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8.1 General Description

Medicaid covers medically necessary transplantation services and the related immunosuppressant drugs and services. Corneal transplants and kidney transplants do not require authorization and are reimbursed directly by the Medicaid Program. The transplants listed below are provided by the Medicaid Program through the State of Hawaii Organ and Tissue Transplant (SHOTT) Program. The policies for each of the transplantation services are provided separately as follows:

- Liver
- Heart-Lung
- Heart
- Lung
- Small Bowel with or without Liver
- Allogeneic Bone Marrow
- Autologous Bone Marrow

8.2 Amount, Duration and Scope

a) Covered transplants must be non-experimental, non-investigational for the specific organ/tissue and specific medical condition.

   - There must be conclusive evidence from published peer-review medical literature that the specific transplant has a definite positive effect on health outcomes. This evidence must include well-designed investigations that have been reproduced by nonaffiliated authoritative sources, with measurable results and with positive endorsements of national medical bodies or panels regarding scientific efficacy and rationale.
   - Published peer-review medical literature must demonstrate that over time the transplant leads to improvement in health outcomes and that beneficial effects outweigh any harmful effects.
   - Published peer-review medical literature must demonstrate that the transplant must at the least be as effective in improving health outcomes as other established treatments.

- Published peer-review medical literature must exist that shows improvement in health outcomes is possible in standard conditions of medical practice, outside clinical investigative settings.

b) Transplants must be performed in facilities certified by Medicare for the specific transplant involved and by physicians knowledgeable in the specific transplantation.

c) Based upon a comprehensive evaluation of the patient and sound medical judgment, the transplant is expected to improve the patient's quality of life and chances for long term survival and:

- There is no significant involvement of other organ systems (e.g., malignancies in other organ systems or tissues, chronic progressive conditions, etc.)

- There are no significant impairments or conditions, which would affect negatively the transplant surgery or supportive medical services and the post-transplantation (outpatient and inpatient) management of the patient. In cases where the patient has a history of current or past alcohol or drug abuse, the patient shall be monitored with random and repeated alcohol and/or drug screening during the assessment process up to the time of transplant.

- There is strong clinical indication that the patient can survive the transplantation procedure and related medical therapy (e.g., chemotherapy, immunosuppression).

- The patient's condition has failed to improve with other conventional medical/surgical therapies; or based upon peer-review medical literature, transplantation affords the best chance of long term survival for the specific condition.

- There is sufficient social support to ensure the patient's compliance with treatment recommendations such as immuno-suppression therapy, other medication regimens and physician visits both before and after transplantation.

- The patient is not HIV-positive.

8.3 Exclusions

The following transplants are not covered:

- Kidney-Pancreas

- Pancreas

- Adrenal to Brain
- Fetal Mesencephalic Transplantation
- Any other transplants not listed

8.4 Limitations

8.4.1 Organ Transplant Guidelines

The State of Hawaii has contracted with a transplant insurer for coverage of the organ/tissue transplants specifically cited below. Coverage of transplants will only be made for those recipients who meet the applicable Medicare criteria, are diagnosed as having a Medicare approved clinical condition for transplantation and are transplanted in a CMS (formerly HCFA)/Medicare approved facility for the specific transplant.

8.4.1.1 Liver

a) Conditions for which approval may be given:

  - Primary biliary cirrhosis
  - Primary sclerosing cholangitis
  - Post-necrotic cirrhosis
  - Alcoholic cirrhosis
  - Alpha-1 antitrypsin deficiency disease
  - Wilson’s disease
  - Primary hemochromatosis
  - Protoporphyria
  - Familial cholestasis (Bylers’s disease)
  - Trauma
  - Toxic reactions

- Extrahepatic biliary atresia, intrahepatic bile duct paucity (Alagill's syndrome)
- Budd-Chiari syndrome

Coverage of liver transplants will only be made for those recipients who meet the applicable Medicare criteria and who are diagnosed as having one of the clinical conditions listed above. Effective December 2, 1999, Medicare removed the exclusion of Hepatitis B from liver transplantation coverage. Therefore, liver transplants can be covered when Hepatitis B is the recipient's underlying cause of end-stage liver disease or a concomitant infection is a covered condition.

b) Conditions for which approval may not be given:

The patient must not have the following:

1) Significant or advanced cardiac, pulmonary, renal, nervous system, or other systemic disease.

2) Systemic infection.

3) Presence or malignancies either hepatic, extrahepatic or metastatic.

4) Acute severe hemodynamic compromise at the time of transplantation if accompanied by compromise or failure of one or more vital organs.

5) Active alcohol or drug abuse.

6) The need for prior transplantation of a second organ, such as lung, heart, kidney, or marrow, if this represents a coexistence of significant disease.

7) A history of a behavior pattern or psychiatric illness considered likely to interfere significantly with compliance with a disciplined medical regime (because a lifelong medical regime is necessary, requiring multiple drugs several times a day, with serious consequences in the event of their interruption or excessive consumption).

c) Selection Criteria:

The guidelines for patient selections are:

1) That the criteria must be based upon both a critical medical need for a transplantation and a maximum likelihood of successful clinical outcome.

2) That the patient must have end-stage liver disease with a life expectancy of less than 12 months and no medical or surgical alternatives to transplantation.

3) That in the case of alcoholic cirrhosis, selection of a patient who needs a liver transplant should include evidence of sufficient social support to assure assistance in alcohol rehabilitation and in immunosuppressive therapy following the operation. Although the center should require abstinence at the time of the operation, Medicare does not specify how long the patient should be abstinent prior to the operation. The MQD/MSB requires that the hospital and the transplant team establish such guidelines. Facilities must submit the period of time they require for abstinence in a patient with end-stage liver disease due to alcoholic cirrhosis.

d) Adverse Factors:

Many factors must be recognized with regard to an adverse outcome after liver transplantation. The manner and extent to which adverse risk is translated into contraindication varies. For example, presence of insulin-dependent diabetes mellitus may have to be considered in relation to transplantation because of possible adverse effects on outcome as well as complications related to chronic immunosuppressive therapy. Plans for long-term adherence to a disciplined medical regime must be feasible and realistic for the individual patient.

8.4.1.2 Heart-Lung

a) Conditions for which approval may be given for adults and children:

- Irreversible primary pulmonary hypertension with congestive heart failure.
- Non-specific pulmonary fibrosis.
- Eisenmenger complex with irreversible pulmonary hypertension and heart failure.
- Cystic fibrosis with severe heart failure.
- Emphysema with severe heart failure.
- COPD with severe heart failure.

Conditions for which approval may not be given:

Approvals will be on a case by case basis.

c) Selection Criteria:

Candidates for heart-lung transplant must meet criteria for both heart transplant and lung transplant.

8.4.1.3 Heart

a) Conditions for which approval may be given for adults and children:

- Ischemic myocardial disease.
- Idiopathic cardiomyopathy.
- Valvular disease.
- Congenital cardiac disease.
- Myocardial disease (e.g. sarcoidosis and amyloidosis).
- Infection (e.g. Chagas disease)
- Drug-induced myocardial destruction.
- Class IV cardiac disease when surgical or medical therapy is not pertinent and estimated survival is less than 6 - 12 months without a transplant.

b) Conditions for which approval may not be given:

- Active infection, systemic illness
- Irreversible liver or kidney failure
- Fixed pulmonary hypertension
- Recent or unresolved pulmonary infarction
- Pre-existing malignancy
- Poorly controlled diabetes or retinopathy, neuropathy, or nephropathy
- Morbid obesity (100% over recommended weight)
- Moribund condition, rapidly fluctuating hemodynamic status

- Unresolved neurologic injury, affecting motor or sensory function that impairs ability to participate in care and decision-making

- History of alcohol or drug abuse, heavy smoking, medically non-compliant or psychologically unstable.

c) Selection Criteria:

Medicare guidelines are:

1) That the patient selection criteria must be based upon both a critical medical need for transplantation and a maximum likelihood of successful clinical outcome.

2) That the patient must have a very poor prognosis (for example, less than a 25% likelihood of survival for six months) as a result of poor cardiac status but must otherwise have a good prognosis for survival with transplant.

3) That all other medical and surgical therapies which might be expected to yield both short- and long-term survival (for example, 3 or 5 years), comparable to that of cardiac transplantation, must have been tried or considered.

4) That many factors recognized at the present time exert an adverse influence on the outcome after cardiac transplantation. The manner and extent to which adverse risk is translated into contraindication varies.

d) Adverse Factors:

Strongly adverse factors include:

1) Advancing age - the selection of candidates not beyond age 50 must be done to ensure an adequately young “physiologic” age and the absence or insignificance of coexisting disease.

2) Severe pulmonary hypertension.

3) Renal or hepatic dysfunction not explained by the underlying heart failure and not deemed reversible (because of the nephrotoxicity and hepatotoxicity of cyclosporine).

4) Acute severe hemodynamic compromise at the time of transplantation if accompanied by compromise or failure of one or more vital end-organs (because of a substantially less favorable prognosis for survival than for the average transplant recipient).

5) Symptomatic peripheral or cerebral vascular disease (because of accelerated progression in some patients after cardiac transplantation and on chronic corticosteroid treatment).

6) Chronic obstructive pulmonary disease or chronic bronchitis (because of poor postoperative course and likelihood of exacerbation of infection with immunosuppression).

7) Active systemic infection (because of the likelihood of exacerbation with initiation of immunosuppression).

8) Recent and unresolved pulmonary infarction, pulmonary roentgenographic evidence of infection, or abnormalities of unclear etiology (because of the likelihood that this represents pulmonary infection).

9) Systemic hypertension, either at transplantation or prior to development of end-stage heart disease, that required multi-drug therapy for even moderate control for patients who would be on cyclosporine protocols.

10) Any other systemic disease considered likely to limit or preclude survival and rehabilitation after transplantation.

11) Cachexia, even in the absence of major end organ failure (because of the significantly less favorable survival of these patients).

12) The need for or prior transplantation of a second organ such as lung, liver, kidney, or marrow.

13) A history of a behavior pattern or psychiatric illness considered likely to interfere significantly with compliance with a disciplined medical regimen.

14) The use of a donor heart, that may have had its effectiveness compromised by such factors as the use of substantial vasopressors prior to its removal from the donor, its prolonged or compromised maintenance between the time of its removal from the donor and its implantation into the patient, or preexisting disease.

- Other factors include:

  1) Insulin-requiring diabetes mellitus.

  2) Asymptomatic severe peripheral or cerebrovascular disease.

  3) Documented peptic ulcer disease.

4) Current or recent history of diverticulitis.

5) Plans for a long-term adherence to a disciplined medical regimen must be feasible and realistic for the individual patient.

8.4.1.4 Lung

a) Conditions for which approval may be given for children and adults:

- Alpha-1 antitrypsin deficiency.
- Primary pulmonary hypertension.
- Pulmonary fibrosis, Idiopathic pulmonary fibrosis.
- Bilateral bronchiectasis.
- Cystic fibrosis (both lungs to be transplanted).
- Bronchopulmonary dysplasia.
- Eisenmenger's syndrome.
- Sarcoidosis lung involvement.
- Scleroderma.
- Lymphangiomyomatosis.
- Emphysema.
- Eosinophilic granuloma.
- Chronic obstructive pulmonary disease.
- Pulmonary hypertension due to cardiac disease.
- Idiopathic fibrosing alveolitis.
- Respiratory failure.

b) Conditions for which approval may not be given:

- End-stage pulmonary disease with limited life expectancy.
- No recent therapeutic use of systemic steroids.
- No other systemic disease.
- Adequate biventricular cardiac function; no significant coronary artery disease.
- Demonstration of medical compliance with medical regimes.
- No contraindications to immunosuppression.
- No major psychosocial problems.
- Ambulatory with rehabilitation potential.
- No chronic infectious pulmonary disease.
- No prior major thoracic surgery or pleurodesis.
- Age <60 years, single lung transplant; <50 years, double lung transplant.
- Each of the criteria should be addressed with consideration of these procedures, although rational argument may be presented to override single criteria exclusions (e.g., age limitations).
- Reasons for non-coverage: Cancer of the lung, either primary or metastatic; acute respiratory insufficiency; all acute conditions; and chronic infections.
- Non covered ICD-9-CM codes.
- Malignant neoplasm or respiratory and intrathoracic organs.
- Pneumonia and influenza.
- Emphysema and pleurisy.
- Abscess of lung and mediastinum.
- Acute respiratory failure.

c) Selection Criteria:

CMS' (formerly HCFA's) National Policy: suggested selection criteria of the National Heart, Lung and Blood Institute (NHLBI) of the National Institutes of Health:

1) A patient is selected based upon both a critical medical need for transplantation and a strong likelihood of successful clinical outcome.

2) A patient who is selected has irreversible, progressively disabling, end-stage pulmonary disease (or, in some instances, end-stage cardiopulmonary disease).

3) The facility has tried or considered all other medically appropriate medical and surgical therapies that might be expected to yield both short and long-term survivals comparable to that of transplantation.

4) Plans for long term adherence to a disciplined medical regimen are feasible and realistic for the individual patient.

d) Adverse Factors:

- Primary or metastatic malignancies of the lung.

- Current significant acute illness that is likely to contribute to a poor outcome if the patient receives a lung transplant or current use of mechanical ventilation for more than a brief period.

- Significant or advanced heart, liver, kidney, gastrointestinal or other systemic or multi-system disease that is likely to contribute to a poor outcome after lung transplantation including significant extra-pulmonary infection.

- Chronic pulmonary infection in candidates for single lung transplantation.

- Continued cigarette smoking or failure to have abstained for long enough to indicate low likelihood of recidivism.

- Systemic hypertension that requires more than two drugs for adequate control.

- Cachexia, even in the absence of major end-organ failure.

- Obesity.

- Previous thoracic or cardiac surgery or other bases for pleural adhesions.
- Age beyond that at which there has been substantial favorable experience.
- Chronic cortisone therapy.
- A history of behavior pattern or psychiatric illness considered likely to interfere significantly with a disciplined medical regimen.

8.4.1.5 Small Bowel with or without Liver

Generally, small bowel and combined small bowel and liver transplants have been done in children and not adults. Adults will not be covered. Children will be covered through the month of their 21st birthday.

- Conditions for which approval may be given:
  a) Small bowel syndrome resulting from inadequate intestinal propulsion due to neuromuscular impairment.
  b) Small bowel syndrome resulting from post-surgical conditions due to resections for:
     1) Intestinal cysts.
     2) Mesenteric cysts.
     3) Small bowel or other tumors involving small bowel.
     4) Crohn's disease.
     5) Mesenteric thrombosis.
     6) Volvulus.
  c) Short gut syndromes in which there is liver function impairment (usually secondary to total parenteral nutrition (TPN)).

8.4.2 Tissue Transplants (Bone Marrow-Allogeneic and Autologous, Stem Cells)

8.4.2.1 Allogeneic Bone Marrow Transplantation

Conditions for which approval may be given:

- Severe combined immunodeficiency disease (SCID).

- Aplastic Anemia including Fanconi's anemia.
- Homozygous beta-thalassemia (Thalassemia major).
- Wiskott-Aldrich syndrome.
- Infantile malignant osteopetrosis (Albers-Schoenberg syndrome or marble bone disease).
- Mucopolysaccharidoses (e.g., Gaucher's disease, metachromatic leukodystrophy, adrenoleukodystrophy) for patients who have failed conventional therapy and who are neurologically intact.
- Myelodysplastic syndromes
- Chronic myelogenous leukemia (CML).
- Acute myelocytic leukemia (AML).
- Follicular Non-Hodgkin's lymphoma in patients who have failed primary therapy without histologic transformation.
- Acute Lymphocytic Leukemia (ALL), recurrent disease or patients in first remission with poor prognostic factors.
- Other leukemias when reasonable and necessary and when sufficient medical evidence exists that the transplantation prolongs survival and decreases mortality in patients who have received transplants for the type of leukemia in question.

The above strict conditions are approved for transplantation under Medicare and include leukemia, leukemia in remission when it is reasonable and necessary.

a) Conditions for which approval may not be given:

- The following conditions are not covered:
  1) Multiple myeloma.
  2) Solid tumors including breast cancer.
- Fetal (cord blood) transplants are not covered.

b) Adverse Factors:

- Active infection
- Incapacity to physically or mentally withstand this rigorous procedure.

8.4.2.2 Autologous Bone Marrow Transplant

a) Conditions for which approvals may be given.

- Neuroblastoma, Stage III or Stage IV, in patients over 12 months of age.
- Testicular Germ Cell tumors at initial or subsequent relapse or that are refractory to standard dose chemotherapy with an FDA approved platinum compound. Refractory cases include:
- Patients with advanced disease who fail to achieve a complete response to second-line therapy; or
- Patients with moderate or minimal extent disease who fail to achieve a complete response to third-line therapy for Testicular Germ Cell tumors that meet the above criteria. Standard protocol involves tandem transplant. Germ cell tumor stage is to be determined using the Indiana University/Einhorn classification or Follicular Non-Hodgkin's lymphoma in patients who have failed primary therapy without histologic transformation.
- Acute leukemia in remission in patients with a high probability of relapse and who have no HLA matched donor. The leukemia type must meet the general conditions (sensitive to chemotherapy/radiation and incurable with conventional chemotherapy/radiation), and be in one of the following categories:

    1) lymphoid
    2) myeloid
    3) monocytic
    4) acute erythema and erythroleukemia
    5) unspecified cell type

- Resistant non-Hodgkin's lymphomas or those presenting with poor prognostic features following an initial response.

- Non-Hodgkin's lymphoma, follicular, in-patients who have failed primary therapy without histologic transformation.

- Hodgkin's Lymphoma, relapsed or refractory disease advanced Hodgkin's disease who have failed conventional therapy and have no HLA-matched donor.

- Multiple myeloma ONLY after receipt of a high dose chemotherapy regime. Coverage of autologous stem cell transplantation for multiple myeloma is effective for services provided on or after July 1, 2000.

b) Conditions for which approval may not be given:

The following conditions are not covered under Medicare:

- Breast cancer.

- Acute leukemia not in remission except for primary resistant acute myelogenous leukemia.

- Chronic granulocytic leukemia.

- Solid tumors (other than neuroblastoma and testicular germ cell tumors).

c) Adverse Factors:

- Active infection

- Incapacity to physically or mentally withstand this rigorous procedure.

8.4.3 Coverage of Immunosuppressant Drugs Following Covered Organ Transplants

a) Effective December 21, 2000, eligible Medicare beneficiaries who receive drugs used for immunosuppressive therapy to prevent transplant rejections will continue to be eligible for this benefit from Medicare without limitations.

b) Medicare will also cover currently Medicare eligible beneficiaries who had their drug coverage terminated prior to December 21, 2000 due to previously imposed time limitations.

8.5 Authorization

8.5.1 Determination Process

8.5.1.1 General

a) Providers within the community or QUEST health plans identify persons who meet the medical conditions for a transplant evaluation.

b) The provider completes the Form 1144 requesting approval for a transplant evaluation and sends it to the Fiscal Agent for review and processing.

c) For all transplant candidates, basic medical information is necessary in order to appropriately refer a patient for evaluation by a participating facility. The following information is requested. Please advise with the referral if any of this information is not available:

- Age
- Weight
- Comprehensive diagnoses list
- Medical history, including medication(s)
- Hospital discharge summary(ies)
- NYHA class, cancer stage, or other functional status information
- Documentation of other organ status (CBC, chem studies, creatinine clearance, pulmonary function tests, chest x-ray, treadmill, cardiac echo or MUGA scan, etc.)
- History of drug or alcohol abuse (length of abstinence and response to treatment program(s), documentation of six months abstinence via drug/alcohol screens).
- History of psychiatric illness (documentation of type and response to therapy).

d) For specific transplants, information in addition to the above is requested.

8.5.1.2 Heart Transplant

a) Cardiac catheterization report(s)

b) History of any cerebral or peripheral vascular problems

c) Echocardiogram and MUGA scan reports, if available

8.5.1.3 Lung Transplant

a) Lung biopsy results, pulmonary function test, or bronchoscopy reports

b) Oxygen saturation with exercise

c) Any previous thoracic surgery

8.5.1.4 Heart/Lung Transplant

Please provide requested information from both the heart and lung categories

8.5.1.5 Liver Transplant

a) Liver biopsy results (if available)

b) Liver enzymes (SGPT, SGOT, Bili, etc.) and clotting studies (APTT, PTT, etc.)

c) Other liver studies such as liver scan, U/S or CT scan results are helpful

8.5.1.6 Small Bowel

a) History of hyperalimentation and nutritional studies

b) History of previous abdominal surgery

c) Colonoscopy reports, CT scans, any type of GI studies

(If a liver transplant is performed in conjuction, please provide the requested information from the liver category as well.)

8.5.1.7 Allogeneic Bone Marrow Transplant

a) Donor match information

b) General outline for treatment plan (type of drugs and dosages, TBI or not, etc.)

c) Pathology reports and marrow analysis are also helpful

8.5.1.8 Autologous Bone Marrow Transplant

(If a scientific study must have full protocol for review plus consent IRB)

a) Detailed treatment plan (protocol to be used, type of purging (if any), drugs and dosages, timing of stem cell infusion, etc.)

b) Pathology reports and marrow analysis are also helpful.

8.5.1.9 SHOTT Program Authorization and Reimbursement Procedures

a) For a QUEST client, the physician also completes an 1128 disability form to submit to Med-QUEST Division for disenrollment from QUEST. Form should have on the top right corner "Transplant Candidate." The physician should coordinate with the recipient's QUEST managed care plan.

b) For QUEST and Fee-for-service clients, if the MQD/MSB Medical Consultant decides that the medical criteria for the medical need for the transplant is met (appropriate diagnoses and covered transplant), he/she conditionally approves the Form 1144.

- MQD returns a copy of the Form 1144 to the referring physician. It is the responsibility of the referring physician to notify the recipient.

- MQD sends a copy of the approved Form 1144 and all attachments to the State of Hawaii Organ and Tissue Transplant (SHOTT) program which then becomes responsible for completion of the transplant evaluation and coordination of the transplant process for MQD.

- Upon notification by the MQD, the SHOTT program is responsible for the active case management of transplants related services and items for the patient.

c) If the SHOTT program requires additional information to decide whether the transplant can be approved, the SHOTT program will request information directly from the referring physician.

- If transplant criteria are met, the SHOTT program makes arrangements to send the patient to a facility for an evaluation. The SHOTT program selects the appropriate transplant facility for the evaluation and for the transplant procedure.

d) The SHOTT program assumes financial responsibility for transplant related services/items from the date the Form 1144 is signed by the MQD/MSB consultant through the post transplant first anniversary visit. All claims for services performed during this period are submitted to the SHOTT program.

e) The SHOTT program is responsible for coordinating care for transplant services including arranging for travel, lodging and meals where needed.

- If either the transplant facility or the SHOTT program decides that the recipient does not meet all required transplant criteria, and the MQD concurs, SHOTT program notifies both referring physician and recipient of the denial in writing recommendation.

f) The recipient may appeal the denial by contacting his/her worker.

g) If Medicaid is the secondary payer to any other health insurer, the SHOTT program is responsible for authorizing meals, transportation, lodging, and any applicable deductible, coinsurance, or the difference between the primary health insurer's payment and the allowance the SHOTT program extends for the service.

h) Contact information for the SHOTT Program is listed in Appendix 1.