



Chapter 8

Medicaid Provider Manual State of Hawaii Organ and Tissue Transplant (SHOTT) Services

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8.1 GENERAL DESCRIPTION

Medicaid covers medically necessary transplantation services and the related medications (such as chemotherapy and immunosuppressant drugs) and services. Corneal 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:

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

8.2 STATE OF HAWAII ORGAN AND TISSUE TRANSPLANT (SHOTT) PROGRAM

The (Med-QUEST Division) MQD'S transplant program is called State of Hawaii Organ and Tissue Transplant (SHOTT) Program. It is administered by MQD's contracted Third Party Administrator (TPA) called the SHOTT contractor. The SHOTT contractor does the following:

- Provides twenty-four hours, seven days a week case management services for SHOTT clients
- Pays for both transplant related, and non-transplant related medical services
- Pays for non-transplant related Medicaid covered medical services provided by Hawaii Medicaid providers at Medicaid Fee-For-Service (FFS) rates
- Enters into contracts or payment arrangements with transplant facilities certified by Medicare for the specific transplants and their medical staffs. These contracts and payment arrangements are approved by MQD.
- Authorizes services following Medicaid FFS authorization requirements
- Arranges for medically needed services and ensures access to these services by providing transportation, lodging, and meals and foreign language/sign language interpretation
- Pays for the transportation, lodging, and meals for the patient's primary care giver (PCG)
- Services covered by the SHOTT contractor
- All Hawaii Medicaid Services with the following exceptions:
 - Home and Community Based Services
 - Hospice (except for brief periods prior to death or during the transition to a QI plan)
 - Copayments for covered Medicare Part D drugs for patients dually eligible for Medicare and Medicaid
 - Experimental drugs or investigational treatments that are not approved by Centers for Medicare and Medicaid Services (CMS)
 - Outpatient medications provided by hospitals, physicians, pharmacies. These medications are provided for SHOTT clients by MQD's Pharmacy Benefits Manager (PBM). Medications billed with drug revenue codes, NDC numbers and NCPDP units for a covered hospital emergency room visit are paid on the hospital's emergency room claim by the SHOTT contractor.
- Dental services for children and youth under 21 years of age. These services are provided by MQD's Dental TPA.

8.3 AMOUNT, DURATION AND SCOPE

a) Covered transplants must be non-experimental and non-investigational for the specific organ or tissue and the specific medical condition being treated.

- There must be conclusive evidence from published peer-review medical literature that the proposed 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 proposed transplant leads to improvement in health outcomes and that beneficial effects outweigh any harmful effects.
- Published peer-review medical literature must demonstrate that the proposed 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 as a result of the proposed transplant in standard conditions of medical practice, outside clinical investigative settings.

CMS Medicare approved clinical protocols and Coverage with Evidence Development (CED) paradigms may be covered. See examples below:

1. For adult bone marrow/stem cell transplant, Phase III clinical trials may be considered if the trial protocols have been reviewed and approved by the National Cancer Institute (NCI) or similar national cooperative body and conform to the rigorous independent oversight criteria as defined by the NCI for the performance of clinical trials.
2. For pediatric bone marrow/stem cell transplants (defined as age 21 or younger per EPSDT), since clinical trials are considered the standard of care in most cases when there is no reasonable alternative, Phase II or III clinical trials may be considered if the trial protocols have been reviewed and approved by the NCI or similar national cooperative body (e.g. Pediatric Oncology Group) and conform to the rigorous independent oversight criteria as defined by the NCI for the performance of clinical trials.
3. For both adults and children, the clinical trial must not be a single institution or investigator study (NCI designated Comprehensive Cancer Center trials are exempt from this requirement).

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

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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.) Low-grade prostate neoplasm that has not been "cured" (by prostate-specific antigen measurement) or in remission less than 5 years is generally recognized as a contraindication.
- There are no significant impairments or conditions which would negatively affect a) the transplant surgery or b) 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.
- For non-urgent solid organ transplant candidates with a recent history of substance abuse, at least three (3) current negative random consecutive drug and alcohol screenings at least a two (2) weeks apart and ongoing attendance in an approved substance abuse program and paper documentation of attendance in the program are required prior to Medicaid approval of admission to the SHOTT program. For non-urgent solid organ transplant candidates with a past-history of substance abuse, must have at least 2 current negative random, consecutive drug and alcohol screenings at least 2 weeks apart. On-going sobriety or abstinence must be well-documented in the medical records. All candidates for non-urgent solid organ transplants must have at least 2 random, consecutive and negative drug, alcohol and nicotine screenings prior to being referred to Medicaid for consideration of transplantation. This requirement may be waived by the Medicaid Medical Director due to emergent need of transplantation.
- There is strong clinical indication that the patient can survive the transplantation procedure and related medical therapy (e.g., chemotherapy, immunosuppression) and there are no contraindications to 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.
- The patient has a Primary Care Giver (PCG) and sufficient social support to ensure the patient's compliance with treatment recommendations such as immunosuppression therapy, other medication regimens and physician visits both before and after transplantation.
- The patient has no active Infection other than that which has caused the underlying organ failure. This includes active fungal infection or sepsis for patients needing bone marrow transplants.
- The patient does not have behavioral problems or psychiatric illness that is anticipated to interfere significantly with a disciplined medical regimen after transplantation, or to be aggravated by the transplant process.

8.4 EXCLUSIONS

The following transplants are not covered:

- CAR-T (Chimeric Antigen Receptor-T) Cell Therapy prior to transplant and as a bridge to transplant
- Spleen
- Any other transplants not listed as covered

8.5 LIMITATIONS

8.5.1 Solid Organ Transplant Guidelines

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

8.5.1.1 Kidney Transplant

a) Conditions for which approval may be given:

- Medicaid recipients whose primary and only health care coverage is Medicaid Fee-for-Service-(FFS) or QUEST Integration (QI).
- Persons who are NOT Medicare eligible and do NOT qualify for Medicare reimbursement of their kidney transplants. (The primary payer for kidney transplants for individuals dually eligible for Medicare and Medicaid is Medicare. The QI plan in which the person is enrolled is responsible for Medicare copayments and deductibles, care coordination, and ancillary services such as transportation, lodging and meals- that are not covered by Medicare).
- Persons in renal failure or who are approaching imminent renal failure and who have in general at least a five-year life expectancy.

b) Organ-specific selection criteria:

For adults

- No age limit for transplant eligibility. However, conditions discovered during the transplant evaluation process may disqualify a person from being a transplant candidate.

For pediatric kidney transplants, additional criteria include:

- Wilm's tumor that is non-metastatic
- Oxalosis, which may require a liver-kidney transplant and will be considered on a case-by-case basis and review of the medical literature

c) Adverse Factors:

- Ongoing or recurring infections that are not effectively treated
- Serious cardiac or other ongoing insufficiencies that create an inability to tolerate transplant surgery
- Serious conditions that are unlikely to be improved by transplantation

- Potential complications from immunosuppressive medications are unacceptable to the patient (e.g. the benefits of remaining on dialysis outweigh the risks associated with transplantation)

8.5.1.2 Kidney-Pancreas Transplant and Pancreas Transplant

Pancreas refers to whole organ transplant only, not partial, living donor or islet cell transplant.

a) Conditions for which approval may be given:

1. Simultaneous cadaveric pancreas-kidney (SPK)

- Insulin-dependent diabetes mellitus with impending irreversible renal failure;
- The patient is an acceptable candidate for pancreas transplantation and has no living kidney donor available

2. Pancreas after Kidney (PAK)

- Achievement of adequate renal function status post kidney transplantation, and
- Extreme labile Type I diabetes not amenable to other treatments such as an insulin pump, and with life-threatening hypoglycemia

b) Conditions for which approval may not be given:

- Pancreatic cancers
- Other benign or pre-malignant pancreatic tumors such as ductal mucinous cystadenomas, etc.

c) Organ-Specific Selection Criteria

Pancreas transplantation is generally limited to those patients with severe secondary complications of diabetes, including kidney failure. However, pancreas transplantation is occasionally performed on patients with labile diabetes and hypoglycemia unawareness. Patients must have a diagnosis of Type I diabetes and:

- Must be beta cell autoantibody positive; or
- Patient must demonstrate insulinopenia defined as a fasting C-peptide level that is less than or equal to 110% of the lower limit of normal of the laboratory's measurement method. Fasting C-peptide levels will only be considered valid with a concurrently obtained fasting glucose \leq mg/dL.
- Patient must have a history of medically-uncontrollable labile (brittle) insulin-dependent diabetes mellitus with documented recurrent, severe, acutely life-threatening metabolic complications that require hospitalization. Complications include frequent hypoglycemia unawareness or recurring severe ketoacidosis, or recurring severe hypoglycemic attacks;
- Patient must have been optimally and intensively managed by an endocrinologist for at least 12 months with the most medically-recognized advanced insulin formulations and delivery systems

d) Adverse factors

- Uncorrectable cardiovascular disease
- Cardiac ejection fraction <30%
- Peripheral vascular disease that is not correctable
- End-organ disease, in other than pancreas or kidney, secondary to insulin-dependent diabetes mellitus

8.5.1.3 Liver Transplant**a) Conditions for which approval may be given include but not limited to the following:**

- Primary biliary cirrhosis
- Primary sclerosing cholangitis
- Post-necrotic cirrhosis
- Alcoholic cirrhosis
- Alpha-1 antitrypsin deficiency disease
- Wilson's disease
- Primary hemochromatosis
- Protoporphyrria
- Familial cholestasis (Bylers's disease)
- Trauma
- Toxic reactions
- Extrahepatic biliary atresia, intrahepatic bile duct paucity (Alagill's syndrome)
- Budd-Chiari syndrome
- Cirrhosis due to Hepatitis B
- Cirrhosis due to Hepatitis C
- Hepatocellular carcinoma that meets the Milan criteria. The Milan criteria are as follows: Single tumor ≤ 5.0 cm; multiple tumors – maximum number 3, largest tumor ≤ 3.0 cm. Tumor histology and aggressiveness will be taken into consideration as well.

For pediatric liver transplantation, potential indications for transplantation may include but not limited to:

- Intractable cholestasis
- Portal hypertension
- Multiple episodes of ascending cholangitis unresponsive to antibiotic suppression and unrelated to instrumentation or procedures of the biliary tract
- Failure of synthetic function
- Intractable ascites
- Encephalopathy
- All of the above plus an unacceptable quality of life
- Metabolic defects for which liver transplantation has been demonstrated can reverse life-threatening illness and prevent irreversible central nervous system damage to include the following: urea cycle defects, selected organic acidemias, Crigler-Najjar syndrome, familial hypercholesterolemia, neonatal iron storage disease, hyperoxaluria Type 1, tyrosinemia, glycogen storage disease (I, III, IV), glycogen debrancher deficiency IB, disorders of bile acid metabolism, lipid storage disease, and protein C deficiency.
- Pediatric hepatic malignancy, including hepatoblastoma, hepatocellular carcinoma, hemangioendothelioma, sarcomas and neuroendocrine tumors, when the tumor does not extend beyond the margins of the liver.

b) Conditions for which approval may not be given in adults:

- Significant or advanced cardiac, pulmonary, renal, nervous system, or other systemic disease
- Significant infection
- Presence of extrahepatic malignancy or metastatic hepatocellular carcinoma that does not meet the Milan criteria
- Recent or unresolved pulmonary infarction
- Acute severe hemodynamic compromise at the time of transplantation if accompanied by compromise or failure of one or more vital organs
- The need for prior transplantation of a second organ, such as lung, heart, kidney, or marrow, if this represents a coexistence of significant disease

Indications for which approval may not be given in pediatric patients:

- Persistent viremia
- Active sepsis
- Severe cardio-pulmonary co-morbidities

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- Severe neurologic disorder
- Gross vascular invasion of hepatocellular carcinoma or malignancy extending beyond the liver margins with the exception of neuro-endocrine tumors metastatic into the liver
- Systemic diseases that will result in the patient's death despite liver transplantation

c) Organic-Specific Selection Criteria:

- Criteria must be based upon both a critical medical need for transplantation and a maximum likelihood of successful clinical outcome. Adult patients should have a minimum Model for End-stage Liver Disease (MELD) score of 10.
- 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.

d) Adverse Factors limited to adults:

- Acute severe hemodynamic compromise at the time of transplant if accompanied by failure of one or more vital organs
- Insulin-dependent diabetes mellitus with end-organ damage
- The need for prior transplantation of another organ such as lung, kidney, heart or marrow if this represents co-existence of significant disease
- Systemic diseases that will result in patient's death despite liver transplantation

8.5.1.4 Heart-Lung Transplant**a) Conditions for which approval may be given for adults and children to include but not limited to the following:**

- 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

b) Conditions for which approval may not be given:

- Refer to conditions under both heart and lung transplants.

c) Selection Criteria:

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

8.5.1.5 Heart Transplant

a) Conditions for which approval may be given for adults and children to include but not limited to the following:

- 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:

1. Systemic illness that will limit survival despite heart transplant including:

- Irreversible liver or kidney failure
- AIDS (Acquired Immunodeficiency Syndrome) (CDC definition of CD4 count of <200 cells/mm³)
- Systemic lupus erythematosus or sarcoid that has multisystem involvement and is still active
- Any systemic process with a high probability of recurring in the transplanted heart
- Morbid obesity, defined as a body mass index of (BMI) > 39 kg/m²

2. Fixed pulmonary hypertension where pulmonary vascular resistance >5 Wood units and/or the trans-pulmonary gradient is >15 mm/Hg.

c) Organ-Specific Selection Criteria:

- Systolic heart failure as defined by ejection fraction <35% but not due to amyloidosis, HIV infection, or cardiac sarcoma.
- Ischemic heart disease with intractable angina not amenable to coronary artery bypass graft or percutaneous revascularization, maximal tolerated medical therapy is not effective, or the patient has been rejected for direct myocardial revascularization or transmyocardial revascularization or the attempted procedure was unsuccessful
- Intractable arrhythmia, either uncontrolled with pacing cardioverter defibrillator, not amenable to electrophysiology guided single- or combination medical therapy, or not a candidate for ablative therapy.
- Hypertrophic cardiomyopathy with Class IV symptoms despite maximal therapy with alcohol injection, myomectomy, mitral valve replacement, maximal medical therapy or pacemaker therapy
- Congenital heart disease in which severe fixed pulmonary hypertension is not a complication

d) Adverse Factors that are relative contraindications to heart transplant include:

- Physiologic age over 65 years
- Peripheral vascular disease not amenable to surgical or percutaneous therapy
- Asymptomatic carotid stenosis >75% or symptomatic carotid stenosis of less severity
- Ankle brachial index <0.7 or substantial risk of limb loss with diminished perfusion
- Uncorrected abdominal aneurysm >4-6 cm
- Systemic infection making immune suppression risky including Hepatitis B or C, cytomegalovirus (positive donor to negative recipient also) and HIV infection
- Severe pulmonary disease, including recent or unresolved pulmonary infarction or pulmonary radiographic evidence of infection, or abnormalities of unclear etiology (because of the likelihood that this represents pulmonary infection)
- Diabetes mellitus with end-organ damage including neuropathy, and/or nephropathy and/or retinopathy
- Unresolved neurological injury, affecting motor or sensory function that impairs ability to participate in care and decision-making

8.5.1.6 Lung Transplant**a) Conditions for which approval may be given to include but not limited to the following:**

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- 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, with signs of right ventricle failure including progressive hepatomegaly and ascites, marked deterioration in functional capacity, hemoptysis, and worsening hypoxemia.
- 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
- Primary or metastatic malignancies of the respiratory or intrathoracic organs
- Acute respiratory insufficiency and failure
- Pneumonia, influenza
- Abscess of lung or mediastinum
- Recent or chronic therapeutic use of systemic steroids
- 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
- Inadequate biventricular cardiac function and/or significant coronary artery disease
- Non-ambulatory with limited rehabilitation potential

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- Presence of chronic pulmonary infection in candidates for single lung transplant
- 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
- Prior major cardiac or thoracic surgery or pleurodesis
- Physiological age beyond that at which there has been substantial favorable experience- typically >65 years for single lung transplant, >50 years for double lung transplant.

c) Organ-Specific Selection Criteria

- A patient is selected based upon both a critical medical need for transplantation and a strong likelihood of successful clinical outcome.
- Patient who is selected has irreversible, progressively disabling, end-stage pulmonary disease (or, in some instances, end-stage cardiopulmonary disease).
- 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.

d) Adverse Factors:

- Continued cigarette smoking or failure to have abstained for long enough to indicate a likelihood of recidivism
- Systemic hypertension that requires more than two drugs for adequate control
- Cachexia, even in the absence of major end-organ failure

8.5.1.7 Small Bowel Transplant with or without Liver**a) Conditions for which approval may be given to include but not limited to the following:**

- Small bowel syndrome resulting from inadequate intestinal propulsion due to neuromuscular impairment
- Small bowel syndrome resulting from post-surgical conditions due to resections for:
 - 1) Intestinal cysts
 - 2) Mesenteric cysts
 - 3) Small bowel tumors not including carcinoid
 - 4) Crohn's disease
 - 5) Mesenteric thrombosis

6) Volvulus

- Short gut syndromes with cirrhosis should be considered for simultaneous liver-small bowel transplant

b) Conditions for which approval may not be given:

- Neuroendocrine tumors (carcinoid, etc.)
- Profound neurological disabilities
- Life-threatening and other irreversible disease not related to the digestive system
- Non-resectable malignancies or those with metastases

c) Organ-Specific Selection Criteria:

- Intestinal failure where a) all medical therapies including total parenteral nutrition have been exhausted, and b) intestinal failure has been demonstrated to be irreversible, with c) one of the following: impaired venous access (reduced to two suitable veins for placement of feeding catheters); life-threatening episodes of catheter sepsis; or progressive liver disease with coagulopathy, ascites, and/or encephalopathy
- Pediatric patients with less than 30-40 cm of intestine, partial colon loss and lack of an ileal-cecal valve are most likely to have irreversible intestinal failure

d) Adverse Factors:

- Severe congenital or acquired immunological deficiencies
- Multi-system autoimmune diseases
- Insufficient vascular patency to guarantee vascular access for up to six months after transplant
- Chronic lung disease of prematurity

For Isolated Small Bowel Transplant Only:

- Age less than one year
- Bridging fibrosis or cirrhosis
- Bilirubin over 3 mg/dl
- Thrombocytopenia

8.5.2 Tissue Transplants (Bone Marrow-Allogeneic and Autologous, Stem Cells)**8.5.2.1 Myeloablative Allogeneic Bone Marrow Transplantation**

a) Conditions for which approval may be given to include but limited to the following:

- 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 (NHL) in patients who have failed primary therapy without histologic transformation
 - Acute lymphocytic leukemia (ALL), in second complete remission or patients in first remission with poor prognostic factors (very high risk for relapse)
- Other leukemias, when reasonable and necessary and when sufficient medical evidence exists that allogeneic stem cell transplantation prolongs survival and decreases mortality for the type of leukemia in question.

b) Conditions for which approval may not be given:

- Inherited genetic disorders other than those listed above
- Solid tumors, including breast cancer
- Hodgkin disease (Hodgkin's lymphoma)

c) Selection criteria:

- No irreversible vital organ disease or cardio-pulmonary failure
- Karnofsky performance score of greater than 60 or Zubrod performance of 0-2
- No sepsis, either bacterial or fungal

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- Liver transaminases should not be elevated, as this may be a predictor for veno-occlusive disease. Liver biopsy is suggested in these cases if feasible.
- Absence of parenchymal central nervous system disease
- There may be disease-specific selection criteria not listed under this general list that may be applicable.

d) Adverse Factors:

- Active infection
- Incapacity to physically or mentally withstand this rigorous procedure.
- Lack of a matched, related donor. Other donors may be acceptable including cord blood transplant (single unit only) or matched unrelated donors

8.5.2.2 Autologous Bone Marrow Transplant**a) Conditions for which approvals may be given to include but not limited to the following:**

- 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:
 - 1) Patients with advanced disease who fail to achieve a complete response to second-line therapy; or
 - 2) 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

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- 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 Disease (Hodgkin's Lymphoma), relapsed or refractory disease who have failed conventional therapy
- For Multiple myeloma, patients should have
 - a) Physiologic age of 65 or younger,
 - b) A second autologous transplant may be considered within six months if it is determined by restaging (no sooner than 90 days after the first transplant) that there is less than a complete response as measured from the start of initial therapy, and
 - c) The current standard of care regimen for both transplants is melphalan-only, at a dosage range of 140-200 mg/kg.

b) Conditions for which approval may not be given:

- Acute leukemia not in remission
- Chronic granulocytic leukemia
- Solid tumors including breast cancer (other than neuroblastoma and testicular germ cell tumors)

c) General selection criteria:

- No irreversible vital organ disease or cardio-pulmonary failure
- Karnofsky performance score of greater than 60 or Zubrod performance of 0-2
- No sepsis, either bacterial or fungal
- Liver transaminases should not be elevated, as this may be a predictor for veno-occlusive disease. Liver biopsy is suggested in these cases if feasible.
- Absence of parenchymal central nervous system disease
- There may be disease-specific selection criteria not listed under this general list that may be applicable.

d) Adverse Factors:

- Active infection

- Incapacity to physically or mentally withstand this rigorous procedure.

8.5.3 Coverage of Immunosuppressant Drugs after Covered Organ Transplants

a) The State of Hawaii Organ and Transplant (SHOTT) program will cover immunosuppressant drugs after covered organ transplants in accordance with federal and state laws and regulations.

b) 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.

8.6 AUTHORIZATION AND DETERMINATION PROCESS

8.6.1 Determination Process

8.6.1.1 Transplant Referral

- a) Physicians within the community work with QI health plans to identify persons who meet the medical conditions for a transplant evaluation.
- b) For a QI member, the health plan or facility completes and submits:
 - An Aid to Disabled Review Committee (ADRC) application packet to the MQD ADRC coordinator for disability determination, with '**Transplant Candidate**' noted on top of Form 1180. The ADRC packet consists of:

DHS Form 1180 "ADRC REFERRAL AND DETERMINATION"

DHS Form 1127 "MEDICAL HISTORY AND DISABILITY STATEMENT"

DHS 1128 "DISABILITY REPORT"

The ADRC packet should be faxed to:

Clinical Standards Office

Med-QUEST Division

(808) 692-8131

- A SHOTT Referral Packet to MQD SHOTT coordinator should include the DHS 1144 "REQUEST FOR MEDICAL AUTHORIZATION" requesting a transplant evaluation, as well as appropriate medical information documenting the client's medical condition, including results of laboratory tests, studies, clinical notes, psychosocial assessment, etc.

The SHOTT referral packet should be submitted via Secure File Transfer Protocol (sFTP) or faxed to:

Health Care Services Branch

Med-QUEST Division

(808) 692-8087

- c) The MQD Medical Director reviews the Form 1144 and the supporting documentation to make a determination on the SHOTT referral. If additional information is required, the MQD Medical Director or the MQD transplant coordinator will request additional information from the referring QI plan and/or the referring physician's office. Determination to forward to SHOTT will be made after all necessary information is available.

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- d) The MQD Medical Director approves or disapproves the transplant request to move forward to SHOTT
- e) If the request for the transplant evaluation is not approved to move forward to SHOTT, the referring QI plan and referring physician is notified by MQD.
- f) If the request for the transplant evaluation is approved to move forward to SHOTT, the MQD transplant coordinator notifies the SHOTT program coordinator/case manager, the referring QI plan, and the referring physician that the referral is forwarded to SHOTT.
- g) Upon approval for the SHOTT program by the MQD Medical Director the QI member will be disenrolled from the health plan and enrolled in SHOTT.
 - 1) Upon notification of SHOTT approval from MQD, the SHOTT contractor contacts patient, obtains the patient's consent to coordinate care, and begins collaboration with the transplant facility.
 - 2) The SHOTT contractor assumes financial responsibility from the date the Form 1144 was signed and approved by the MQD Medical Director.
- h) If the patient is determined not to be a suitable transplant candidate by the transplant facility or if the patient decides against transplantation, SHOTT and the MQD Medical Director in consultation with the transplant facility will decide:
 - 1) Whether the patient should remain in SHOTT until transplant criteria are met
OR
 - 2) Whether the patient should be transitioned back or continue with QI health plan.

SHOTT will notify the patient of the decision and if the decision is to transition care to the QI plan, SHOTT will begin coordinating the transfer with the QI plan.

- i) Throughout the referral process, the SHOTT contractor communicates closely with MQD's transplant coordinator and medical director regarding the status of referred clients. Throughout the referral process, the SHOTT contractor and MQD transplant coordinator will also communicate closely with the health plan/provider requesting the referral.

EMERGENT and URGENT Requests:

- Emergent requests are made when the patient's death is expected during the hospitalization unless he/she receives a transplant. The transplant facility in collaboration with the transplant physician directly contacts the MQD Medical Director. If the MQD Medical Director gives verbal approval for the transfer to SHOTT, the transplant facility and QI plan must follow up by sending the completed DHS 1144, relevant medical records, and ADRC packet to the MQD. The date of the verbal approval is the effective date of SHOTT enrollment.

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- Urgent request can also be made by the QI plan or referring physician in cases when the patient is in need of an urgent transplant (example: patient with acute myelogenous leukemia is in remission and has a ready and willing donor)
 - For urgent and emergent requests, the health plan or transplant facility should indicate 'URGENT TRANSPLANT REQUEST' or "EMERGENT TRANSPLANT REQUEST" on both the ADRC packet and the 1144 and should communicate with MQD transplant coordinator. These requests will be given priority.

8.6.1.2 Documentation Necessary for Transplant Referral

Information needed by the MQD Medical Director or transplant coordinator in addition to a complete DHS 1144 and an ADRC packet:

Transplant Required Documents

1. Requesting physician's name and contact information
2. Primary Care Giver (PCG) name and contact information
3. Type of organ(s) needed
4. List of medications the patient is taking
5. List of diagnoses the patient has
6. Laboratory studies from the last six months before application, and a hemoglobin A1C level if the patient is a diabetic
7. Any diagnostic studies done, including: ultrasounds, EKG, CT scans, biopsies, catheterizations, MRI scans, PET scans, etc.
8. Doctor's clinic or office notes from the last six months
9. Results of three (each): urine drug screens, blood alcohol screens and nicotine if the patient is a smoker or has not quit smoking in the last six months
- 10.. Results of HIV testing
11. If the patient has a substance abuse history, a detailed account of the patient's treatment for the substance abuse
12. Any history of incarceration
13. Any psychosocial evaluation results
14. If the patient has a history of noncompliance, a detailed history of such and what measures have been taken (if any) to ameliorate it

8.6.2 Additional Documentation

8.6.2.1 Heart Transplant

- a) Cardiac catheterization report(s)
- b) History of any cerebral or peripheral vascular problems
- c) Echocardiogram and MUGA scan reports, if available

8.6.2.3 Lung Transplant

- a) Lung biopsy results, pulmonary function test, or bronchoscopy reports
- b) Oxygen saturation with exercise
- c) Any previous thoracic surgery

8.6.2.4 Heart/Lung Transplant

Please provide requested information from both the heart and lung categories

8.6.2.5 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

8.6.2.6 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 conjunction, please provide the requested information from the liver category as well)

8.6.2.7 Stem Cell (Bone Marrow) Transplant

1. Requesting physician's name and contact information plus what type of transplant is anticipated
2. Statement that there is at least one (1) matched related or unrelated donor or if no matched donor, that the patient would qualify for umbilical cord stem cell transplant or stems cell transplant from a haploidentical related donor

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3. List of medications the patient is taking
4. List of diagnoses the patient has and the stage of cancer, if malignancy is the reason for transplant
5. Doctor's clinic or office notes from the last six months
6. Laboratory studies from the last three months before application
7. Any diagnostic studies done, including: ultrasounds, EKG, CT scans, bone marrow biopsies, flow cytometry results, catheterizations, MRI scans, PET scans, etc.
8. Either a summary list or a letter that delineates the patient's full treatment history for either cancer or a genetic disorder (not just what the patient is currently getting or has gotten recently)
9. Results of HIV testing
10. If the patient has a substance abuse history, a detailed account of the patient's treatment for such
11. If the patient has a history of noncompliance, a detailed history of such and what measures have been taken, if any, to ameliorate it
12. Pathology reports and marrow analyses are also helpful

8.6.2.7.1 Allogeneic Bone Marrow Transplant

(If a scientific study must have full protocol for review plus consent IRB and the patient consent form)

8.6.2.7.2 Autologous Bone Marrow Transplant

Same as allogeneic except no donor information required.

8.7 TRANSPLANT FACILITY ACCEPTS PATIENT

The QI plan refers the patient to a transplant facility that is contracted with the SHOTT program. If the transplant facility determines that the patient meets its criteria and is willing to accept the patient, this information is included in the medical records sent to the MQD Medical Director with the DHS 1144 form.

- a) If enrollment in the SHOTT program is approved by the MQD Medical Director, SHOTT's case manager contacts the transplant facility and arranges for the patient to obtain services needed by the transplant facility.

8.8 AWAITING TRANSPLANT OUT-OF-STATE OR NOT ON THE PATIENT'S ISLAND OF RESIDENCE

- a) If the patient's transplant facility is out-of-state or not on his/her island of residence, he/she may remain either in the facility or nearby housing while awaiting a transplant. His/her medical status is monitored by the transplant facility. The SHOTT case manager has regular contact with the facility and the client/caregiver.
- b) If the client is allowed to return home to await the transplant. The transplant facility and the referring physician monitor the client's medical status. The SHOTT case manager coordinates all services.
- c) The SHOTT case manager arranges for lodging near the transplant facility for the client/caregiver while awaiting the impending transplant. After discharge from the transplant facility, the client stays near the hospital in lodging arranged by the SHOTT case manager until medically released by the transplant facility. The client and caregiver return home once medically cleared by the transplant facility.

8.9 ONE YEAR ANNIVERSARY – AFTER SUCCESSFUL TRANSPLANT

a) The SHOTT case manager arranges with the transplant facility for the client's one-year post transplant follow-up visit following the twelfth month anniversary of the successful transplantation.

b) The transplant facility notifies SHOTT if the patient is cleared for discharge from transplant facility services. The SHOTT case manager notifies the MQD transplant coordinator, transitions care to the QI plan and the MQD disenrolls the patient from SHOTT and enrolls him/her in a QI plan.

8.10 MEDICAID AS A SECONDARY PAYOR

a) The SHOTT contractor coordinates with the primary payor. The SHOTT contractor pays for non-emergency transportation, lodging, and meals if these are not covered by the primary payer. If the transplant facility is not contracted with SHOTT, SHOTT enters into an agreement with the transplant facility and its physicians for payment as a secondary payer. Non-transplant medical services are limited by the Hawaii Medicaid FFS rates. Thus, if the primary insurer's payment is more than the Medicaid FFS rate, no payment is made, if the primary insurer's payment is less than the Hawaii Medicaid FFS rate, payment will be the difference between the Hawaii Medicaid FFS rate and the rate paid by the primary insurer.

Secondary claims for medications provided to the patient cannot be paid by the MQD's PBM, they are paid by the SHOTT contractor using the same rules as cited above for medical services.

b) Medicare as the primary payor

1) The client/physician can choose any Medicare approved facility.

2) The SHOTT contractor is responsible for Medicare copayments and deductibles and for transportation, lodging, and meals for the client and caregiver. Payment to Hawaii hospitals for Medicare/Medicaid dual eligible follows MQD policies.

Medications not covered by Medicare Part D and covered by Medicaid should be billed to MQD's PBM. Medications not covered by Medicare Part D and not covered by MQD's PBM can be billed to the SHOTT contractor. No copayments can be paid for Medicare Part D covered medications.

3) If the client becomes eligible for Medicare after the transplant but prior to the one-year anniversary, the SHOTT contractor will continue case management. For clients who received kidney transplants and were notified of Medicare eligibility effective after the transplant, the MQD Medical Director determines whether the client should remain in SHOTT or be transitioned to a QI plan.

8.10.1 COBRA Information

If the client is eligible for Consolidated Omnibus Budget Reconciliation Act (COBRA) coverage, and the SHOTT contractor has the approval of the MQD Finance Office, the SHOTT contractor will pay the COBRA premium.