-case basis:

- Patients with certain forms of underlying disease states such as multiple myeloma, scleroderma, oxalosis, sickle-cell anemia and severe vascular disease.
- Patients with serious psychosocial problems such as psychosis or drug addiction that impairs the capacity to comply with complex medical regimen
- Patients over the age of 65 depending on general state of health
- Pediatric patients are considered if they are stable on dialysis, have normal blood pressure and no infection at the time of the transplant.

#### *Absolute Contraindications*

The absolute contraindication is the presence of disseminated or recent malignancy and active infection.

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If a patient is accepted as transplant candidate, the possibility of living-related donation is explored and encouraged. Patients who require cadaver transplantation are listed locally in Southern California, and with the National UNOS Registry to wait for a suitable donor. The waiting time for a donor organ may vary considerably depending on the patient's blood type, and the presence of pre-formed tissue antibodies.

#### Kidney-Pancreas Transplants

While not currently a Medi-Cal approved procedure, combined kidney-pancreas transplants are under consideration for Medi-Cal approval.

#### *General Criteria (UCLA Medical Center)*

Patients with the following characteristics are considered for whole-organ pancreas transplant in conjunction with kidney transplants:

- Presence of Type 1 diabetes
- Evidence of secondary complications of diabetes
- Nephropathy with present or impending need dialysis
- Neuropathy
  - Peripheral
  - Autonomic
- Retinopathy
- Secondary complications not so far advanced so as to be judged to be beyond reasonable probability of stabilization or improvement following PTx (pancreas transplant)
- Chronic immunosuppression (IS) or complications judged to be less serious than those of the left untreated.
- Ability to withstand the surgery and immunosuppression
- Psychosocially stable
- Ability to comprehend and comply with therapeutic and follow-up regimens
- Absence of contraindications

#### *Absolute Contraindications*

- Insufficient cardiac reserve
- Non-correctable coronary artery disease
- Ejection fraction <50%
- Recent myocardial infarction
- Extensive peripheral vascular disease
- Lack of well-defined secondary complications
- Active infection or malignancy
- Significant history of non-compliance
- Ongoing substance abuse
- Major psychiatric illness

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- Significant obesity (>100 kgs.)
- Age > 50 years (relative)

Studies by Mansky and others have demonstrated that Type 1 diabetes 45 years of age and older and/or with duration of disease greater than 25 years have high incidence of significant coronary artery disease (CAD) even if asymptomatic. Thus all such patients undergo stress imaging studies and/or angiography as part of their evaluation process. Patients less than age 45 and with duration of the disease less than 25 years are potential candidates for stress imaging studies and/or angiography, if clinical features of CAD are present.

Some transplant programs will perform the combined procedure, but will bill Medi-Cal only for the kidney transplant.

### **Facilities**

Medi-Cal approved transplant facilities available in California, include:

### **BONE MARROW TRANSPLANTS**

#### Adults

- Alta Bates Hospital (Berkeley)
- University of California, San Diego
- University of California, Irvine
- Cedars Sinai Medical Center, Los Angeles
- University of California, Davis

#### Pediatrics

- Children's Hospital, Los Angeles
- Children's Hospital of Orange
- San Diego Children's Hospital, San Diego
- Children's Hospital Oakland

#### Adults & Pediatrics

- City of Hope Hospital, Duarte
- Stanford Medical Center/Lucile Packard Children's Hospital (Palo Alto)
- University of California, Los Angeles
- University of California, San Francisco

### **LIVER TRANSPLANTS**

#### Adults

- California Pacific Medical Center, San Francisco
- Cedars Sinai Medical Center, Los Angeles
- Loma Linda University Medical Center, San Bernardino
- Scripps Clinic – Green Hospital, San Diego
- University of California, Irvine



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- University of California, San Diego
- University of California, Davis
- University Hospital, Los Angeles
- St. Vincent Hospital, Los Angeles

#### Adults & Pediatrics (Cadaver and/or Living Donor)

- Stanford Medical Center/Lucile Packard Children's Hospital (Palo Alto)
- University of California, Los Angeles
- University of California, San Francisco

#### Adult Living Donor Liver Transplant

- Stanford Medical Center, Palo Alto
- Cedars Sinai Medical Center, Los Angeles
- University of California, San Francisco
- University of California, Los Angeles
- University Hospital, Los Angeles

#### Pediatrics Only

- Children's Hospital, Los Angeles

#### Kidney-Pancreas Transplants

##### Adults Only

- California Pacific Medical Center, San Francisco

### **HEART TRANSPLANTS**

#### Adults Only

- California Pacific Medical Center, San Francisco
- Cedars Sinai Medical Center, Los Angeles
- Sharp Memorial Hospital, San Diego
- Sutter Memorial hospital, Sacramento
- University of California, San Diego
- University of California, San Francisco
- University Hospital, Los Angeles
- St. Vincent Hospital, Los Angeles

#### Pediatrics Only

- Children's Hospital, Los Angeles

#### Adults & Pediatrics

- Loma Linda University Medical Center, San Bernardino
- Stanford Medical Center/Lucile Packard Children's Hospital (Palo Alto)
- University of California, Los Angeles

### **LUNG AND LUNG TRANSPLANTS**

#### Adults

- University of California, San Diego

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- University Hospital, Los Angeles
- University of California, San Francisco

Pediatrics Only

- Children's Hospital, Los Angeles

Adult & Pediatrics

- Stanford Medical Center/Lucile Packard Children's Hospital (Paolo Alto)

## **REFERENCES/AUTHORITIES:**

Medi-Cal Provider Manual

Health & Safety Code Section 53887